

**BRUNEL UNIVERSITY**  
LONDON

**CHALLENGES IN MEDICAL VISUALIZATION:  
AN INTERACTIVE APPROACH TO EXPLORE  
THE EFFECT OF 3-D TECHNOLOGY ON THE  
VISUALIZATION OF PAIN**

**A THESIS SUBMITTED FOR THE DEGREE OF DOCTOR OF  
PHILOSOPHY**

**BY**

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## **ABSTRACT**

Pain experienced as a result of a disabling medical condition is a frequent problem in the clinical community and can often be present in any individual with this kind of health concern. Such pain is typically characterized by severe implications reflected on both a person's personal life, as well as on a country's health and economic systems. Research on pain has revealed that patients not only experience several types of pain that could prove to be challenging to address, but also that each individual can interpret the same type, location and severity of this pain in different subjective ways, making the need for more effective pain measurement methods an imperative and troublesome effort.

In retrospect, the healthcare field is currently trying to enhance the available medical methods with alternatives that would be more efficient in providing accurate pain assessment. Most efforts revolve around traditional methods of measuring pain characteristics, which typically involve the 2-Dimensional (2-D) representation of the human body, often used to collect information regarding the type and location of pain. However, these 2-D pain drawings can be limited in their ability to efficiently visualize pain characteristics for diagnosis purposes. Nonetheless, patients have been shown to prefer such drawings.

This research develops an alternative interactive software solution to help in addressing the aforementioned situation, by employing the capabilities that advancements in 3-Dimension (3-D) technology offer. Subsequently, in the anticipation that limitations of current 2-D pain visualization will be solved, the developed approach facilitates the measurement of pain experiences via a 3-D visualization model of the patient.

To ensure that it can effectively perform in real-world medical practice, the 3-D pain drawing is evaluated in this research through real-life case studies that are carried out

in designated settings. The research findings have shown that the developed approach can potentially make significant contributions to society, science/technology and healthcare provision, with patients and clinicians suggesting that 3-D technology can be a promising means in the pursuit for more effective pain measurement solutions.

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## LIST OF PUBLICATIONS

The following papers have been published (or have been submitted for publication) as a direct or indirect result of the research presented in this thesis:

### JOURNALS

1. (Under Review) F. Spyridonis, J. Gawronski, G. Ghinea & A.O. Frank (2011) “Patients’ acceptance of 3-D visualization technology for pain assessment: A pilot study in spinal cord injury rehabilitation”, *International Journal of Medical Informatics*.
2. F. Spyridonis & G. Ghinea (2011) “3D Pain Drawings and Seating Pressure Maps: Relationships and Challenges”, *IEEE Transactions on Information Technology in Biomedicine*, 15 (3), pp. 409-415.
3. F. Spyridonis & G. Ghinea (2010) “Current Studies Towards Using a 3D Visualisation Approach in the Assessment of Pain: A Cohort Overview”, *Posture and Mobility Group*, 27 (2), pp. 10-14.
4. G. Ghinea, F. Spyridonis, T. Serif & A.O. Frank (2008) “3D Pain Drawings – Mobile Data Collection using a PDA”, *IEEE Transactions on Information Technology in Biomedicine*, 12 (1), pp. 27-33.

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2. J. Gawronski, A. O. Frank, F. Spyridonis & G. Ghinea (2011) “Pain experienced following spinal cord injury: A pilot study using repeated VAS

scores”, *Joint Summer Meeting of the British Society of Rehabilitation Medicine & The Society for Research in Rehabilitation*, Newcastle-under-Lyme, UK, July 3-5<sup>th</sup>, 2011.

3. F. Spyridonis & G. Ghinea (2010) “A Pilot Study to Examine the Relationship of 3D Pain Drawings with Objective Measures in Mobility Impaired People Suffering from Low Back-pain”, *32nd Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC2010)*, Buenos Aires, Argentina, August 31st-September 4th, 2010.
4. F. Spyridonis & G. Ghinea (2010) “Pressure Mapping as a Complement in 3D Pain Drawings in the Back-pain Assessment Process: A Proposed Method”, *4th International Conference on Bioinformatics and Biomedical Engineering (iCBBE 2010)*, Chengdu, China, June 18th-20th, 2010.

## **BOOK CHAPTERS**

1. F. Spyridonis & G. Ghinea, “A Portable Wireless Solution for Back Pain Telemonitoring: A 3D-based, Virtual Reality Approach”, pp. 425-461, *Studies in Computational Intelligence*, Vol. 309/2010, Springer-Verlag, 2010.

# TABLE OF CONTENTS

ABSTRACT.....	II
ACKNOWLEDGEMENTS.....	IV
LIST OF PUBLICATIONS.....	V
TABLE OF CONTENTS.....	VII
LIST OF FIGURES .....	XI
LIST OF TABLES .....	XIII

## CHAPTER ONE - INTRODUCTION

1.1 OVERVIEW .....	- 1 -
1.2 RESEARCH CONTEXT AND RATIONALE.....	- 2 -
1.2.1 QUALITY OF SERVICES AND COST STATUS IN HEALTHCARE .....	- 2 -
1.2.2 MANAGING ACUTE AND CHRONIC CONDITIONS: THE IMPORTANCE OF VISUALIZATION FOR PAIN .....	- 3 -
1.3 RESEARCH AIM AND OBJECTIVES .....	- 6 -
1.4 OVERVIEW OF THE RESEARCH APPROACH .....	- 8 -
1.5 RESEARCH CONTRIBUTIONS IN BRIEF .....	- 9 -
1.6 ROADMAP OF THE THESIS .....	- 10 -

## CHAPTER TWO - UNDERSTANDING THE PAIN EXPERIENCE

2.1 OVERVIEW .....	- 12 -
2.2 PART ONE: UNDERSTANDING PAIN EXPERIENCE .....	- 13 -
2.2.1 DEFINITION OF PAIN .....	- 13 -
2.2.2 CLINICAL CLASSIFICATION OF PAIN .....	- 15 -
2.2.3 PAIN AS A SUBJECTIVE EXPERIENCE .....	- 17 -
2.3 PART TWO: VISUALIZING THE PAIN EXPERIENCE .....	- 18 -
2.3.1 ASPECTS OF PAIN TO CONSIDER .....	- 18 -
2.3.2 VISUALIZING CLINICAL PAIN INFORMATION .....	- 19 -
2.3.2.1 <i>Pain Severity Visualization Tools</i> .....	- 21 -
2.3.2.2 <i>Pain Experience Visualization Tools</i> .....	- 25 -
2.3.3 VISUALIZING THE SPATIAL LOCATION OF PAIN .....	- 26 -
2.3.3.1 <i>Current Techniques to Completing a Pain Drawing</i> .....	- 28 -
2.3.3.2 <i>Current Techniques to Scoring a Pain Drawing</i> .....	- 30 -
2.3.3.3 <i>The Pain Drawing as a Psychological Screening Tool</i> .....	- 34 -
2.3.3.4 <i>A Closer Look at the Pain Drawing</i> .....	- 35 -
2.4 SUMMARY .....	- 38 -

## **CHAPTER THREE - VISUALIZATION FOR BETTER HEALTHCARE**

<b>3.1 OVERVIEW</b> .....	<b>- 40 -</b>
<b>3.2 WHAT IS VISUALIZATION?</b> .....	<b>- 41 -</b>
3.2.1 VISUALIZATION CHARACTERISTICS .....	- 43 -
3.2.2 APPLICATIONS TO REAL WORLD .....	- 46 -
<b>3.3 MEDICAL VISUALIZATION</b> .....	<b>- 49 -</b>
3.3.1 OVERVIEW OF ADVANCEMENTS IN MEDICAL IMAGING .....	- 50 -
3.3.2 USING VISUALIZATION IN REAL-LIFE MEDICINE .....	- 53 -
3.3.3 MEDICAL VISUALIZATION AND PAIN .....	- 58 -
<b>3.4 SUMMARY</b> .....	<b>- 59 -</b>

## **CHAPTER FOUR - RESEARCH APPROACH AND METHODOLOGY**

<b>4.1 OVERVIEW</b> .....	<b>- 61 -</b>
<b>4.2 ADOPTING A SUITABLE RESEARCH APPROACH</b> .....	<b>- 62 -</b>
<b>4.3 CHARACTERISTICS OF DESIGN SCIENCE RESEARCH</b> .....	<b>- 63 -</b>
4.3.1 THE DESIGN SCIENCE RESEARCH CYCLE .....	- 63 -
4.3.1.1 <i>Applying the DSR Cycle to this Research</i> .....	- 65 -
4.3.2 DESIGN SCIENCE RESEARCH OUTPUTS .....	- 67 -
4.3.2.1 <i>Relating This Research Results to DSR Outputs</i> .....	- 69 -
4.3.3 WHY DESIGN SCIENCE RESEARCH? .....	- 71 -
<b>4.4 ARTEFACT DEVELOPMENT: WHICH METHODOLOGY?</b> .....	<b>- 72 -</b>
4.4.1 INTEGRATING A METHODOLOGY INTO THIS RESEARCH .....	- 73 -
<b>4.5 RESEARCH STRATEGY</b> .....	<b>- 75 -</b>
4.5.1 DATA COLLECTION METHODS .....	- 76 -
4.5.1.1 <i>Constructing the Interview Agenda</i> .....	- 77 -
4.5.2 ARTEFACT EVALUATION METHOD .....	- 79 -
4.5.3 DATA ANALYSIS TECHNIQUES .....	- 80 -
<b>4.6 SUMMARY</b> .....	<b>- 81 -</b>

## **CHAPTER FIVE - ARTEFACT DESIGN AND IMPLEMENTATION**

<b>5.1 OVERVIEW</b> .....	<b>- 82 -</b>
<b>5.2 ITERATION A: INITIAL DESIGN AND IMPLEMENTATION</b> .....	<b>- 83 -</b>
5.2.1 DESIGNING THE PROTOTYPE .....	- 83 -
5.2.1.1 <i>The Need for a Mobile Solution</i> .....	- 83 -
5.2.1.2 <i>Identifying the User Requirements</i> .....	- 85 -
5.2.1.3 <i>The Design Process Explained</i> .....	- 87 -
5.2.2 IMPLEMENTING THE PROTOTYPE .....	- 92 -
5.2.2.1 <i>Delivery Hardware Platforms</i> .....	- 92 -
5.2.2.2 <i>Delivery Software Platform</i> .....	- 94 -
5.2.2.3 <i>Application Walkthrough</i> .....	- 96 -

5.2.3 END OF ITERATION A .....	- 102 -
<b>5.3 ITERATION B: SECOND DESIGN AND IMPLEMENTATION .....</b>	<b>- 102 -</b>
5.3.1 DESIGNING THE REFINED ARTEFACT .....	- 102 -
5.3.1.1 <i>Defining Additional User Requirements</i> .....	- 103 -
5.3.1.2 <i>The Refined Prototype Architecture</i> .....	- 104 -
5.3.2 IMPLEMENTING THE REFINED PROTOTYPE .....	- 107 -
5.3.2.1 <i>Delivery Hardware Platforms</i> .....	- 107 -
5.3.2.2 <i>Delivery Software Platform</i> .....	- 108 -
5.3.2.3 <i>Refined Prototype Walkthrough</i> .....	- 108 -
<b>5.4 SUMMARY .....</b>	<b>- 112 -</b>

## **CHAPTER SIX - CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK PAIN**

<b>6.1 OVERVIEW .....</b>	<b>- 114 -</b>
<b>6.2 UNDERSTANDING BACK PAIN .....</b>	<b>- 115 -</b>
6.2.1 PREVALENCE AND IMPACT OF BACK PAIN .....	- 115 -
6.2.2 UNDERLYING CAUSES .....	- 116 -
<b>6.3 VISUALIZATION OF BACK PAIN: STATE-OF-THE-ART .....</b>	<b>- 117 -</b>
<b>6.4 METHODS AND MATERIALS OF THE CASE STUDY .....</b>	<b>- 119 -</b>
6.4.1 INSTRUMENTATION .....	- 120 -
6.4.2 DESCRIPTION OF PARTICIPANT GROUPS .....	- 121 -
6.4.3 PROTOCOL AND ALGORITHM .....	- 122 -
6.4.4 DATA ANALYSIS .....	- 123 -
<b>6.5 EVALUATION RESULTS .....</b>	<b>- 124 -</b>
6.5.1 CLINICAL EVALUATION .....	- 125 -
6.5.2 PATIENT EVALUATION .....	- 126 -
<b>6.6 SUMMARY .....</b>	<b>- 129 -</b>

## **CHAPTER SEVEN - CASE STUDY TWO: 3-D VISUALIZATION TECHNOLOGY AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY**

<b>7.1 OVERVIEW .....</b>	<b>- 131 -</b>
<b>7.2 PRESENCE OF PAIN IN MOBILITY IMPAIRED PEOPLE .....</b>	<b>- 132 -</b>
7.2.1 VISUALIZING PAIN: APPROACHES AND CONCERNS .....	- 133 -
<b>7.3 COMMUNICATION OF PAIN .....</b>	<b>- 134 -</b>
7.3.1 CURRENT OBJECTIVE PAIN ASSESSMENT METHODS .....	- 135 -
<b>7.4 METHODS AND MATERIALS OF THE CASE STUDY .....</b>	<b>- 138 -</b>
7.4.1 INSTRUMENTATION .....	- 139 -
7.4.2 DESCRIPTION OF PARTICIPANT GROUP .....	- 140 -
7.4.3 PROTOCOL AND ALGORITHM .....	- 140 -
7.4.4 DATA ANALYSIS .....	- 141 -
<b>7.5 EVALUATION AND DISCUSSION OF RESULTS .....</b>	<b>- 142 -</b>

7.5.1 VISUAL INTERPRETATION .....	- 143 -
7.5.2 PAIN VISUALIZATION EFFICIENCY .....	- 154 -
7.5.3 ADDITIONAL FINDINGS AND OBSERVATIONS .....	- 156 -
<b>7.6 SUMMARY .....</b>	<b>- 158 -</b>

## **CHAPTER EIGHT - CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION**

<b>8.1 OVERVIEW .....</b>	<b>- 160 -</b>
<b>8.2 PAIN AFTER SPINAL CORD INJURY .....</b>	<b>- 161 -</b>
8.2.1 ASSESSING THE SCI PATIENT .....	- 162 -
<b>8.3 CURRENT APPROACHES TO SCI PAIN VISUALIZATION.....</b>	<b>- 163 -</b>
8.3.1 THE NEED FOR 3-D VISUALIZATION OF SCI PAIN .....	- 164 -
<b>8.4 METHODS AND MATERIALS OF THE CASE STUDY .....</b>	<b>- 165 -</b>
8.4.1 INSTRUMENTATION.....	- 165 -
8.4.2 DESCRIPTION OF PARTICIPANT GROUP .....	- 166 -
8.4.3 PROTOCOL AND ALGORITHM .....	- 166 -
8.4.4 DATA ANALYSIS .....	- 168 -
<b>8.5 EVALUATION RESULTS .....</b>	<b>- 168 -</b>
<b>8.6 SUMMARY .....</b>	<b>- 173 -</b>

## **CHAPTER NINE - CONCLUDING DISCUSSION AND REMARKS**

<b>9.1 OVERVIEW .....</b>	<b>- 174 -</b>
<b>9.2 RESEARCH ACHIEVEMENTS AND FINDINGS .....</b>	<b>- 175 -</b>
<b>9.3 RESEARCH CONTRIBUTIONS .....</b>	<b>- 185 -</b>
9.3.1 CONTRIBUTIONS TO SOCIETY.....	- 185 -
9.3.2 SCIENTIFIC/TECHNOLOGICAL CONTRIBUTIONS .....	- 187 -
9.3.3 CONTRIBUTIONS TO HEALTHCARE PROVIDERS.....	- 190 -
<b>9.4 RESEARCH LIMITATIONS AND FUTURE ENDEAVOURS.....</b>	<b>- 193 -</b>

<b>REFERENCES.....</b>	<b>- 199-</b>
------------------------	---------------

<b>APPENDIX A – SUPPLEMENTARY MATERIAL .....</b>	<b>- 214 -</b>
--	----------------

A.1 UNDERLYING PHILOSOPHICAL ASSUMPTIONS.....	- 214 -
A.2 OVERVIEW OF SOFTWARE DEVELOPMENT APPROACHES.....	- 216 -

<b>APPENDIX B – INTERVIEWS AGENDA .....</b>	<b>- 221 -</b>
---	----------------

<b>APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D PAIN DRAWING .....</b>	<b>- 224 -</b>
--	----------------

## LIST OF FIGURES

FIGURE 1-1. COMPARISON OF PERFORMANCE FOR QUALITY OF SERVICES.....	- 3 -
FIGURE 1-2. THE PREVALENCE OF CHRONIC PAIN IN EUROPE .....	- 4 -
FIGURE 2-1. AN EXAMPLE OF A VISUAL ANALOGUE SCALE .....	- 21 -
FIGURE 2-2. EXAMPLES OF GRAPHIC RATING SCALE .....	- 21 -
FIGURE 2-3. AN EXAMPLE OF VERBAL RATING SCALE .....	- 22 -
FIGURE 2-4. AN EXAMPLE OF BEHAVIOURAL RATING SCALE .....	- 22 -
FIGURE 2-5. AN EXAMPLE OF NUMERICAL RATING SCALE.....	- 23 -
FIGURE 2-6. A 2-D PAIN DRAWING.....	- 26 -
FIGURE 2-7. AN EXAMPLE COLOURED 2-D PAIN DRAWING .....	- 29 -
FIGURE 2-8. A DERMATOME MAP .....	- 30 -
FIGURE 2-9. THE BODY REGIONS METHOD .....	- 32 -
FIGURE 2-10. THE GRID METHOD.....	- 33 -
FIGURE 3-1. OVERVIEW OF DATA TYPES AND TASKS .....	- 45 -
FIGURE 3-2. VISUALIZATION IN DERIVATIVES RISK MANAGEMENT AND IN GEOGRAPHIC INFORMATION .....	- 47 -
FIGURE 3-3. VISUALIZATION USED FOR A FILM DATABASE AND HIERARCHICAL DATA ...	- 47 -
FIGURE 3-4. ‘AUDIORADAR’ AND SEISMIC DATA VISUALIZATION.....	- 48 -
FIGURE 3-5. VISUALIZATION USED FOR FLOOD DISASTER AND ‘EMDIALOG’ .....	- 49 -
FIGURE 3-6. EXAMPLE OF AN X-RAY .....	- 50 -
FIGURE 3-7. EXAMPLES OF CAT, MRI, AND ULTRASOUND IMAGING.....	- 51 -
FIGURE 3-8. ‘INFOZOOM’ AND ‘SENTINEL’ .....	- 55 -
FIGURE 3-9. VISUALIZATION USED FOR GENES AND PROTEINS .....	- 56 -
FIGURE 3-10. ENHANCED IMAGE OF BLOOD VESSELS AND SIMULATION OF BONES IN 3-D IN FACIAL SURGERY .....	- 57 -
FIGURE 3-11. VISUALIZATION USED FOR LIVER AND SPINE SURGERIES .....	- 58 -
FIGURE 4-1. THE GENERAL METHODOLOGY OF DESIGN SCIENCE RESEARCH.....	- 65 -
FIGURE 4-2. RAPID PROTOTYPING .....	- 74 -
FIGURE 5-1. SYSTEM USE CASE DIAGRAM .....	- 87 -
FIGURE 5-2. INITIAL ARTEFACT ARCHITECTURE.....	- 89 -
FIGURE 5-3. DATABASE RELATIONSHIP DIAGRAM.....	- 90 -
FIGURE 5-4. INTERACTION BETWEEN THE THREE MODULES .....	- 91 -
FIGURE 5-5. THREE-TIER WIRELESS SYSTEM MODEL .....	- 91 -
FIGURE 5-6. SEQUENCE DIAGRAM OF INTERACTION BETWEEN THE THREE TIERS .....	- 92 -
FIGURE 5-7. SCREENSHOT OF THE PDA .....	- 93 -
FIGURE 5-8. INTRODUCTION SCREEN.....	- 96 -

FIGURE 5-9. CREATING A NEW PATIENT PROFILE .....	- 97 -
FIGURE 5-10. PAIN FACTORS AND MEDICATION .....	- 98 -
FIGURE 5-11. PAIN DISCOMFORT LEVEL .....	- 99 -
FIGURE 5-12. 3-D PAIN DRAWING .....	- 100 -
FIGURE 5-13. APPLICATION'S LOCAL DATABASE .....	- 101 -
FIGURE 5-14. THE REFINED PROTOTYPE ARCHITECTURE .....	- 105 -
FIGURE 5-15. INTRODUCTION AND NEW PATIENT PROFILE.....	- 109 -
FIGURE 5-16. PAIN FACTORS AND DISCOMFORT .....	- 110 -
FIGURE 5-17. THE REFINED 3-D PAIN DRAWING IN THE SITTING POSTURE.....	- 111 -
FIGURE 6-1. THE 2-D AND 3-D PAIN DRAWINGS .....	- 121 -
FIGURE 6-2.HISTOGRAMS OF RESPONSES TO QUESTIONS 1-4 .....	- 127 -
FIGURE 6-3.HISTOGRAMS OF RESPONSES TO QUESTIONS 5-8 .....	- 127 -
FIGURE 7-1. SCREENSHOTS OF THE PRESSURE MAPPING APPROACH.....	- 141 -
FIGURE 7-2. 3-D PAIN DRAWING WITH INITIAL AND FINAL PRESSURE AND GRADIENT MAPS FOR PARTICIPANT 1 .....	- 144 -
FIGURE 7-3. 3-D PAIN DRAWING WITH INITIAL AND FINAL PRESSURE AND GRADIENT MAPS FOR PARTICIPANT 2 .....	- 146 -
FIGURE 7-4. 3-D PAIN DRAWING WITH INITIAL AND FINAL PRESSURE AND GRADIENT MAPS FOR PARTICIPANT 6 .....	- 148 -
FIGURE 7-5. 3-D PAIN DRAWING WITH INITIAL AND FINAL PRESSURE AND GRADIENT MAPS FOR PARTICIPANT 3 .....	- 149 -
FIGURE 7-6. 3-D PAIN DRAWING WITH INITIAL AND FINAL PRESSURE AND GRADIENT MAPS FOR PARTICIPANT 4 .....	- 151 -
FIGURE 7-7. 3-D PAIN DRAWING WITH INITIAL AND FINAL PRESSURE AND GRADIENT MAPS FOR PARTICIPANT 5 .....	- 153 -
FIGURE 8-1. COMPARISON OF OVERALL PERFORMANCE.....	- 169 -
FIGURE 8-2. HISTOGRAMS OF RESPONSES TO QUESTIONS 1-2 .....	- 170 -
FIGURE 8-3. HISTOGRAMS OF RESPONSES TO QUESTIONS 3-4. ....	- 170 -
FIGURE 8-4. HISTOGRAMS OF RESPONSES TO QUESTIONS 5-6 .....	- 172 -
FIGURE 8-5. HISTOGRAMS OF RESPONSES TO QUESTIONS 7-8 .....	- 173 -
FIGURE A-1. THE WATERFALL MODEL .....	- 216 -
FIGURE A-2. THE SPIRAL MODEL .....	- 217 -

## LIST OF TABLES

TABLE 2-1. CHARACTERISTICS OF NOCICEPTIVE AND NEUROPATHIC PAIN .....	- 16 -
TABLE 3-1. BENEFITS OF USING VISUALIZATION .....	- 42 -
TABLE 3-2. BENEFITS OF 3-D OVER 2-D .....	- 45 -
TABLE 4-1. SEVEN GUIDELINES FOR CONSTRUCTING ARTEFACTS .....	- 64 -
TABLE 4-2. CLASSIFICATION OF THE ARTEFACT .....	- 68 -
TABLE 4-3. MAPPING OF DSR CYCLE TO THE SEVEN GUIDELINES AND THE DSR OUTPUTS.....	- 71 -
TABLE 4-4. SUMMARY OF SOFTWARE DEVELOPMENT METHODOLOGIES.....	- 73 -
TABLE 4-5. QUALITATIVE AND QUANTITATIVE DATA COLLECTION TECHNIQUES.....	- 76 -
TABLE 6-1. MAJOR CAUSES OF BACK-PAIN.....	- 117 -
TABLE 6-2. PARTICIPANT GROUPS.....	- 122 -
TABLE 6-3. FUNCTIONALITY EVALUATION QUESTIONNAIRE.....	- 124 -
TABLE 7-1. OBJECTIVE PAIN ASSESSMENT METHODS .....	- 136 -
TABLE 7-2. PARTICIPANTS AND CORRESPONDING PRESSURE VALUES .....	- 143 -
TABLE 7-3. COMPARISON OF SURFACE AREAS .....	- 155 -
TABLE 8-1. PARTICIPANT GROUP.....	- 167 -
TABLE 8-2. QUESTIONNAIRE AND RESULTS .....	- 171 -
TABLE 9-1. SUMMARY OF RESEARCH APPROACH AND METHODOLOGY.....	- 176 -

# CHAPTER ONE

## INTRODUCTION

### 1.1 OVERVIEW

The research described in this thesis investigates the application of 3-D visualization technology advancements to the field of healthcare, and specifically to the efficient management of pain. While the boundaries of this research area can be significantly broad, the focus of the present work is mainly to understand and address issues relating to the management of pain-related conditions from a technological perspective – to specifically integrate current expertise of 3-D technology in the management of pain that is often present in various medical acute/chronic conditions, in order to arrive at an efficient solution to the successful assessment of pain.

The present introductory chapter, therefore, begins by setting the context of this research, which is framed by two major issues that currently trouble the healthcare sector: *1) the imperative need for improved quality of services*, achieved with *2) the least possible costs*. Towards the efforts to alleviate the problem, focus is placed on a particularly troublesome area - that of the successful management of pain - and the possibility of 3-D visualization technology to address this issue is identified. The research aim and objectives are subsequently established based on the aforementioned discussion of the research context, and the research approach undertaken to achieve them is introduced. This chapter is finally concluded by presenting an overview of this research's contributions followed by a roadmap of the remaining of the thesis.

### **1.2 RESEARCH CONTEXT AND RATIONALE**

Society as we know it is substantially dependent on the utilization of computers and graphics technology in most aspects of our everyday life, such as the movies industry, the workplace, and education, to name just a few. The use of computer graphics in visualizing complex phenomena is, therefore, not a recent trend. In fact, the area of ‘*Scientific Visualization*’ consists of an active research community that constantly exploits advancements in computer graphics techniques to assist other scientific communities in understanding their data through 2-D image planes (Nelson and Elvins, 1993).

The potential of visualization technology in society is therefore well-established and the healthcare area can be a major example of the benefits it could provide. To put the discussion into context, the current state of this demanding area of our everyday life is characterized by the exponential need for *advanced quality of service*, in terms of patient care, at the *lowest possible costs*, for which advances in visualization technology could play a major role.

#### **1.2.1 QUALITY OF SERVICES AND COST STATUS IN HEALTHCARE**

In England quality of services is given a significant amount of attention. While a recent National Health Service (NHS) assessment showed that there has been a noteworthy improvement over the years (see Figure 1-1) in the quality of services that the NHS Trusts provide (Healthcare Commission report, 2008), in practical terms, the quality of healthcare still varies considerably depending on where a person lives and the types of services they need. Similar is the situation in the USA with recommended care being delivered only a little over half of the times (KPMG LLP report, 2009), something that could be proved tragic to the people involved.



Figure 1-1. Comparison of Performance for Quality of Services (Source: Healthcare Commission report, 2008)

In retrospect, people without appropriate access to care delay seeing a clinician until a condition becomes severe and then use high cost emergency room visits to receive treatment. As a result, inefficiencies are caused in the healthcare system, and the overall cost of healthcare is increased. This assumption is not far from reality. In fact, more than 50% of the UK hospital and community health services budget is spend on *general* and *acute* conditions, while at the same time an impressive increase in costs for treatment of *long-term* or *chronic* conditions has been further noticed in the past two years (Colin-Thome and Belfield, 2008).

### 1.2.2 MANAGING ACUTE AND CHRONIC CONDITIONS: THE IMPORTANCE OF VISUALIZATION FOR PAIN

Addressing an acute or a chronic medical condition has always constituted a great challenge for healthcare stakeholders. However, the burden becomes even more challenging when a condition can and often falls within both spectrums of acute and chronic (see subsection 2.2.2). In fact, there are medical conditions that start as acute and later stay with the patient as chronic. Such is the case with pain. Although acute pain is relatively easy to manage, chronic pain presents without a doubt a significant challenge to citizens and the economy of countries.

## CHAPTER ONE - INTRODUCTION

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Evidence from a pan-European consensus report - *the Pain Proposal* – reported by Baker et al. (2010), suggests that one in five Europeans (19%) is estimated to have some form of chronic pain- in most cases for over five years, while there are also cases of people who suffered from pain for 20 years or longer. Figure 1-2 presents the prevalence of chronic pain across Europe.

Country	Chronic Pain
 Austria	21 % <sup>1</sup>
 Belgium	23 % <sup>1</sup>
 Denmark	16 – 21 % <sup>1,11,18</sup>
 Finland	19 % <sup>1</sup>
 France	15 – 32 % <sup>1,19</sup>
 Germany	17 – 45 % <sup>1,20</sup>
 Ireland	13 % <sup>1</sup>
 Italy	26 % <sup>1</sup>
 Netherlands	18 – 25 % <sup>1,21</sup>
 Norway	26 – 30 % <sup>1,22</sup>
 Spain	12 – 23 % <sup>1,23</sup>
 Sweden	18 – 54 % <sup>1,24</sup>
 Switzerland	16 % <sup>1</sup>
 UK	13 – 48 % <sup>1,25,26,27</sup>

Figure 1-2. The Prevalence of Chronic Pain in Europe  
(Source: Baker et al. 2010)

There is no doubt that the current report is representative of the situation in several other countries or regions. Nonetheless, efficient intervention seems to be limited in most cases. While several approaches that attempt to address the nature of pain exist in the clinical literature (see chapter two), their applicability is often questioned. Specifically, these traditional approaches have relied on the visualization of pain information through a paper-based, 2-D representation of the human body, which can be limited in its ability to accurately visualize pain characteristics, making them difficult and time consuming for both patients and clinicians to use. Although there is significant amount of research with regard to addressing the aforementioned situation, there is also an overall lack of success that is also accounted to the

## CHAPTER ONE - INTRODUCTION

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subjective and multidimensional nature of pain that make it even more difficult to measure.

As technology has improved, however, the trend has subsequently shifted to 3-D computer graphics, which have become more widespread and are nowadays the gold standard for visualization. In the area of Information Technology (IT), the concept of 3-D is intimately associated with that of Virtual Reality (VR). This is the simulation of a real or imagined environment that can be experienced visually in the 3-D of width, height, and depth, and that may additionally provide an interactive experience. As such, by being able to interact with the environment, anomalies caused by 2-D depth perception can be removed, potentially allowing for more accurate and consistent visualization ability.

This is exactly what this research has provided through the employment of 3-D visualization technology. While advancements in medical imaging (see chapter three) are absolutely crucial and fundamental for the diagnosis of a great range of medical conditions that might or might not involve pain, they are similarly overly insufficient in visualizing pain and particular pain characteristics. It is a fact that identifying and collecting information about a painful medical condition through medical imaging is the essential first step towards a successful diagnosis; however, accurately visualizing specific parts of this information to the clinical staff involved could constitute the missing link for efficient pain management. This is exactly what visualization technology aims to provide. As such, in this research 3-D visualization technology was employed in the attempt to assess pain, recognizing the great potential it could offer for reducing costs, as well as for increasing the quality of healthcare provision.

### 1.3 RESEARCH AIM AND OBJECTIVES

The discussion in the previous section has highlighted the need for a more efficient approach towards the successful management of pain that might often be present in a diverse range of medical conditions. The potential of visualization technology can be a key factor in addressing this concern. To this end, the purpose of this thesis was twofold: The first was to gain a deep understanding of contemporary issues in pain assessment and in current visualization technology. The second was to implement a novel solution that would integrate 3-D visualization technology and pain assessment methods, and which would function as an improvement to other approaches that currently exist.

Accordingly, this research attempted to identify the potential impact 3-D visualization technology will have in healthcare, and specifically in the assessment of pain. Along these lines, the main aim of this research was:

*To develop a novel approach to pain visualization based on 3-D technological advancements for the purpose of investigating its effect in addressing existing limitations in the field under study, in a way that will help direct stakeholders (clinical staff, patients, healthcare providers) to attain improved management quality of medical conditions that involve some form of pain.*

**Five** important **objectives** have been subsequently established as the means to fulfil the aforementioned purpose and aim of this research:

1. Identify and explore the research background, as well as investigate the research approach that can address the research aim, which can guide us to the development of this work's artefact;

## CHAPTER ONE - INTRODUCTION

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2. Design and develop an alternative approach to pain visualization that addresses any limitations identified from the review of the research background;
3. Evaluate the 3-D approach through real-life case studies with respect to the complexity of pain characteristics and the diversity of medical conditions involving some type of pain;
4. Establish the reliability of 3-D technology in the visualization of pain characteristics;
5. Validate and evaluate the research findings with respect to their contribution to the research field under study.

Specifically, the three real-life case studies presented in this thesis address the following questions in relation to the aforementioned third objective:

- i. How is the introduction of 3-D technology in everyday medical practice **perceived** by the medical staff?
- ii. What are the patients' perceptions with regards to the **functional** characteristics of the 3-D approach?
- iii. How valuable is 3-D visualization technology in addressing the **subjective** nature of pain?
- iv. What is the capacity of 3-D technology to support patients in most **efficiently** visualizing and communicating their pain to clinical staff?
- v. Is a 3-D approach a more **usable** and **feasible** means of visualizing pain characteristics as compared to methods currently in use?

### 1.4 OVERVIEW OF THE RESEARCH APPROACH

In fulfilling the research aim and objectives discussed in the previous section, this research undertook the Design Science research approach. In the lines of Vaishnavi and Kuechler (2004), as well as Hevner et al. (2004), this research paradigm is described as a technology-oriented, problem-solving approach that designs **artefacts** for the purpose of helping to understand, explain and very frequently improve on the behaviour of aspects of Information Systems (IS).

Nevertheless, there is still a considerable amount of debate as to what a design artefact particularly represents, for which a more elaborated discussion is provided in chapter four. In a nutshell, March and Smith (1995) followed by Hevner et al. (2004) categorize artefacts in *i) a construct, ii) model, iii) method, or iv) an instantiation*. Considering that the aim of this research was to develop a novel technological approach, the artefact produced by this work was mainly classified as an instantiation.

In implementing the aforementioned instantiation, a *Rapid Prototyping* software methodology approach was followed that allows for a fast development lifecycle while in parallel evaluating the system, and so allowing for its constant refinement (Sommerville, 2011). Specifically, the design and development of the prototype was achieved in two interrelated iterations, and its evaluation was performed by utilizing three real-life case studies. Finally, the data collection was carried out by taking advantage of the potential that qualitative and quantitative methods offer when used in combination – the necessary user requirements for developing the software were identified using qualitative techniques such as interviews, while its aforementioned evaluation was performed by employing both qualitative and quantitative techniques in the form of surveys and case studies. A more detailed discussion of the research approach followed is provided in chapter four of this thesis.

### 1.5 RESEARCH CONTRIBUTIONS IN BRIEF

In line with the discussion so far, the research presented in this thesis can make the following significant contributions:

- To the areas of **science and/or technology**, the most significant contribution is the introduction of a novel 3-D pain drawing, which is more realistic, accurate and efficient than the well-established 2-D representation currently in use to visualize pain characteristics. This new pain drawing can also be effectively redesigned and used for designing, implementing and evaluating innovative 3-D user interfaces for medical purposes.
- To the area of **healthcare provision** this research can contribute to the improvement of the quality of services through the 3-D approach, which could be utilized by healthcare institutions and employed for the purpose of providing more effective pain assessment capabilities that could eventually reduce pain-related healthcare costs.
- An improvement to the quality of services through the 3-D pain drawing is anticipated to have a significant positive impact on **society**, as the social and working lives of pain sufferers could be improved by empowering the efforts for social inclusion of these people, which often could not be provoked due to their pain.

Overall, this research suggests that visualization of the pain experience shaped by a 3-D technological approach can be more efficient for addressing pain characteristics and can have positive implications in healthcare-related areas – a more detailed description of these contributions is provided in chapter nine.

### 1.6 ROADMAP OF THE THESIS

The roadmap of the thesis is subsequently structured as follows.

Starting from the baseline hypothesis that 3-D visualization technology can significantly contribute to the field of healthcare, and specifically to the management of pain-related medical conditions, **chapter one** has provided an introduction to the background of this research by discussing the relative general research context on the basis of which the present work was founded. The research aim and objectives have been further established, and a brief summary of the research approach to be used in addressing them, as well as the contributions of the present research have been lastly presented.

In the literature review of **chapter two** the complex nature of pain, and current approaches to the visualization of pain characteristics are placed in the light of the research. The review of the literature then moves on to a more explicit discussion with the focus being on presenting current trends in the application of visualization technology in the real-world, as well as on discussing state-of-the-art, real-life applications in relation to healthcare, in **chapter three**. This discussion aims at placing visualization technology into the context of this research by providing a collective perspective on the changing nature of visualization, pinpointing the shift towards the efficient employment of 3-D technology in healthcare practices.

In **chapter four** the research approach undertaken to carry out this research is outlined, and its appropriateness is demonstrated. Drawing upon the multidisciplinary nature of IS, it is argued that a combination of Design Science research with qualitative and quantitative methods allows a richer understanding and development of complex research areas that involve technological enhancements. This chapter also provides an insight and justification of the software methodology employed for the purpose intended.

## CHAPTER ONE - INTRODUCTION

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The aim of **chapter five** is to link the research approach discussed in chapter four with the solution's design and development lifecycle. It discusses the important role of users in the overall process, as well as it describes specific design and development aspects in terms of technology used. The necessary involvement of users in providing feedback to the research design is particularly highlighted.

**Chapters six, seven, and eight** present the results of the evaluation case studies performed for the developed solution. They are categorized into three distinct discussion scenarios, each of which focuses on various pain-related medical conditions, and on a particular aspect of the solution to be addressed with regard to this research's objectives. A statistical analysis was carried out for all case studies' results to validate and present the findings in a more meaningful way.

Finally, **chapter nine** discusses the findings of this research in relation to the aim and objectives established in chapter one, and presents the contributions yielded from the efforts of this work in terms of value added to society, science/technology, and relative healthcare providers. Lastly, the limitations encountered during the duration of this research are acknowledged, and suggestions for future work are presented.

## CHAPTER TWO

# UNDERSTANDING THE PAIN EXPERIENCE

## 2.1 OVERVIEW

It is distinctly well-established that the experience of pain has been increasingly challenging the pain community for quite a long time (Baker et al. 2010). While it is generally observed that advances in pain medicine have led to the successful development of several specific assessment methods, the community itself acknowledges the need for a constant researching approach towards initially understanding, and further introducing additional innovative ways of addressing the inexplicably vague nature of pain.

This chapter, by employing such an explorative attitude, principally attempts to provide a comprehensive overview of the pain concept, as identified in the clinical literature, in our efforts to introduce, in non-medical terminology, a basic understanding of the fundamental mechanisms of pain. This understanding would facilitate our next discussion that will focus on identifying the underlying reasons for the gaps that currently exist in the successful assessment of pain, and which highlight the need for immediate action.

Accordingly, the structure of this chapter is as follows. In the first part, a review of the literature with regards to the definition of pain, its clinical classification, and the issue of subjectivity will be presented. Similarly, the second part aims to provide a thorough understanding of the assessment tools currently in use to visualize the pain

experience. Specifically, the tools that can be employed to assess pain severity, pain affect and pain location are discussed in consecutive sections. The chapter concludes with a justification of the need to move from 2-Dimensions to more advanced visualization practices for pain.

## **2.2 PART ONE: UNDERSTANDING PAIN EXPERIENCE**

### **2.2.1 DEFINITION OF PAIN**

As with every context or discipline, it is of great importance to understand in depth the phenomenon studied. It is quite significant, therefore, to distinguish and further understand what pain as a feeling is, and where it stands as a medical condition within this broader definition. As Lee (2001) describes, in the late 19<sup>th</sup> century, anatomists defined pain as the *'delicate threads ... attached to ... the skin'*. Based on these findings, a primitive theoretical model was proposed implying that without injury there would be no pain. Although considered out-of-date, this is the most commonly accepted theoretical framework that even nowadays continues to dominate many clinicians' approach to pain management.

Nevertheless, controversy in the clinical literature seems to indicate that there is no commonly accepted definition with regards to the understanding of the underlying mechanisms of pain. What seems to be closer to reality though is a definition proposed by Kirkaldy-Willis and Bernard (1999), which, on top of physical injury, opts to expand the already established pain conception by further including the psychological dimension as well. Thus, by quoting their words, pain could be *"a basic bodily sensation induced by a noxious stimulus, received by naked nerve endings, characterized by physical discomfort (as pricking, throbbing or aching) and typically leading to evasive action and acute mental or emotional distress or suffering..."* In other words, they define pain as the result of a noxious stimulus, or emotional distress and suffering, or a result of both.

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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In accordance with the aforementioned definition is the following given by Provenzano et al. (2007), where “*pain is a private experience with complex sensory, affective, and evaluative qualities that must be measured if people in distress are to be helped*”. Mannion et al. (2007) further describe it as “*a multidimensional phenomenon*” that in addition to the qualities mentioned, “*includes physiologic..., affective, cognitive, behavioral, and socio-cultural aspects*”, as well as being “*associated with emotional reactions, such as anxiety, distress, or depression that in their turn might influence the person’s private, social, and professional activities*”.

Melzack and Walls with their ‘Gate-control’ theory of pain, as well as Melzack and Casey’s ‘Multi-dimensional’ model of the pain experience, indicate similar results (cited in Lee, 2001). In specific, the former is based on the assumption that rather than describing pain experience through a dedicated, ‘one-way’ pain system, consecutive psychological assessments of patients’ pain experiences should also be further employed. The implications of the ‘Gate-theory’ for the measurement of pain, although heavily criticized, were quite significant: *patient self-report of pain intensity has been accepted for the first time as the best available source of information.*

Along the same lines, the ‘Multi-dimensional’ model expands on the aforementioned theory by arguing against the conventional conception that pain varied only in intensity. On the contrary, Melzack and Casey’s proposed model of the pain experience included three distinctive dimensions; first, a sensory dimension corresponding to the established view of pain experience with regards to information about the location and intensity of pain. Second, an affective dimension that deals with the emotional aspects of the pain experience, and third, a cognitive dimension where the reaction to pain is described by the interaction of the previous two dimensions with higher cognitive functions and previous experiences.

The definitions and views discussed so far are also supported by Coll et al. (2004), who similarly suggest that pain affects emotional, social, familial, occupational, and physical functioning, while further influenced by psychological and cultural factors. Indeed, the broad definitions just given acknowledge the great challenge that pain assessment constitutes for the pain community. Considering the vast variety of the underlying factors that exist in the pain assessment process, it is rational to assume that patients' suggestive description of pain could be affected as a result of the influence of these factors in their efforts to accurately communicate their pain.

### 2.2.2 CLINICAL CLASSIFICATION OF PAIN

The previous section has highlighted the need for a universal language of pain that could act as the fundamental basis towards its successful assessment. However, the challenge of pain assessment is also heavily dependent upon the successful classification of the pain experience. Being able to physiologically classify, therefore, the type of pain that a patient is suffering from is of similar great importance for pain assessment, as it allows clinicians to subsequently identify and choose the correct treatment and monitoring process. To this end, Wincent et al. (2003) have divided pain into two main categories: *Nociceptive* and *Neuropathic* pain.

1. *Nociceptive Pain*. Broadly defined, nociceptive pain is a form of pain usually originating from “*primary activation of nociceptors due to a known ongoing pathological process, e.g., neoplastic infiltration, inflammation, ischaemia, visceral stretching, distension, etc.*” and it resides mainly in somatic, visceral, or nervous tissues.
2. *Neuropathic Pain*. This pain is defined by “*specific criteria associated with functional abnormalities of the nervous system, usually as a result of an injury or a disease process, affecting the peripheral nerves, spinal cord, or brain*”. Moreover, such pain is often referred to as neurogenic or neuropathic.

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

Typical examples are neuralgia and other forms of post-traumatic neuropathies. The following Table 2-1 summarizes the discussion.

Table 2-1. Characteristics of Nociceptive and Neuropathic Pain (Adapted by Wincent et al. 2003)

Tissue Origin		Temporal Characteristics	Common clinical characteristics
Somatic tissue	Bone, connective tissue, fascia, muscles, tendons, joints, and skin	Continuous	Well localised and constant. Referred pain. Sometimes radiating.
Somatic tissue	Bone, connective tissue, fascia, muscles, tendons, joints, and skin	Intermittent	Activity-related, muscle spasm
Visceral tissue	Viscera	Continuous	Deep and poorly localised pain. Autonomous and somatic reflexes. Referred pain
Visceral tissue	Intestinal obstruction and urogenital spasm	Intermittent	Spontaneous interval pattern. High intensity. Rarely related to movement and load. Referred pain
Nervous tissue with <i>intact</i> nervous system	Nerve trunk (nociceptive nerve pain)	Continuous	Often presents with neurological signs. Sometimes objective findings in neurological examination
Nervous tissue with <i>intact</i> nervous system	Nerve trunk (nociceptive nerve pain)	Intermittent	Often presents with neurological signs. Sometimes objective findings in neurological examination
Nervous tissue with nervous system <i>dysfunction</i>	Peripheral and/or central nervous system	Continuous	Sometimes radiating. Neuroanatomically correlated distribution and somatosensory dysfunction
Nervous tissue with nervous system <i>dysfunction</i>	Peripheral and/or central nervous system	Intermittent	Paroxysmal and lancinating pain. Sometimes unrelated to movement, load, and posture

Furthermore, the pain literature suggests that in addition to the above classification, the pain that a patient is suffering from can be further sub-categorized in one of three groups, with regards to the duration of their experience: *a. acute*, *b. sub-acute*, and *c. chronic*. Acute is pain that has short duration, usually about a week, and it is characterized by mild to severe pain. Similarly, sub-acute pain lasts between seven

days and seven weeks and is normally mild. Chronic pain, however, is described as pain that lasts for longer than three months and affects between 5-10% of the population (Matsen, 2001).

### **2.2.3 PAIN AS A SUBJECTIVE EXPERIENCE**

So far, we have focused our discussion on identifying two important points: initially, we have attempted to distinguish the underlying factors that form the concept of pain, as derived through the various definitions suggested by the clinical literature. Secondly, in the light of a fundamental understanding of what pain is and what pain could be, we have further tried to present how pain can be distinctively classified. The above efforts might as well constitute the prerequisite for a successful pain assessment. Nevertheless, evidence from the literature suggests that they could similarly have a negative effect on the overall process.

By definition (see subsection 2.2.1) the best available sources of information that clinicians can rely on when assessing pain are *suggestive descriptions* or *self-reports* from a patient. In a previous subsection, we have also established the fact that pain is a highly subjective experience, as it is characterized by complex qualities associated with a variety of underlying factors. Subsequently, patients that self-report pain may have been influenced by these factors, while having to deal with such pain.

Owing to this problem, patients can often experience difficulty in accurately communicating their pain, which can be one of the most important reasons for under-treatment of such a chronic condition. This view is derived by McCaffery's (1989) definition in which "*pain is whatever the experiencing person says it is and exists whenever they say it does*", as well as by Katz and Melzack (1999) who support that "*pain is a personal and subjective experience that can only be felt by the sufferer*".

### 2.3 PART TWO: VISUALIZING THE PAIN EXPERIENCE

It is because of the implications of the above discussion that many approaches to the assessment of pain characteristics have evolved over the last decades. According to the literature (Malliou et al. 2005), these assessment approaches have been categorized as follows:

- ***Self-report measures.*** Using this method, the clinician records pain measurements such as the worst pain or the least pain, as perceived by the patient reporting it.
- ***Observational measures.*** This kind of measures includes the clinician observing the patient regarding aspects such as behaviour or activity performance, as related to pain.
- ***Physical-functional performance tests.*** Finally, this kind of tests is a method of measuring the performance of a patient in functional tests, in order to prove pain effects in functional activities.

#### 2.3.1 ASPECTS OF PAIN TO CONSIDER

Nevertheless, the aforementioned assessment approaches have been developed and are currently used in order to address several pain aspects that one needs to first take into consideration when interpreting the pain experience. Based on a review made by Haefeli and Elfering (2006), these aspects could be broadly split into three main categories:

1. ***Pain severity.*** This aspect contains the pain-related interference with *activities (disability)* and the *intensity* of pain, which is defined as how much a patient is in pain. It was further found that those two characteristics of pain severity could be of either a uni-dimensional or a multi-dimensional form, depending on the specific instruments tested. The difference between them is that for the former, only pain intensity was considered, whereas for the latter

other characteristics such as emotional factors are also addressed (Lee, 2001). Moreover, several other tools have been further developed that aim to assess the pain-related interference with activities of daily living such as walking, dressing, etc., as well as the pain intensity of the patient in assessment.

2. **Chronicity.** Pain can be also assessed based on the *period of time* that persists. This aspect, therefore, deals with characterizing pain as being either chronic or not. According to this characterization then, a specific treatment plan can be designed and followed.
3. **Pain experience.** This consists of measures with regards to *pain intensity* and *pain affect*. Since pain intensity has been described before, we will only deal with pain affect. So, as a notion, pain affect describes the “*degree of emotional arousal or changes in action readiness caused by the sensory experience of pain*”, or in other words, how much a person suffers. Accordingly, a lot of factors such as social situation, work situation, and setting and history of prior injury may influence pain perception, as described by Haefeli and Elfering (2006).

All the pain aspects mentioned above are direct indicators of patients’ clinical condition. Considering, therefore, all these different pain aspects that each pain assessment method needs as a prerequisite in order to address a patient’s clinical condition, and by taking into account all the various pain assessment methods that have been consequently developed with regards to the aforementioned purpose, it is rational to assume that a vast array of assessment tools covering the above conditions have been accordingly evolved.

### 2.3.2 VISUALIZING CLINICAL PAIN INFORMATION

It has to be made clear that although all of the aforementioned methods are considered to be valuable and necessary in order to assess a patient’s pain

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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experience, in practice, the clinical literature indicates *self-report* to be the gold standard for the intended purpose, mainly because of its consistency with the definition of pain, which is the reason why it is so widely used. Malliou et al. (2005) suggest that self-report is typically instantiated in the form of a questionnaire, which has been found to have many advantages in the pain assessment process (Wincent et al. 2003), since:

- A. Traditional history-taking procedures do not focus on the multi-dimensional nature of pain;
- B. Relevant information must come directly from the patient, which is of great importance concerning pain development over time;
- C. In the hands of an experienced clinician it helps the patient to define his or her experiences;
- D. Different procedures in pain assessment are usually performed and documented, something that is instructive for both the clinician and the patient;
- E. Serves as a checklist to avoid missing any important information;
- F. Can be the subject for computerized work-up;
- G. May be the source for outcome studies

According to Lin et al. (2006), the question items often employed to form such a questionnaire consist of various assessment tools, which are specifically designed to address the multiple pain aspects, as we have discussed at the end of the previous subsection. Thus, several assessment tools that address *pain severity* (including intensity and chronicity), and *pain experience* (including pain affect and pain-related interference with daily living activities) currently exist and are used to visualize the patient pain characteristics.

**2.3.2.1 PAIN SEVERITY VISUALIZATION TOOLS**

As mentioned in a previous subsection, pain severity aspects are considered to be either uni-dimensional, or multi-dimensional. Since the tools that are going to be described next deal only with the intensity of pain, they would be characterized as uni-dimensional in nature. So, traditionally, three tools have been used to visualize pain intensity, namely the *Visual Analogue Scale (VAS)/ Graphic Rating Scale (GRS)*, the *Verbal Rating Scale (VRS)*, and the *Numerical Rating Scale (NRS)*.

A. **Visual Analogues Scale/ Graphic Rating Scale.** According to Lee (2001), the VAS is one of the most common pain intensity measurement tools. It typically consists of a 10-cm straight horizontal line with endpoints that define the limits, such as “no pain” or “pain as bad as it could be”. Usually, horizontal lines are preferred, since it is argued that scores are more normally distributed (Figure 2-1).



Figure 2-1. An example of a Visual Analogue Scale (Adapted by Haefeli and Elfering, 2006)

Moreover, if descriptive terms like ‘mild’, ‘moderate’, ‘severe’, or a numerical scale are added to the VAS, one speaks of a Graphic Rating Scale, as shown in Figure 2-2 (Haefeli and Elfering, 2006).

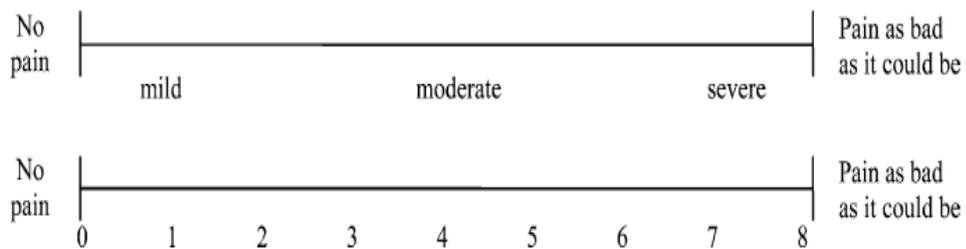


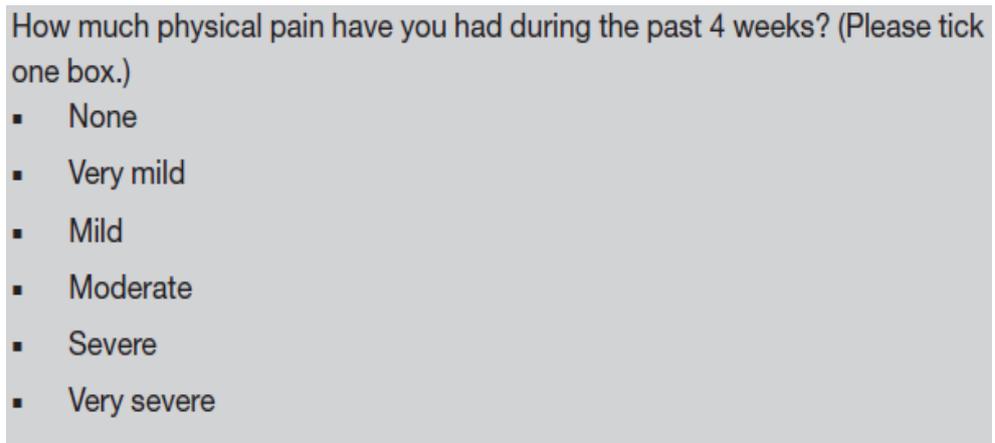
Figure 2-2. Examples of Graphic Rating Scale (Adapted by Haefeli and Elfering, 2006)

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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Pain intensity thus, is determined by measuring the distance from the lower end of the scale to the mark made by the patient.

*B. Verbal Rating Scales.* Similarly to VAS/GRS, Verbal Rating Scales also consist of two endpoints, and of a set of four-to-six adjectives that are used to describe different levels of pain (Figure 2-3), as explained by Haefeli and Elfering (2006).

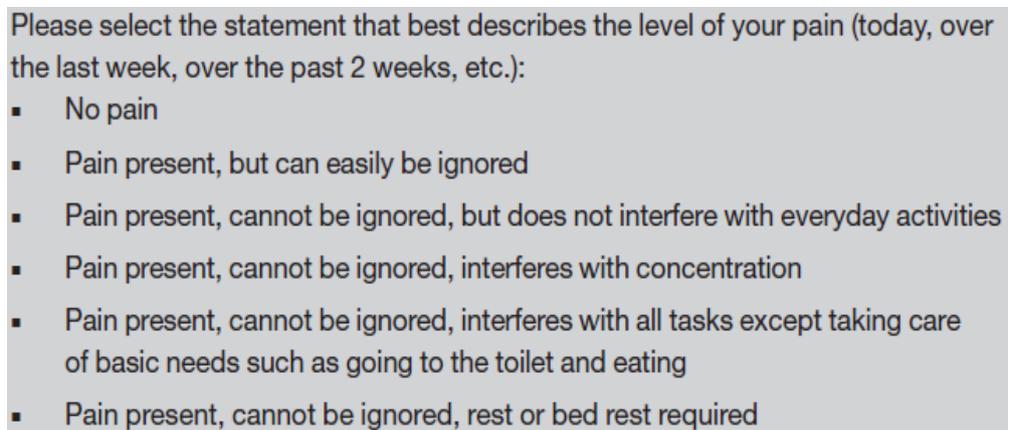


How much physical pain have you had during the past 4 weeks? (Please tick one box.)

- None
- Very mild
- Mild
- Moderate
- Severe
- Very severe

Figure 2-3. An Example of Verbal Rating Scale (Adapted by Mannion et al. 2007)

A different form of a VRS is the Behavioural Rating Scale (BRS), where pain level is described by sentences indicating behavioural activities (Figure 2-4). Unlike VAS/GRS, the VRS is usually in the form of a questionnaire, rather than a straight horizontal line.



Please select the statement that best describes the level of your pain (today, over the last week, over the past 2 weeks, etc.):

- No pain
- Pain present, but can easily be ignored
- Pain present, cannot be ignored, but does not interfere with everyday activities
- Pain present, cannot be ignored, interferes with concentration
- Pain present, cannot be ignored, interferes with all tasks except taking care of basic needs such as going to the toilet and eating
- Pain present, cannot be ignored, rest or bed rest required

Figure 2-4. An Example of Behavioural Rating Scale (Adapted by Mannion et al. 2007)

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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C. **Numerical Rating Scales.** The last of the tools that are going to be described is the Numerical Rating Scale, on which patients are asked to rate their pain intensity from a scale of 0-10 or 0-100 (Lee, 2001). Zero usually represents “no pain”, whereas the upper limit represents “the worst pain possible”. Figure 2-5 shows an example of a NRS.

“If a zero (0) means ‘no pain’ and a ten (10) means ‘pain as bad as it could be’, on this scale of 0–10, what is your level of pain? Put an “X” through that number.”<sup>28</sup>

0	1	2	3	4	5	6	7	8	9	10
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Figure 2-5. An Example of Numerical Rating Scale (Adapted by Mannion et al. 2007)

Although the pain severity assessment tools just described are all considered to be valid, there seems to be considerable debate in the clinical literature as whether they are also reliable for the intended purpose. To this end, several studies have been conducted in order to prove their reliability. In a study performed by Mannion et al. (2007) on patients with chronic pain, six different forms of the pain tools described (traditional VAS, 101-point NRS, 11-point box scale, 6-point BRS, 4-point VRS, and 5-point VRS) were compared. This was done based on the following criteria: ease of administration of scoring, rates of correct responding, sensitivity (as defined by the number of available response categories), and responsiveness to change, as well as in terms of the predictive relationship between each scale and the linear combination of pain intensity indices.

The tools produced similar results concerning their predictive validity and the proportion of patients not responding as instructed (e.g. leaving response blank, marking between two categories, marking two answers, etc.). Indeed, according to Lee (2001), several similar problems exist with the use of the aforementioned tools. Despite their apparent simplicity, approximately 7-11% of adults, and up to 25% of the aged fail to complete it. As such, VAS methods are sometimes criticized as being

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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difficult to understand, with 7–16% higher failure rates being reported for VASs than for the VRSs and NRSs. This problem is often found, though, in individuals with physical or cognitive impairment and in the elderly. The VAS is also less reliable in illiterate patients (Mannion et al. 2007).

When considering the remaining criteria (responsiveness to change, ease of administration, sensitivity), the 101-point NRS proved to be the most practical tool. In practice, patients prefer the NRS to the VAS since only 2% fail to complete it (Lee, 2001). Moreover, the feasibility of its use, as well as that it is easily possible to administer it, e.g. verbally, have similarly been proven (Haefeli and Elfering, 2006). In addition, Mannion et al. (2007) have also discovered that in patients with a chronic disease such as osteoarthritis, the *“VAS and VRS responses were shown to be highly correlated ( $r \approx 0.7-0.8$ ) and the tools produced similar effect sizes after treatment”*. Therefore, results suggest that the VRS was easier to administer and interpret, and at the end the VRS emerged as the overall scale of choice in both younger and older cohorts.

To this end, evidence from the clinical literature seems to indicate that the VRS, as well as the NRS are the most reliable tools that patients feel more comfortable using; however, they are not as appropriate to detect changes over time as are VASs and GRSs, who have been shown to represent the real difference in pain intensity when used for measurement at two different points of time (Haefeli and Elfering, 2006). *Therefore, since pain is a condition that in order to understand one needs to look at its development over time (Stratford et al. 2004), the VAS and/or the GRS are the pain intensity measurement tools that are considered to be the most appropriate for the intended purpose.*

### 2.3.2.2 PAIN EXPERIENCE VISUALIZATION TOOLS

Accordingly, Haefeli and Elfering (2006) conducted a review at the available tools often used to visualize pain experience, and specifically, pain affect. Based on their study, the aforementioned tools (VRS, NRS, etc.) could be used to measure pain affect; however, due to the fact that measuring affect is multi-dimensional in nature, that is intensity and affect are both considered in the assessment, the results show that these tools have the same disadvantages as when measuring pain intensity alone. For that reason, more sophisticated tools have been developed for the intended purpose, such as the *Pain-O-Meter*, and the *McGill Pain Questionnaire* described below.

1. ***Pain-O-Meter***. This tool, quoted from their review, “*consists of a mechanical VAS and two lists of terms describing the pain affect. Each of these terms has an associated intensity value ranging from one to five. The respondents must decide, which of the 11 possible words best describe their pain. Then the associated intensity values are summed together to build the Pain-O-Meter-affective scale*”. This scale has been proved to be a reliable and sensitive approach, specifically in different settings, such as analgesic treatment or differentiation between chest pain caused by myocardial infarction and other chest pain. However, more research on validity and reliability in different settings should be performed to further understand this tool.
2. ***McGill Pain Questionnaire (MPQ)***. Similarly, they describe the MPQ as a tool that consists of three main measures: pain-rating index, the number of words chosen to describe pain, and the present pain intensity based on a 1-5 intensity scale. Specifically, the MPQ is administered by reading a word list to patients, and asking them to choose only those words that describe their pain at present. Pain scores are then calculated by summing the rank scores for each category (Lee, 2001). The MPQ is the most extensive tool to

measure pain affect. It has been used in many studies and has recently been reviewed extensively (Haefeli and Elfering, 2006), with the results showing that the MPQ has been shown to be able to discriminate between specific types of pain. In a study of 120 patients, carried out by Lee (2001), it was found that a distinct pattern of words from the MPQ distinguished back pain patients with an identifiable etiology for their back pain from patients with no known cause for their pain at 87% of the time.

In addition to the visualization of the clinical aspects identified in subsection 2.3.1, the consensus of the pain literature indicates that for a more comprehensive assessment of a patient in pain, another distinctive pain aspect should be also taken into significant consideration – **the location of the reported pain**. This is going to be described in more detail in the subsection that follows.

### 2.3.3 VISUALIZING THE SPATIAL LOCATION OF PAIN

In addition to visualizing pain intensity and affect-related clinical information, the patient is also asked to mark on a diagram, usually a 2-D representation of a human body, where the pain is *located*, and the *type* of pain that he or she is suffering from. This type of diagram is known in the pain literature as a “pain drawing”, and is shown in Figure 2-6.

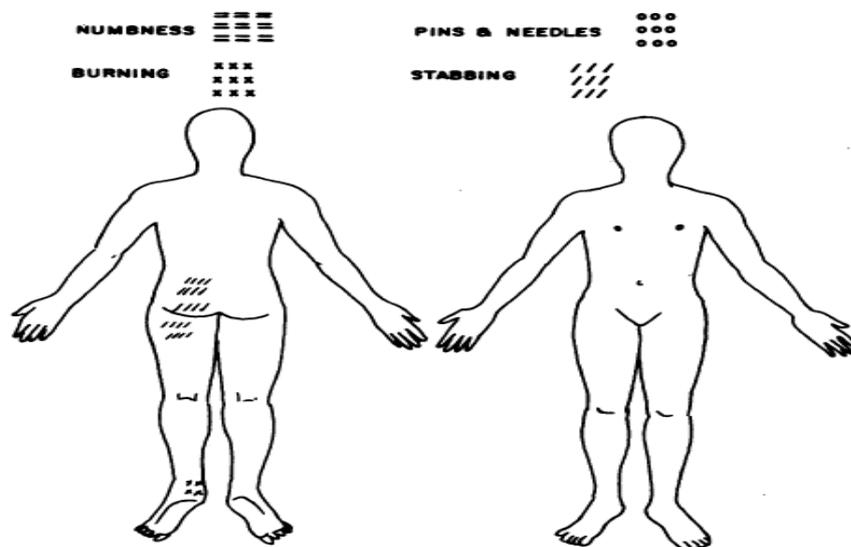


Figure 2-6. A 2-D Pain Drawing (Adapted by Mooney et al. 1976)

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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The pain drawing is a tool that has been used since the 1940s in the assessment of patients in pain (Ohnmeiss, 2000), and is considered to be a simple self-assessment method, originally proposed as a visual aid tool to enable the recording of the spatial location and type of pain that a patient is suffering from.

One of the main advantages that lead to its popularity is that it improves the communication between a clinician and the patient. Indeed, spoken description of pain by a patient to the clinician might not be sufficient due to educational, language, and experience differences that might occur amongst them (Mooney et al. 1976). By using pain drawings though, this two-way communication is improved by providing a common framework based on which the patient describes the pain by marking it on the pain diagram, and the clinician interprets it by examining it, enabling them in that way to overcome the aforementioned differences.

This topographical representation of pain therefore, is very useful in summarizing patients' description of the location and type of pain, in an interpretable way for the clinician, and makes it possible to determine whether pain is of organic or non-organic nature (Takata and Hirotoni, 1995). Moreover, in a study that examined various tools in their ability to differentiate patients with back pain from those with other types of pain, the pain drawing showed 100% sensitivity, but its specificity was only 47% in men and 39% in women (Mannion et al. 2007).

In addition to improving communication, additional benefits of pain drawings have been described in the pain literature. Ohnmeiss (2000) cites in her work results of studies that demonstrate consistency of patients in completing drawings, even with elderly subjects, while Jamison et al. (2004) highlight their importance in corresponding to imaging tests, as well as in being able to help clinicians to categorize patients into diagnostic groups (e.g. osteoporosis, tumor) based on their pain drawings.

Moreover, in overall, pain drawings are considered to be economic and simple to complete, and can also be used to monitor change in a patient's pain situation (cited in Serif and Ghinea, 2005). As a result, based on their ability to help identify patient diagnostic groups, pain drawings have been used in various medical situations, including diagnosis of lumbar disc disease, evaluation of changes in pain, as well as prediction of treatment outcome (Ohnmeiss, 2000).

### **2.3.3.1 CURRENT TECHNIQUES TO COMPLETING A PAIN DRAWING**

Nevertheless, because of the several uses of pain drawings, the need for different methods of interpreting them has also been identified. However, no standard method for *filling them out* and *scoring* them currently exists. According to some protocols, patients might be asked to either mark or shade those body areas where they usually feel pain (Haefeli and Elfering, 2006). Slight variations of this method also exist, with the patient instead of marking or shading the pain within the outline of a blank human diagram, might be asked to respond to a pre-shaded drawing. This variation is argued to have the advantage of making it easier for the patient to recognize on the pre-shaded body where most of the symptoms tend to occur (Lacey et al. 2003).

Traditionally, however, according to Sanders et al. (2006), in earliest uses of pain drawings the patient would fill them out by marking the location of the pain on a blank diagram using a symbol, without mentioning any sensation (pain, burning, etc.), as it was the clinician's responsibility to identify it through the discussion. More recently though, the patient is asked to also indicate their pain sensation on the drawing, with the most common way of doing it being the use of a specific symbol indicating various sensation types, as shown in Figure 2-6.

Similarly, there is no gold standard regarding specific pain *sensation types* that could be used to describe pain on the drawing. Serif and Ghinea (2005) cite in their study that there is a range of sensation types which have been used in the literature,

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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including Chan et al.'s (1993) use of *pins and needles*, *burning*, *stabbing*, and *deep ache* in their pain drawings, and Uden et al.'s (1988) use of *dull*, *burning*, *numb*, *stabbing or cutting*, *tingling or pins and needles*, and *cramping*. Accordingly, Ohnmeiss (2000) uses *aching*, *numbness*, *pins and needles*, *burning*, and *stabbing*, whereas Masferrer et al.(2003) further explored the use of color as a representation for the different sensation types being experienced (see Figure 2-7). The results from this study showed that the ability of color pain drawings to express the pain experienced remained the same as with previous monochrome approaches.

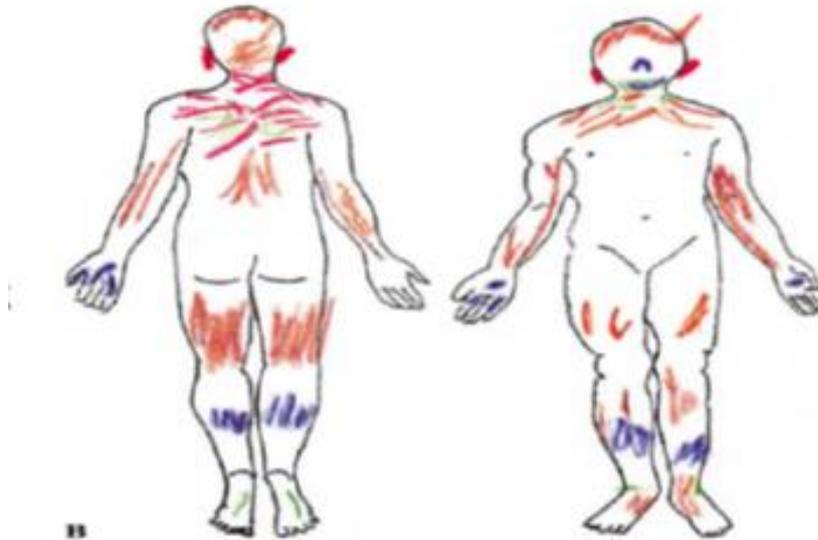


Figure 2-7. An Example Coloured 2-D Pain Drawing (Adapted by Masferrer et al. 2003)

Overall, pain drawings are considered to be a flexible tool with regards to the use of pain sensation types to fill out such a drawing. It is, though, noticeable that all sensation types tend to share the same or similar notations, and be represented by either symbols or color-coded, as the aforementioned studies indicate. On the other hand, however, the usefulness of sensation in diagnosing pain has been questioned by many studies, which conclude that pain sensation seems less reliable, most likely because it is subjective; however it was suggested that it could assist in differentiating certain conditions (Sanders et al. 2006).

### 2.3.3.2 CURRENT TECHNIQUES TO SCORING A PAIN DRAWING

In order for the pain drawing to be interpreted, it first needs to be assessed by a clinician. A very common technique of assessing a drawing is by visual interpretation, where the clinician usually looks to see if the pain marks or shades follow dermatome patterns. *Dermatomes* can be described as “a ‘segmental field’ of the skin that is innervated by a spinal nerve” (Sanders and Mann, 1995), which could be used to determine the level of injuries that might have occurred in the spinal cord. This makes them an accurate tool in localizing the source of certain pain types (Sanders and Mann, 2000) (Figure 2-8).

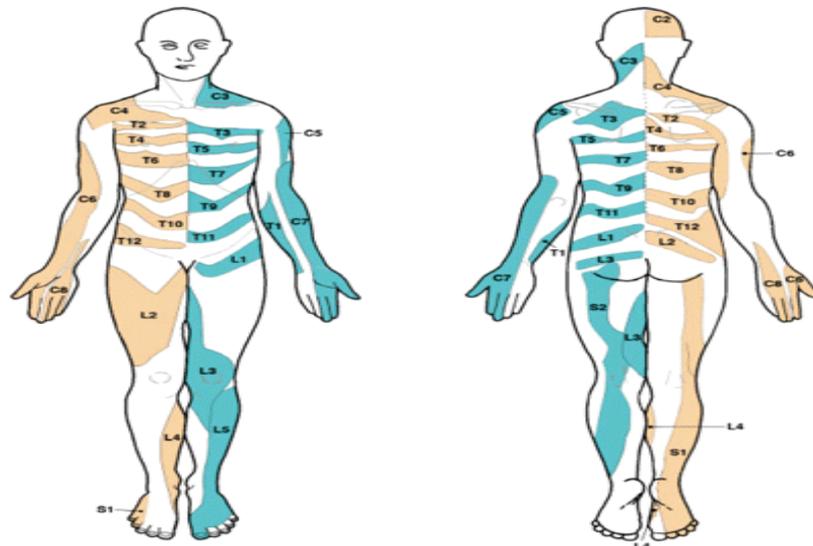


Figure 2-8. A Dermatome Map (Adapted by Apok et al. 2011)

In addition to assessing a drawing by visual interpretation, several more manual scoring techniques have been devised that would allow for further interpretation of the pain descriptions, and which are specifically useful for studies or clinicians who would like to quantify drawings for further analysis. Generally speaking, these techniques broadly fall into one of four categories: *Penalty Point System*, *Visual Inspection Method*, *Body Region Method*, and *Grid Method*. It has to be noted here that the first two methods require subjective interpretation, whilst the last two record the presence or absence of pain within defined regions (Ohnmeiss, 2000).

- ***Penalty Point System.*** Using this method, pain drawings are scored using the penalty point system described by Ransford et al. (1976), where points are assigned for any not natural marking of pain on the diagram (such as pain outside the body area), for the use of extra words or symbols to describe pain or its severity, as well as for pain in specific unusual body areas. The drawings are then classified as “normal” if two or fewer points are assigned, or as “abnormal” if the points are more than two (Ohnmeiss, 2000). Moreover, by using such a penalty-point scoring method it was found that pain drawings could also predict 93% of the patients that needed further psychological evaluation, just by looking at their completed pain drawing (cited in Serif et al. 2005). Therefore, in that case, pain drawings could also be used as an economical psychological tool, in conjunction with their normal pain location recording use.
- ***Visual Inspection Method.*** As cited in Serif et al. (2005), pain drawings are usually evaluated with this method by experienced evaluators, who are able by looking at the drawing to say what is the situation with the patient, and if further psychological testing is needed. To this end, Uden and Landin (1987) initially used this method in their study to identify patients suffering from lumbar disc herniation. The results of their study showed that pain drawings could be classified as either *indicative* or *non-indicative* of symptomatic disc disease, depending on whether the pain was mainly in a radicular pattern from the back into one or both lower extremities (indicative), or whether it was restricted to low back only, as indicated by unusual marks outside the body region to describe pain (non-indicative).

- **Body Regions Method.** In this case, pain drawings are scored using a transparency of the human body divided into regions, which is laid over a drawing (Figure 2-9), and the presence or absence of pain within a region is recorded, as described by Margolis et al. (1986).

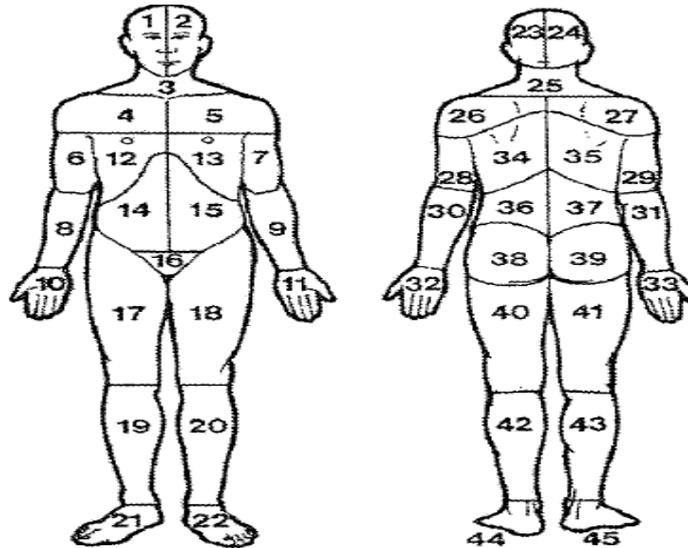


Figure 2-9. The Body Regions Method (Adapted by Ohnmeiss, 2000)

However, a possible bias with this scoring system is that this technique includes 45 body regions, many of which probably could not be used in relation to specific pain conditions. To this end, in another study carried out by Ohnmeiss et al. (1995), having in mind this bias possibility, they reduced the division of the body into five general regions, namely low back and buttocks, posterior thigh, posterior leg, anterior thigh, and anterior leg.

- **Grid Method.** As cited in Ohnmeiss (2000), Gatchel et al. (1986) initially described this technique by making a transparency of a grid (Figure 2-10) which is laid over a pain drawing. The drawing was then scored by counting the number of squares the patient indicated pain.

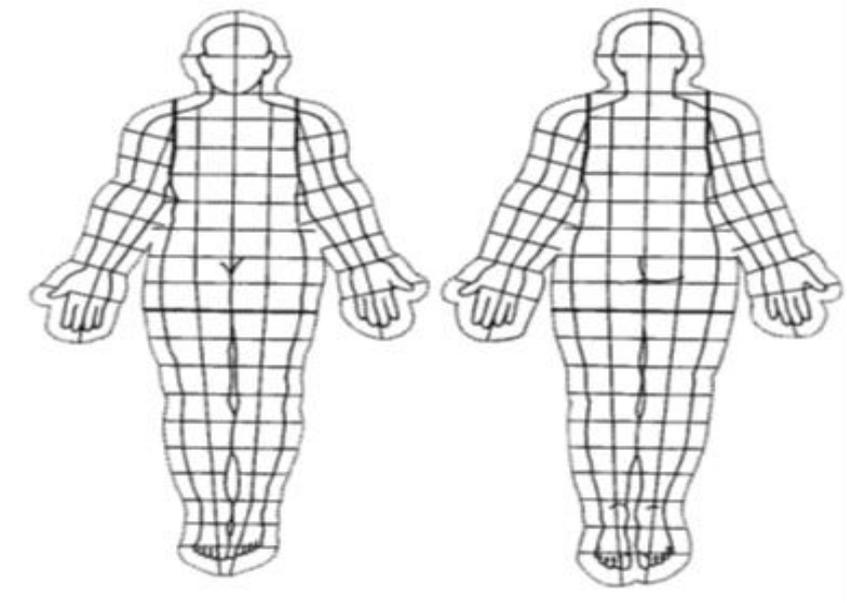


Figure 2-10. The Grid Method (Adapted by Ohnmeiss, 2000)

Several studies exist in literature regarding the usefulness of the grid method in identifying various pain patterns. Takata and Hirotsu (1995) cite in their work results of Capra and Mayer's (1985) study that demonstrate the ability of the grid method to differentiate between localized, mechanical, and radicular or referred patterns of pain. On the other hand though, Sanderson and Wood (1993) found that when grid assessment was used before operations in patients with spinal stenosis, the results showed a negative correlation between the outcomes of operation with the area of the body covered with symbols.

In the past, most of the pain drawings scoring methods were performed manually by a clinician based on his or her experience. However, more recently, various studies have taken a different approach and adopted the use of automated computer scoring by exploiting artificial intelligence methods. To this end, Sanders and Mann (2000) used artificial neural networks to assess pain drawings, while Jamison et al. (2004) used a computerized decision model to score them in order to identify real or imagined pain. After comparing the results of the automated computer techniques to the results of experienced clinicians, it was found that these techniques were able to

classify pain drawings almost as well as clinical experts (cited in Sanders and Mann, 2000).

### **2.3.3.3 THE PAIN DRAWING AS A PSYCHOLOGICAL SCREENING TOOL**

Although pain drawings are currently used to identify the pain location and sensation type, it is worth mentioning that, initially, they were introduced by clinicians as a psychological screening tool utilized to identify patients with psychological issues, which was felt to be one of the main reasons for pain indication. Nevertheless, there is much confusion in the literature as to what exactly pain drawings are actually measuring. Most of the research work has been done in relation to their ability as a psychological screening tool, with the results being rather conflicting.

So, in a study carried out by Parker et al. (1995), three methods of scoring pain drawings were evaluated for their ability to predict psychological distress, with the results showing that none of them were able to identify distressed patients. Similarly, results obtained by Greenough and Fraser (1991), who assessed eight psychometric instruments, showed that pain drawings had a sensitivity of only 42% in identifying patients with psychological issues.

Because of the aforementioned implications, in order to identify a patient's psychological state before the actual treatment begins, clinicians nowadays, in addition to pain drawings, also ask patients to fill in specific psychometric questionnaires of different types, with the main ones being (cited in Ghinea et al. 2002):

- i. The *Modified Somatic Perception Questionnaire (MSPQ)*, which assesses somatic anxiety;
- ii. The *Roland and Morris (1983)* questionnaire, which is used to measure the patient's pain-caused disability; and

- iii. The *Zung* (1965) questionnaire, which assesses depression via the respondent giving answers to 20 questions using a self-rating scale

The most common psychological screening tool currently in use, however, is the *Minnesota Multiphasic Personality Inventory (MMPI)*. According to Mooney et al. (1976), the MMPI consists of 566 affirmative statements to which a patient responds true or false. It was found that the MMPI results do reflect the state of the patient, however only at the time of taking the test. Subsequently, Ransford et al. (1976) combined the MMPI with the pain drawing, with the results of this combination indicating that they could predict 93% of the patients that needed further psychological evaluation.

### **2.3.3.4 A CLOSER LOOK AT THE PAIN DRAWING**

Based on the discussion so far, the consensus of the literature seems to indicate that the pain drawing is considered to be a valuable and useful tool in visualizing aspects of pain such as the location and sensation type, as well as in identifying psychological disturbances. Nevertheless, the various studies that have been performed on the reliability of the pain drawing have also revealed that they have several disadvantages that are worth mentioning.

**Firstly**, one of the biggest questions, for which the answer is still vague, is the repeatability concern. Evidence from the clinical literature indicates that patients are usually repeatable when completing drawings, especially on occasions separated by a mean of 71 days (cited in Ohnmeiss, 2000). Therefore, the conclusion drawn was that the effective interpretation of the drawing should be performed when pain recording occasions are separated by enough time, so that patients will not be able to remember the responses given the first time.

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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**Secondly**, a noteworthy issue also raised through our discussion is the fact that, in most of the studies reported, the pain assessment tools were usually stored in a paper format, something that makes the storing of this information an impractical and sometimes a subject to error task. Jamison et al. (2004) argue that despite the ease of administration and use of such paper-based assessment techniques, practically, they have several drawbacks. First of all, use of such paper-based tools can lead to “*noncompliance, missing data, and fabrication of information if the respondents have not completed the requested information at the designated times*”. Moreover, the process of transferring the information from paper forms to the computer for analysis and evaluation is also a potential source of error.

To compound the issue, computer-based tools have emerged that have many strengths. Compared to paper-based techniques, they were found to be extremely useful in capturing time-stamped data (Jamison et al. 2006), particularly necessary for recording pain variations over time. In addition, numerous advantages have been described in the clinical literature, such as their portability, ease of data sharing, instant access (Jamison et al. 2006), as well as direct transfer of information, and their ability of a dynamic graphical display to visualize data (Provenzano et al. 2007).

Indeed, several studies in the literature indicate that electronic tools could be very practical in recording pain information. Thus, Ghinea et al. (2002), digitally linked pain drawings as part of the assessment process with positive results, while Wilkie et al. (2003) found that a touch-screen version of the McGill pain questionnaire when combined with a pain drawing to indicate the location of pain had adequate acceptability across various age and ethnic groups. Moreover, as Marceau et al. (2007) also suggest, patients using electronic tools for the intended purpose were found to be more compliant than those using paper-based tools, and had higher satisfaction over the course of their study.

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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**Finally**, the biggest drawback of the pain drawing concerns its performance when it comes to *accurately visualizing patients' pain descriptions*. Specifically, notwithstanding their advantages, 2-D pain drawings also have limitations, as they do not capture the 3-Dimensional nature of the human body. Thus, patients are often unable to visually express the pain that they are experiencing, as statements of the form “*I have a pain on the inside of my thigh*” are not easily captured in a 2-D pain drawing, as it constitutes a limited dimension perspective of the human body on which specific pain sites cannot be easily marked as painful. This could potentially result in a time-consuming process with possible irrelevant medical data collected that can lead to a report that obscures important information.

To this end, over the years there have been a number of research studies to continue and extend research in respect to improving the pain drawing. All of the studies (Gomez et al. 2002; Lin et al. 2006; Masferrer et al. 2002; Parker et al. 1995) had slight variations but were still conceptually the same, using the same 2-D approach. Accordingly, the review of the pain literature presented over the previous sections has similarly highlighted a general consensus with regards to the widespread use of the 2-D pain drawing for the intended purpose.

Nevertheless, visualization in two dimensions has been thoroughly explored, and results from a significant number of studies seem to suggest that 2-D visualization is not anymore useful for a complete understanding of the ‘object’ under investigation, mainly because it lacks the natural depth cues (e.g. perspective, shading, and occlusion) (St. John et al. 2001). As such, the application of more advanced visualization practices towards the enhancement of the 2-D pain drawing seems to be imperative.

### **2.4 SUMMARY**

The work presented in this chapter has mainly focused on providing a fundamental understanding of pain, and the methods and tools currently in use to visualize its characteristics. The first point highlighted was the lack of a universal definition of pain. Although there appears to be a vast variety of approaches in defining pain, a review of the clinical literature has revealed that the majority of the reported studies points to the common pain characteristics that the aforementioned definitions share.

Along the same lines, this chapter has also demonstrated a similar lack of a standard procedure for assessing and visualizing pain-related characteristics. Evidence from the pain literature, however, showed that in most cases the methods and tools used are conceptually the same, typically revolving around several specific instruments that are either used to assess pain severity, location and type, and/or the psychological state of a patient. As a result of their multifunctional nature, these tools have been extensively reviewed and discussed in the clinical literature with regards to their usefulness in identifying and assessing pain, with mixed results in this respect. In accordance with these reviews, the VAS and/or GRS has been eventually decided to be employed in this research, as they offer the ability for more realistic measurement of pain over time (see subsection 2.3.2.1).

Moreover, despite their widely accepted usefulness (Haefeli and Elfering, 2006; Jamison et al. 2004; Lee, 2001; Mannion et al. 2007; Mooney et al. 1976; Ohnmeiss, 2000; Serif and Ghinea, 2005), there is a lack of consensus regarding the applicability of these specific tools in assessing persons with pain. For example, asking an individual with a spinal cord injury a question about pain interference with walking, a common question in many quality of life measures is not applicable for someone who uses a wheelchair every day (Bryce et al. 2007). In addition, they were also found to have several major drawbacks, such as their paper-based format and the limited visualization ability of the 2-D pain drawing.

## CHAPTER TWO – UNDERSTANDING THE PAIN EXPERIENCE

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Finally, perhaps one of the most important and controversial issues raised through this review of the literature was the subjectivity of pain. Specifically, the literature indicates that several studies have been conducted over the years in order to thoroughly understand this issue. However, the results produced mostly showed that more efficient measurements than the existing ones need to be identified, so as to fully comprehend pain.

The need, therefore, for a computer-based solution that would be able to address the issue of the impractical paper format, and especially allow for a more accurate and improved visualization of pain experience than the current 2-D pain drawing, has been found to be significantly eminent.

## CHAPTER THREE

# VISUALIZATION FOR BETTER HEALTHCARE

### 3.1 OVERVIEW

Advancements in technology over the last decades have facilitated researchers across various disciplines to produce considerable amounts of data that contain significant information about a problem under study. However, the issue appears when it comes to efficiently convey all this information to the interested parties, in a meaningful way, so that they can analyse and use it for their intended purpose. Visualization technology can be the linking component that could allow the two sides to more effectively explore these huge amounts of information, in a more comprehending way to the whole community involved.

This chapter, therefore, attempts to put the aforementioned capabilities that visualization technology could offer into the context of the need for more effective pain visualization approaches. As such, a review of the current state of the art of visualization will be presented, with a particular emphasis on medical visualization that has become an important assessment tool in the practice of modern medicine. Whilst a solid overview of medical visualization technology will be provided, this chapter does not constitute an exhaustive review of the general aspects and disciplines of visualization technology.

Accordingly, in the next section the concept and the most important characteristics of visualization are described, and some illustrative real-life applications are presented. The chapter then continues to the field of medical visualization, where a comprehensive overview of advancements in medical imaging is provided, and it concludes with examples of visualization technology in real-life medicine and with the rationale for adopting it for the purpose of improved pain management.

### 3.2 WHAT IS VISUALIZATION?

**‘Visualize’** Form a mental image of, imagine; make visible to the eye.

Oxford Advanced Learner’s English Dictionary, 2001

Visualization is a relatively new concept in Information and Communication Technology (ICT) that has influenced a variety of domains in their ability to convey and understand data. But, how could visualization be described? In the pursuit of a suitable answer, different definitions have emerged, with the Oxford Advanced Learner’s English Dictionary (see above) giving the most concise, yet also the most generic terminology used to describe visualization. Card et al. (1999), on the other hand, provide a more specific perspective on the above question by defining visualization as *‘the use of computer-supported, interactive, visual representations of data to amplify cognition’*. A closer look at these definitions could help us unveil some of the benefits of using visualization, irrespective of the domain or contributing discipline. In support of the above statement, the literature (Kapler and Wright, 2004) similarly seems to suggest the existence of several advantages, summarized in Table 3-1 below.

## CHAPTER THREE – VISUALIZATION FOR BETTER HEALTHCARE

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Table 3-1. Benefits of Using Visualization (Compiled from Kapler and Wright, 2004)

<b>List of Benefits</b>
1. Large amounts of information can be quickly and easily comprehended by a human observer.
2. Information visualization techniques amplify cognition by increasing human mental resources, reducing search times, improving recognition of patterns, increasing inference making, and increasing monitoring scope.
3. The time, effort and number of work products required to perform analysis, decision-making and communication of tasks is reduced.

The benefits of visualization contributed to the formation of the field of '*Scientific Visualization*', and were brought to the fore in 1987 in a National Science Foundation report - *Visualization in Scientific Computing* (Johnson, 2004). Considering the advantages it could offer, this field aims at using computer graphics in order to create visual images that would help scientists understand data derived from complex numerical representations of scientific phenomena (Bryson, 1996; Nelson and Elvins, 1993). Simply put, scientific visualization is typically used to solve a problem and graphically convey the solution results.

Notwithstanding its advantages, the aforementioned field was often questioned with regards to the visual quality of the produced findings. To address this concern, a distinctive area of research – '*Information Visualization*' – was established nearly 15 years ago, which combines aspects of graphics, scientific visualization, Human-Computer Interaction (HCI), and IT to visualize physical objects or abstract phenomena that were unlikely to be represented using only scientific visualization techniques (Gershon and Page, 2001). Using appropriate Information Visualization techniques, therefore, complex multi-dimensional data could be managed by forming mental models of these data and obtaining a better understanding of their specific features (Spence, 2001).

In comparing the two fields, scientific visualization is typically used to graphically represent new information derived from large amounts of scientific data sets, whereas information visualization involves functionality that graphically conveys information that derives from abstract data (Card et al. 1999). Nevertheless, in spite of their different communications purposes, their underlying foundation is essentially the same, as will be discussed in the subsection that follows.

### 3.2.1 VISUALIZATION CHARACTERISTICS

Ben Shneiderman is recognized as one of the founding fathers of the field of HCI, and is perhaps best known for his contributions in the field of visualization. According to his work (Shneiderman, 1996), visualizations consist of a taxonomy that comprises *seven data types*, and *seven tasks*. The data types are the following:

**1-Dimensional (1-D).** This includes linear data types such as text documents and source code. The items under study include lines of text with a string of characters. Visualization issues for this data type consist of what fonts, colour or size should be used.

**2-Dimensional (2-D).** This consists of planar or map data such as geographic maps or floor plans. The visualization issues typically considered are size, colour, opacity, etc.

**3-Dimensional (3-D).** Real-world objects such as molecules, the human body or buildings are typical examples of this data type. Computer-assisted systems are consequently built to handle such complex 3-D objects, as users must often cope with understanding their position and orientation when viewing these objects. Specific issues to deal with, therefore, in this particular case are position, orientation, perspective, transparency, landmarks, and color coding.

**Temporal.** Times lines are the most well-known examples of this data type often used for medical records, project management or historical presentations, for the purpose of finding specific events during some period of time (before, after, or during a time period or moment). The difference between 1-D and temporal data types is that in temporal data items have a start and finish time and that items may overlap.

**Multidimensional.** Most relational and statistical databases, as well as scattergrams are considered to be typical examples of multidimensional data types. The purpose here is to identify patterns, correlations and outliers among the variables under study.

**Tree.** This is a collection of items where each item normally has a link to one parent item. Visualizations of trees could be in the form of a table of contents or a treemap.

**Network.** In order to overcome the possibility of not capturing the relationship between items in a tree structure, this data type was devised to allow items to be linked to a random number of other items. A typical visualization example is a node and link diagram where users often want to know the shortest path connecting to items.

Shneiderman continues the description of his taxonomy by similarly discussing seven tasks that allow us to interact with these data types by performing several specific actions on them. Figure 3-1 illustrates the seven tasks that are typically performed on some of the data types discussed above.

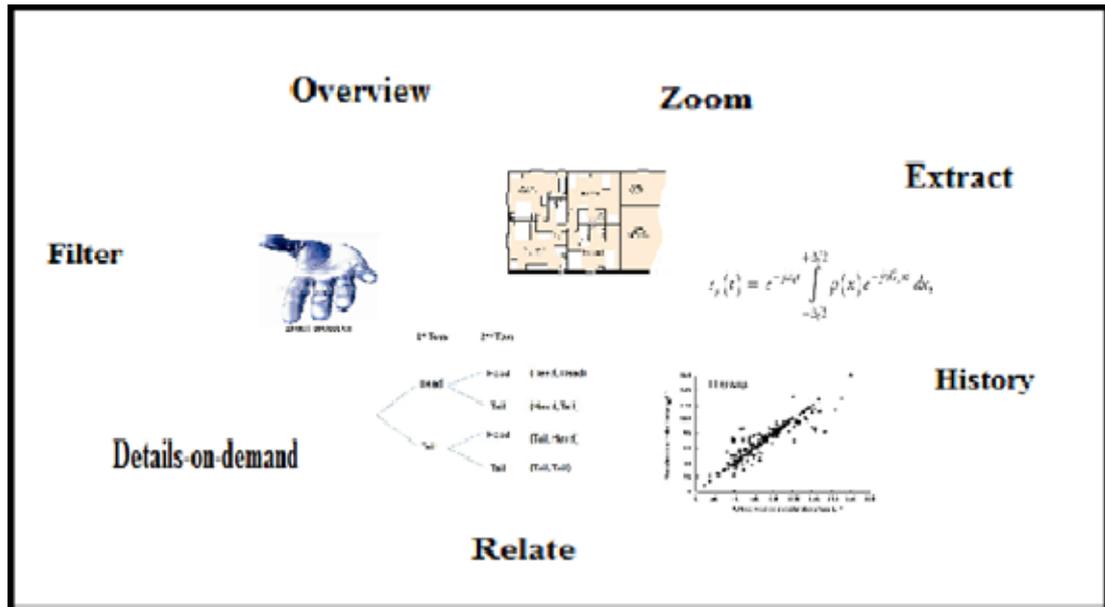


Figure 3-1. Overview of Data Types and Tasks

The aforementioned data types and tasks are considered to be representations of our reality. For this reason, most work has nowadays shifted towards the employment of mainly the 3-D data type for visualizing data sets, as it offers the ability for a more natural and improved perception of our reality as opposed to e.g. the 2-D data type. Indeed, results from experimental studies have highlighted significant benefits that 3-D offers over 2-D, as discussed by Marcus et al. (2003), shown in Table 3-2 below.

Table 3-2. Benefits of 3-D over 2-D

List of Benefits
Displaying data in three dimensions can make it easier for users to manipulate the data
Understanding of a 3-D structure improves when users have the ability to manipulate it
3-D makes it possible to make the layout of a designed object more consistent with its intended role and visualize it as perceived in its natural environment

Nevertheless, while several approaches to visualization and manipulation of information have been defined above, it is essential that they will not be used in isolation. On the contrary, it is beneficial that real-life applications would ideally employ all seven tasks mentioned, especially when it comes to effectively visualizing information. The following subsection, therefore, attempts to provide an overview of

several examples with such real-life applications and how they employ the characteristics described in the aforementioned discussion for the intended purpose.

### **3.2.2 APPLICATIONS TO REAL WORLD**

With reference to the beginning of section 3.2 of this chapter, perhaps the best definition of visualization could be provided by looking at some real-world examples that could also aid us in identifying how our discussion so far could be applied to several everyday cases.

It is without a doubt a fact that the amount of information that is available to us nowadays is significantly enormous. For instance, in the business world, large amounts of information are exchanged every day and information visualization can be extremely helpful in better conveying them.

Wright (1997) in his work specifically demonstrates how visualization techniques could be applied to the business world in six business industries. For illustration purposes, our example comes from derivatives risk management. Visualization can assist managing this situation by giving traders the opportunity to visually display through 3-D graphs and further process as much financial data as they require, in order to make quick trading decisions (Figure 3-2).

Accordingly, Lin et al. (1999) have used visualization to display in effective 3-D visual form geographic information (Figure 3-2). Moreover, with respect to the data types identified in the previous section, several more well-established real-life examples could be identified in Geisler's (1998) survey. Along the same lines as Lin et al. (1999), he suggests that the most common type of 2-D data visualization is Geographic Information Systems (GIS) that are mainly used for mapping purposes, e.g. Google Maps.

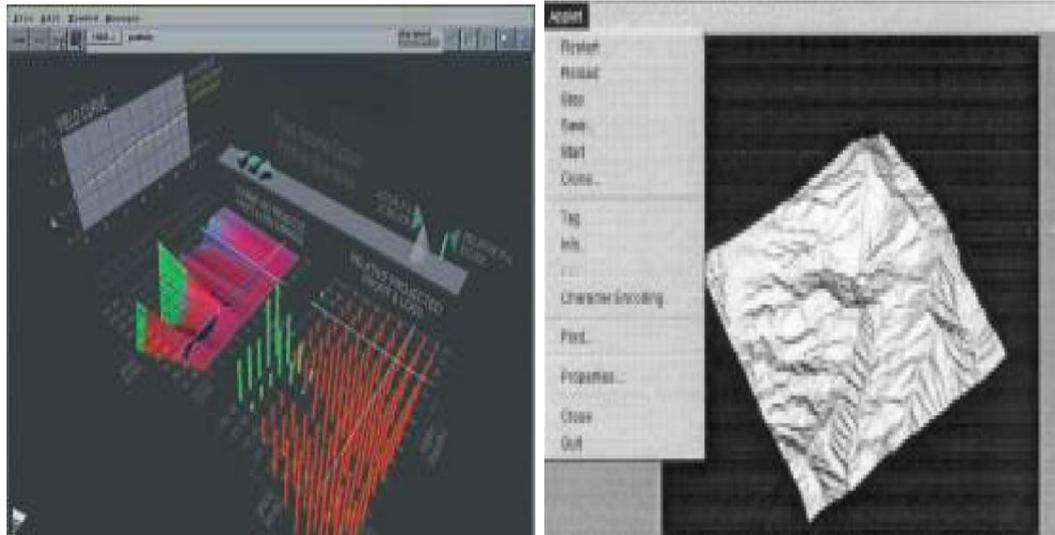


Figure 3-2. Visualization in Derivatives Risk Management (Left) and in Geographic Information (Right) (Adapted from Wright, 1997 and Lin et al. 1999)

In terms of visualizing multi-dimensional data, ‘FilmFinder’ is an application specifically developed to provide a visualization of a film database, while ‘CamTree’ is a 3-D approach used to visualize hierarchical data (Figure 3-3). Both of the aforementioned applications are developed based on some of the tasks identified in subsection 3.2.1, such as *extraction* in the case of ‘FilmFinder’, and *Zoom* in the case of ‘CamTree’.

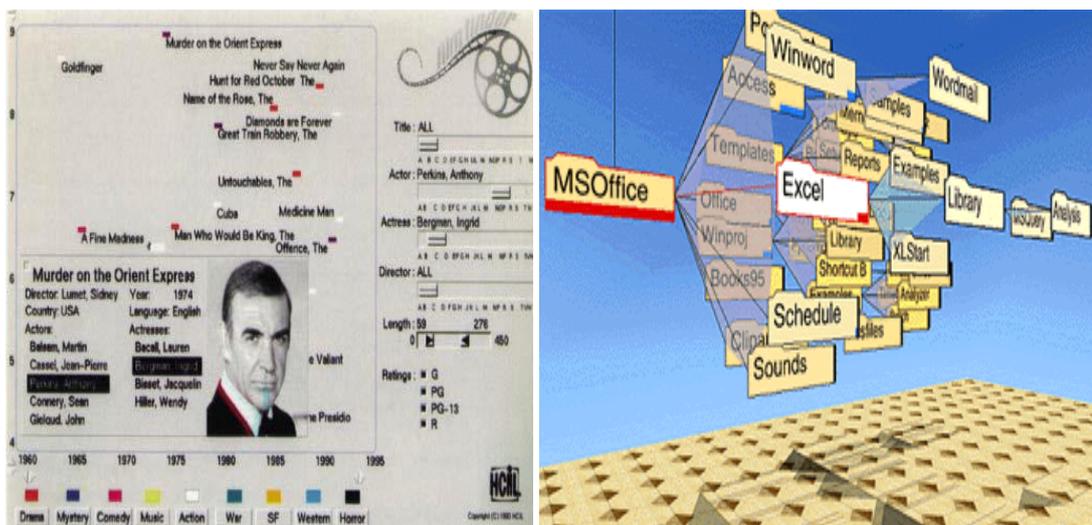


Figure 3-3. Visualization used for a Film Database (Left) and Hierarchical Data (Right) (Adapted from Geisler, 1998)

## CHAPTER THREE – VISUALIZATION FOR BETTER HEALTHCARE

More recently, Hilliges et al. (2006) have designed a music player called ‘AudioRadar’ that provides a coherent visualization of a songs playlist in a 2-D form by grouping similar songs together, while Tateyama et al. (2008) in their work have demonstrated a system for visualizing seismic data in 3-D for the purpose of understanding earthquake activity (Figure 3-4).

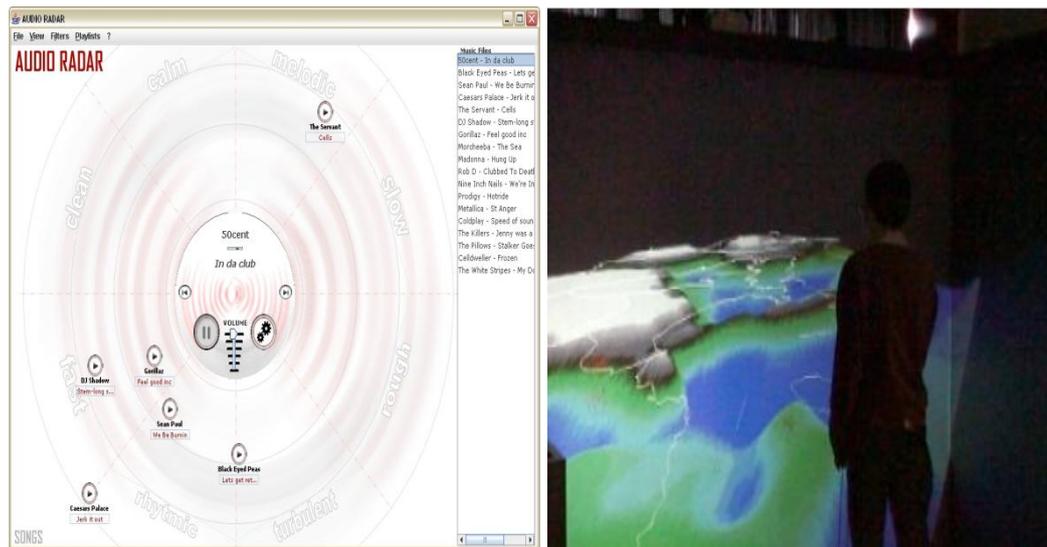


Figure 3-4. ‘AudioRadar’ (Left) and Seismic Data Visualization (Right) (Adapted from Hilliges et al. 2006 and Tateyama et al. 2008)

Along the same lines, a similar system has been implemented by Miura et al. (2010) that helps for rapid and effective recovery from a flood disaster by visualizing the undertaken measures and links between them in a tree structure (Figure 3-5). From a different perspective, ‘EMDialog’ is an interactive application that is used to visualize in 2-D information what is commonly available to museums, libraries and galleries (Hinrichs et al. 2008) (Figure 3-5), while ‘Cardiogram’ is a visual analytics system developed by Sedlmair et al. (2011) that supports automotive engineers in debugging traces from in-car communication networks.

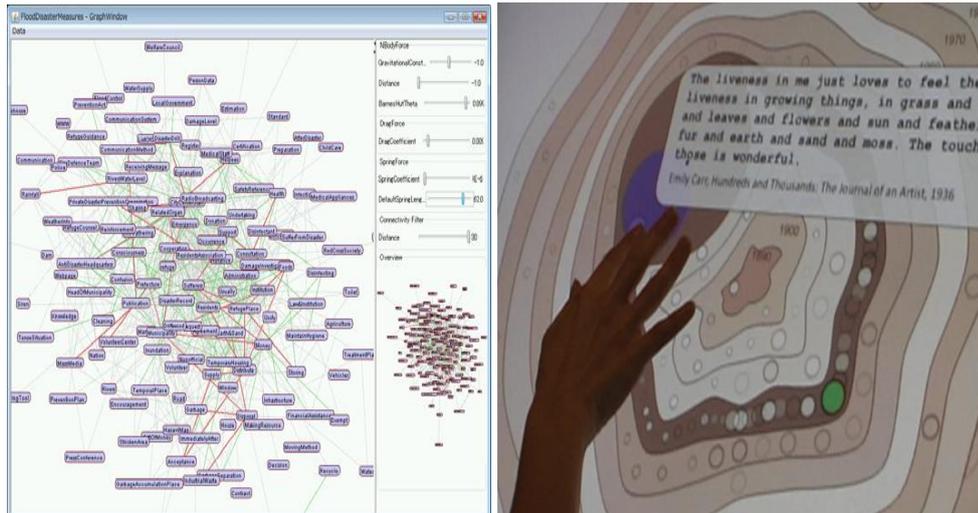


Figure 3-5. Visualization used for Flood Disaster (Left) and 'EMDialog' (Right)  
(Adapted from Miura et al. 2010 and Hinrichs et al. 2008)

Considering the above real-life applications, we have explored how visualization is influencing our lives in ways that not so long ago would have been considered impractical. Another very important example of this fact is the application of visualization to medicine.

### 3.3 MEDICAL VISUALIZATION

Although traditionally the focus has been on 2-D visual forms of data, in the previous subsection we have seen examples of how advancements in visualization technology could contribute to the way information is more realistically displayed. From these examples therefore, it is obvious that 3-D visualization technology can be a successful means to better convey the required information to the interested parties, as compared to its e.g. 2-D equivalent.

Accordingly, considering the benefits 3-D visualization offers (see Table 3-2), most of the visualization efforts in medicine nowadays are similarly being mainly done in 3-D, as it will be discussed in the subsections that follow. Before providing a description of such efforts, however, it is necessary that at this point we first begin by understanding how medical visualization has advanced over the years.

### 3.3.1 OVERVIEW OF ADVANCEMENTS IN MEDICAL IMAGING

The field of medical imaging still lies at the backbone of medical visualization. The Institute of Electrical and Electronic Engineers (IEEE) Global History Network (GHN) offers a very good insight into the history and development of medical imaging tests; according to their work, much of the advancements in this field are attributable to the invention of *X-ray* (Figure 3-6) back in 1896 by Wilhelm Conrad Rontgen.

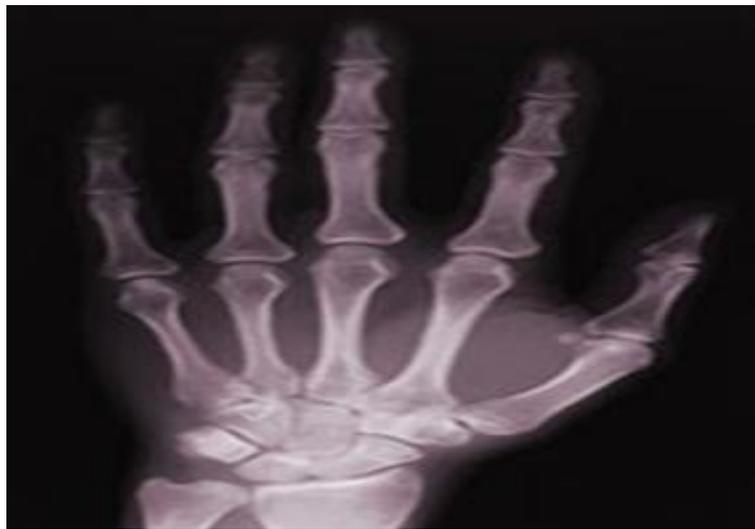


Figure 3-6. Example of an X-ray (adapted from IEEE GHN )

X-ray is a medical breakthrough that is solely based on a radiation produced by cathode rays, which were one of the most popular subjects of study at the time. This radiation was a type of electromagnetic wave that was invisible or could not be felt in nature, but which, however, seemed to be able to pass through tangible materials. This meant that images of bones surrounded by soft tissues could be easily obtained. It is because of this quality that X-ray technology was immediately employed by the medical community who used them for diagnosis and treatment purposes e.g. kill cancer tissues. Nevertheless, by the 1950s X-rays were overused, while at the same time awareness of the overexposure to radiation, as well as of their limitation to show features of soft tissue, also started to grow.

## CHAPTER THREE – VISUALIZATION FOR BETTER HEALTHCARE

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To this end, research into the development of X-rays and the wide spread use of modern computers have naturally lead to the emergence of three extremely important techniques of looking inside the body that have become a standard of practice for diagnosis. With respect to X-rays limitations, therefore, in the 1960s Allan Cormack invented a scanning method that was able to project gamma rays, which, unlike X-rays, emit electromagnetic radiation of a shorter wavelength through an object on a rotating platform. As a result, the *Computer Assisted Tomography (CAT)*, as it was later named, was able to create cross-sectional images by obtaining traditional X-ray images from many different directions and then by using a computer it could calculate the shapes and positions of objects by blocking the X-rays (Figure 3-7).

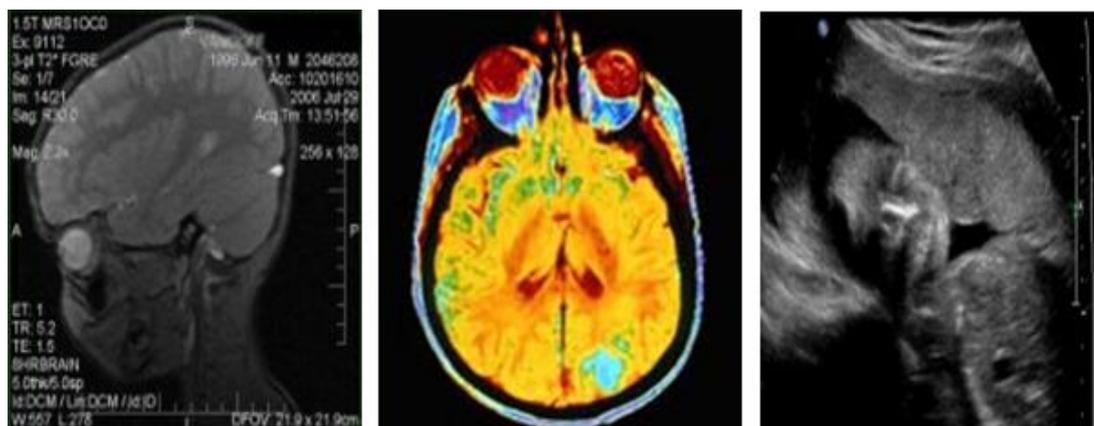


Figure 3-7. Examples of CAT (left), MRI (middle), and Ultrasound (Right) Imaging  
(Adapted from IEEE GHN)

Recognizing its potential, in the early 1970s Godfrey Hounsfield developed the first CT scanner that was able to produce medical images, getting a shared Nobel Prize with Cormack for their contribution in medicine.

Around the same period of time, although the idea was first established in the 1940s by Felix Bloch and Edward Purcell, in the 1970s Raymond Damadian formed a company to produce and distribute *Magnetic Resonance Imaging (MRI)* machines. Compared to X-rays and CAT, MRI takes into consideration the different chemical elements that are associated with different tissues in the human body. By taking advantage, therefore, the characteristic of different chemical elements to respond

## CHAPTER THREE – VISUALIZATION FOR BETTER HEALTHCARE

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differently in rapidly changing magnetic fields, he eventually discovered that it is possible to form medical images out of this fact (Figure 3-7). Its advantage over the previous techniques, therefore, is its ability to provide clear high-definition images of the soft tissues within the bony architecture.

Nevertheless, in practice, MRI technology was also found to require high-intensity magnetic fields, and hence, the equipment is large and expensive to afford. To this end, *Ultrasound imaging* was used as a cost-effective method prior to CAT/MRI scan, as it was shown that it was able to produce similar results. This technique takes advantage of Sonar technology, which works by transmitting pulses of sound and detecting the echoes produced when the sound is reflected back by objects (Figure 3-7). The first medical use of Ultrasound imaging was demonstrated in the late 1940s by George Ludwig, John Julian Wild, John M. Reid, and Douglass Howry, but it was not until the early 1960s that the product was commercialized.

Finally, perhaps the least commonly used medical imaging technique is *Nuclear scanning*. Developed in the late 1990s, this technique includes single-photon emission CT to produce 3-D spatial images, valuable for the exclusion of tumor, fracture, and infection.

Several examples exist in the clinical literature with regards to the usefulness of the discussed medical imaging techniques. For example, Ruzsics et al. (2008) have examined the feasibility of CT in diagnosing heart disorders, with results demonstrating that this technique could enable a non-invasive diagnosis of heart problems. Accordingly, physicians often use MRI for studies related to the musculoskeletal system, or for the conduction of neurologic tests. Such a study is the one performed by Banwell et al. (2007) in order to examine how MRI could be used to aid in the diagnosis and care of children with multiple sclerosis, while before them

Van Den Bossche and Van Den Wiele (2004) had similarly used nuclear scanning to measure the performance of receptors in oncology.

Apart from the imaging techniques just described, others also exist and are in wide use in medical practice. However, since the intention of this research is not to provide a thorough description of them, but only to offer an overview of the advancements in the field, only the most commonly used have been mentioned. Still, although they are a valuable tool in the medical practice, the currently available imaging techniques also have several limitations. Excessive usage naturally causes increased healthcare costs, in addition to the theoretical health risk that implies due to the high emission of radiation. This is the main reason why imaging tests are recommended only as a supplementary method that should be used in conjunction with other assessment techniques (Finch, 2006).

### **3.3.2 USING VISUALIZATION IN REAL-LIFE MEDICINE**

In previous sections we have discussed that the main interest of medical imaging is the acquisition of visual images that will aid in the diagnosis process. Nuclear scanning has notably been the first effort to extend the scope of this field into exploiting the advantages of the use of the third dimension to better visualize and communicate the findings of these images to the clinical staff. It is rational to assume, therefore, that there is a trend towards the application of modern visualization techniques in medical imaging.

In fact, visualization techniques can be a significant aid to medical imaging, as according to Chittaro (2001) they would offer several advantages:

- Visualize medical data in more intuitive, easy to understand, easy to learn, easy to recognize, easy to navigate, easy to manage formats;

- Visually magnify subtle aspects of the diagnostic, therapeutic, patient management, and healing process, which otherwise could be difficult to notice;
- Prevent information overload and allow members of the clinical staff to master larger quantities of information

An early example of the application of visualization in medical imaging is a virtual environment developed by Nielsen and Hansen back in the 1997 for the purpose of visualizing neuro-images that have been traditionally visualized using stacks of 2-D images. The limitation of this approach is that it does not provide a faithful picture of the spatial location of regions under study. To this end, part of their work was to extend the visualization of such medical data to an interface prototype that employs the Virtual Reality Modelling Language (VRML) combined with Java-applet technology that would display the acquired neuro-images in a 3-D visual form.

Along the same lines, visualization has similarly been applied to general medical practice, as demonstrated by Spenke (2001) who proposed a data analysis tool called ‘InfoZoom’ that could be applied to a database with results of blood examinations. The aim of his study was to visually represent large data sets in a way that would be more understandable to the user as compared to manually exploring them. The tool works by displaying database contents as tables (Figure 3-8) that are used not only for visualization of the data, but also allow the user to perform direct manipulations such as zoom into certain areas of the table, or directly modify the database through the table.

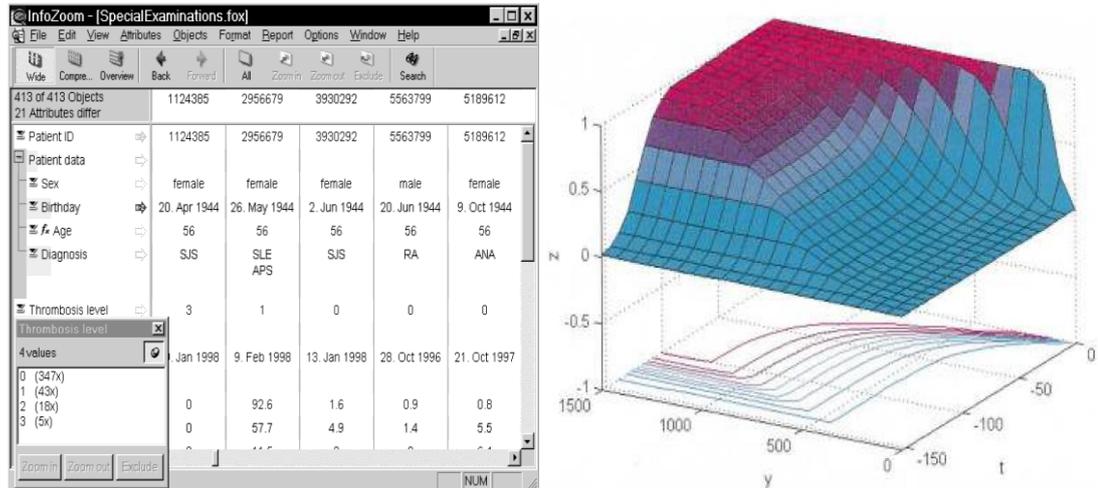


Figure 3-8. ‘Infozoom’ (Left) and ‘SENTINEL’ (Right) (Adapted from Spenke, 2001 and Lowe et al. 2001)

Accordingly, a user interface for visualization information during anaesthesia was proposed by Lowe et al. (2001). Anaesthetists commonly need to frequently interact with monitors to review a significant amount of data; however, for reasons of screen space this information cannot be displayed at any one time. ‘SENTINEL’, as the prototype was named, not only overcomes the aforementioned issue, but also visualizes the result in a more meaningful way to the anaesthetist using 3-D graphical plots such as the one shown in Figure 3-8 above.

Several well-established studies for the visualization of medical data are further illustrated in Chittaro (2001). ‘Lifelines’ is a system used to visualize a patient’s history regarding different aspects of the medical record such as consultation, medication, etc. The ‘Cube’ is a technique that allows the physician to perform a ‘side-by-side’ visual examination of different patient cases with the purpose of identifying interesting patterns. Finally, the ‘AsbruView’ system employs a 3-D approach to visualize medical therapy plans by resembling a running track on which the clinician has to run along as the treatment of the patient evolves.

More recently, following the work of ‘Lifelines’, Noah et al. (2009) have developed ‘DietVis’ – a system used to visualize personal history data of patients for dieticians. From a different perspective, Mukhopadhyay et al. (2010) have employed Fotios Spyridonis

## CHAPTER THREE – VISUALIZATION FOR BETTER HEALTHCARE

visualization techniques in order to represent associations among biological entities such as genes in a 2-D form, while as a step further Luther et al. (2011) used 3-D technology to augment the visualization of protein characteristics (Figure 3-9).

Along the same lines, the benefits of 3-D have similarly been employed in several other medical applications areas such as in echocardiography (Nishimura et al. 2009), as well as in the visualization of complex fractures (Ma et al. 2010).

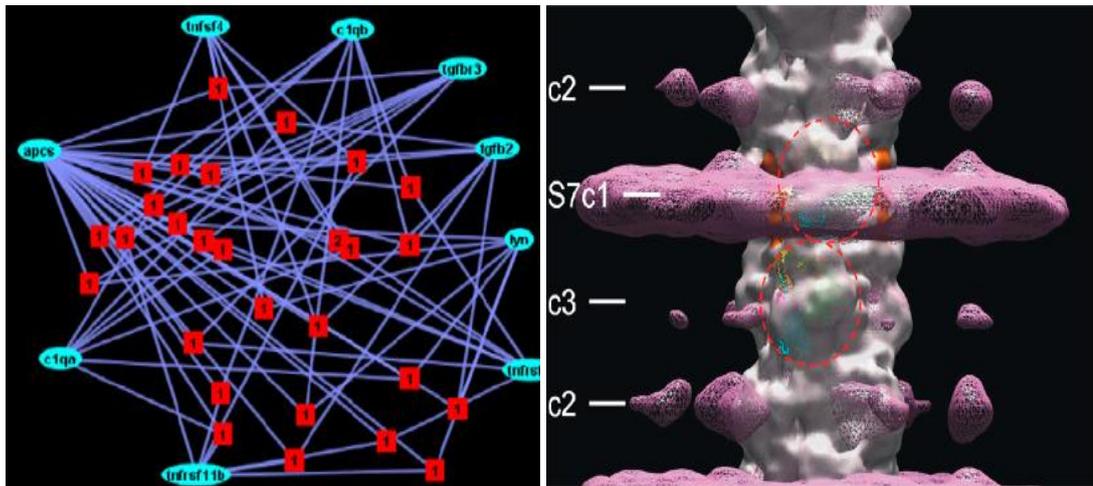


Figure 3-9. Visualization used for Genes (Left) and proteins (Right) (Adapted from Mukhopadhyay et al. 2010 and Luther et al. 2011)

In fact, impressive results are possible when medical visualization techniques or systems are extended into three dimensions. An early example is the *Visible Human Project* initially introduced in 1986 by the U.S. National Library of Medicine. The aim of this project is to develop complete, anatomically detailed, three-dimensional representations of the normal male and female human bodies, as well as to create a large digital library of MRI, CT scans and cryosection images that would be available via the internet to a large and diverse community of users.

Further independent studies have been performed since then in order to extend and improve the project's functionality. Specifically, due to the large size of the datasets created, it would potentially take a significant amount of time to download only the information required by each user. To this end, North and Korn (1996) proposed two

user interfaces that could be employed to overcome this concern. The former takes advantage of users' knowledge of anatomical structures, and it then allows browsing of the Visible Human digital body in order to select and retrieve images of a certain body part. Similarly, the latter utilizes users' knowledge of medical terminology of human anatomy, and therefore it enables selection and retrieval of Visible Human images based on such medical terms.

As a step further, Sato et al. (1998) have later used 3-D visualization to enhance the representation of anatomical structures, such as the images of smaller size structures (e.g. blood vessels) acquired using medical imaging techniques – for example MRI. The results of this study provided a significantly improved visualization of the studied structures, as demonstrated in Figure 3-10. Accordingly, Agus et al. (2009) presented a prototype system that exploited a combination of 3-D visualization, a light field display and direct volume rendering for the purpose of enhancing understanding of images acquired by CT, MRI, or nuclear scans. Similarly to the study performed by Sato et al. (1998), the findings of this research work also highlighted the usefulness of 3-D visualization in improving the understanding of anatomical structures in study. Even more recently, McGhee (2010) also described in his study the advantages of 3-D visualization to create 3-D imagery of data that are derived from MRI scans.

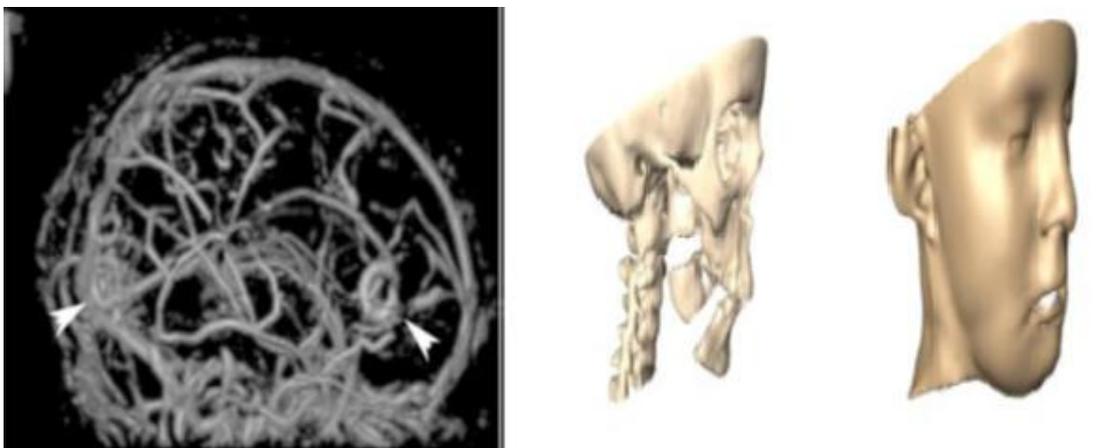


Figure 3-10. Enhanced Image of Blood Vessels (Left) and Simulation of Bones in 3-D in Facial Surgery (Right) (Adapted from Sato et al. 1998 and Zachow et al. 2001)

## CHAPTER THREE – VISUALIZATION FOR BETTER HEALTHCARE

The applicability of 3-D visualization in medical planning and simulation has also been demonstrated in the clinical literature. Specifically, a prototype solution was developed that allowed the simulation of bones on 3-D patient models (Figure 3-10) for complex facial surgical interventions (Zachow et al. 2001). The same feature benefit was anticipated by employing 3-D visualization to perform liver surgery via a 3-D planning model (Hansen et al. 2010), while the ability to aid spine surgery via a system that is used to enhance a navigated surgery procedure through 3-D visualization has been similarly demonstrated by Salah et al. (2011) (Figure 3-11).



Figure 3-11. Visualization used for Liver (Left) and Spine (Right) Surgeries (Adapted from Hansen et al. 2010 and Salah et al. 2011)

Finally, Muhler et al. (2011) in their work have further attempted to bring complex and enhanced 3-D visualizations, such as the above, into the web for surgical therapy planning and educational purposes.

### 3.3.3 MEDICAL VISUALIZATION AND PAIN

The review of the relevant literature has revealed an overall paucity and lack of visualization methods for the management of pain experience. Although most of the described visualization efforts in the medical field are concerned with providing a better understanding of medical information, this does not mean that they can be equally applicable in better visualizing pain.

Accordingly, the medical imaging tests (X-rays, MRI, etc.) described in this chapter have not always been efficient in visualizing the necessary information with respect to pain. For instance, in a study carried out by Van Den Bosch et al. (2004), the conclusions showed that using imaging techniques for the assessment of back pain in several cases is not efficient, and that imaging could only be justified in the assessment of more serious back pain cases (fracture, possible tumor, and possible infection). Along the same lines, Jensen et al. (1994) specifically used MRI in order to examine the prevalence of abnormal findings in people without back pain. The results of their study indicated that only 36% of those examined had normal back pain and that the discovery by MRI of other abnormalities may frequently be coincidental, in accordance to Van Den Bosch's findings.

The above studies highlight the occasional impracticality of several medical visualization techniques in efficiently conveying information about the pain experience, *as they focus more on the diagnosis rather than the pain sensation*. Although the aforementioned studies were examples used in isolation only for illustrative purposes, it seems rational to argue that we cannot make a large scale generalization for all visualization systems or techniques in existence. However, considering the high prevalence of pain nowadays, it is similarly rational to assume that medical visualization has indeed not been sufficient. In fact, only a few (if any) visual forms of pain have been produced or have focused **on the sensation experienced**. To this end, a need for solutions seems to have also been exposed that would take into consideration the need for more effective visualization of the pain experience, as well as would employ the benefits that visualization technology offers.

### 3.4 SUMMARY

The work described in this chapter highlights the great potential that visualization technology has in medical practice. Having explored the fundamentals of visualization, the state-of-the-art projects and real-life applications that were

## CHAPTER THREE – VISUALIZATION FOR BETTER HEALTHCARE

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presented, all demonstrate how this technology can help the medical community to understand information more effectively, by enabling them to examine and interact with large amounts of medical data, and speedily extract the required information.

Notwithstanding their advantages, the discussions provided so far in chapters two and in the present chapter seem to also highlight the impracticality of the current visualization approaches (see 2-D pain drawing, medical imaging) in effectively visualizing the pain experience/sensation, urging for better approaches. The employment and application of 3-D technology, however, has been shown to have several advantages in enhancing visualization within the context of everyday medical practice and research.

In this respect, the same feature benefit could be anticipated from devising a 3-D adaptation of the 2-D pain drawing for the enhanced visualization of the pain experience. In this work, therefore, we examine to address the aforementioned challenges by applying Information Visualization techniques (Spence, 2001; Shneiderman, 1996) to the world of pain drawings.

Specifically, this research will draw upon the capabilities that Information Visualization technology could offer in better visualizing through 3-D representations, e.g. anatomical organs and structures or temporal information, as demonstrated through this chapter's real-life examples such as the 'Visible Human' project and 'Lifelines', respectively. In doing so, similar features and functionality will be integrated in the efforts to augment the 2-D pain drawing for an improved visualization of the pain experience.

## CHAPTER FOUR

# RESEARCH APPROACH AND METHODOLOGY

### 4.1 OVERVIEW

Previous chapters have highlighted the applicability of 3-D visualization in everyday healthcare. The question raised, however, is whether current 3-D visualization techniques and systems would be accordingly useful for certain specific medical domains, with the findings of the review of the clinical literature demonstrating the existence of such a gap with regards to the efficient assessment of pain. In our work, therefore, we aim to alleviate this gap by exploring how 3-D visualization could be efficiently tailored to assist in the pain management process.

Hence, the purpose of the work described in this chapter is twofold: firstly, to explain the research methodology employed in examining what is the most suitable design approach that could be used to meet the current research's aim; secondly, this chapter also describes the software methodology used to instantiate the design into a prototype that would be employed to investigate the applicability of 3-D visualization in pain assessment.

Accordingly, this chapter's discussion starts by attempting to gain an insight of the multidisciplinary nature of IS research, and continues with a discussion about the rationale for selecting Design Science Research (DSR) for the purpose of this work. Its most prominent characteristics are then presented, and the mapping between the current research's nature and DSR is subsequently demonstrated. Lastly, this chapter

concludes with a discussion about the selection of Rapid Prototyping as the software development methodology that best suits this research, and the research strategy employed is finally presented.

### **4.2 RESEARCH APPROACHES IN IS RESEARCH**

The area of IS is characterized by many as a multidisciplinary field, owing to the considerable number of diverse disciplines that contribute to its knowledge base, including engineering, natural sciences and psychology (Purao, 2002; Gregor, 2002). This presence of diversity in IS has long been the focus of controversy and debate for many in the discipline, with perceptions on this issue considerably varying as to whether there is either a beneficial or harmful value in adopting many and different research traditions (see Benbasat and Weber, 1996; Robey, 1996; Mingers, 2001). The selection of a suitable research approach to be followed in IS research, therefore, is perhaps one of the most challenging and critical decisions for a researcher.

Herbert Simon (1996) in his book *“The Sciences of the Artificial”* makes a clear distinction between two fundamental types of research that appear to predominate – namely, ‘*natural science*’ or ‘*behavioural science*’ research, and ‘*science of the artificial*’ or ‘*design science*’ research. The former focuses on how ‘things’ (natural and social phenomena) are and how they work within physical, biological, social, and behavioural domains, whereas the latter focuses on how to design and construct effective ‘artefacts’ and artificial systems with our desired properties by producing and applying knowledge (Carlsson, 2006; March and Smith, 1995).

It is well-established that IS research is largely based on the behavioural science approach; nevertheless, Carlsson (2006) seems to argue that it should be also complemented with knowledge resulting from the design science approach. As such, the author agrees with the statement cited in Carlsson (2006) that ‘*one way to advance the IS field is to increase IS design science research*’.

Therefore, in light of the discussion so far, and the nature of the research aim of this work, design science research following an underlying philosophical perspective that is characterized by a shift between interpretive and positivist research seems to be as the most suitable approach for the author. A description of how design science research could be employed for the purpose of this research is fully discussed in the following sections, while for the interested reader, a more detailed discussion of underlying philosophical assumptions and the rationale for adopting the aforementioned philosophical perspective is provided in Appendix A.

### **4.3 CHARACTERISTICS OF DESIGN SCIENCE RESEARCH**

Different terminology has been used so far to describe design science research; the most fitting, however, seems to be the definition provided by Hevner et al. (2004). In their work, they describe design science research as *a technology-oriented, problem-solving approach that seeks to design innovations (artefacts) that can help to define the ideas, practices, and products based on which the analysis, design, implementation and use of information systems can be effectively and efficiently achieved*. In retrospect, the outcome of design science research could be identified as the design and development of innovative artefacts that will be used in the improvement of the performance of existing information systems.

#### **4.3.1 THE DESIGN SCIENCE RESEARCH CYCLE**

In accomplishing the aforementioned outcome, a formal process needs to be followed. In anticipation of this, March and Smith (1995) identify *building* (the process of constructing an artefact for a specific purpose) and *evaluating* (the process of determining how well the artefact performs) as two distinctive activities that constitute the basis for a successful design and construction of an artefact in IS research.

## CHAPTER FOUR – RESEARCH APPROACH AND METHODOLOGY

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However, the design science research build and evaluate processes are not well understood (March and Smith, 1995). To this end, building on the work of March and Smith, Hevner et al. (2004) have introduced a set of *seven guidelines* around the successful building and evaluation of artefacts, shown in Table 4-1 below.

Table 4-1. Seven Guidelines for Constructing Artefacts (Adapted by Hevner et al. 2004)

<b>Guideline</b>	<b>Description</b>
1. Design as an Artifact	Design-science research must produce a viable artifact in the form of a construct, a model, a method, or an instantiation
2. Problem Relevance	The objective of design-science research is to develop technology-based solutions to important and relevant business problems.
3. Design Evaluation	The utility, quality, and efficacy of a design artifact must be rigorously demonstrated via well-executed evaluation methods.
4. Research Contributions	Effective design-science research must provide clear and verifiable contributions in the areas of the design artifact, design foundations, and/or design methodologies.
5. Research Rigor	Design-science research relies upon the application of rigorous methods in both the construction and evaluation of the design artifact.
6. Design as a search process	The search for an effective artifact requires utilizing available means to reach desired ends while satisfying laws in the problem environment.
7. Communication of Research	Design-science research must be presented effectively both to technology-oriented as well as management-oriented audiences.

Consequently, regarding what should be included in the process of constructing an IT artefact, Vaishnavi and Kuechler (2004) have extended the work of the above authors and suggest a process that consists of five iterative steps (Figure 4-1) that constitute the general Design Science Research Cycle (DSRC).

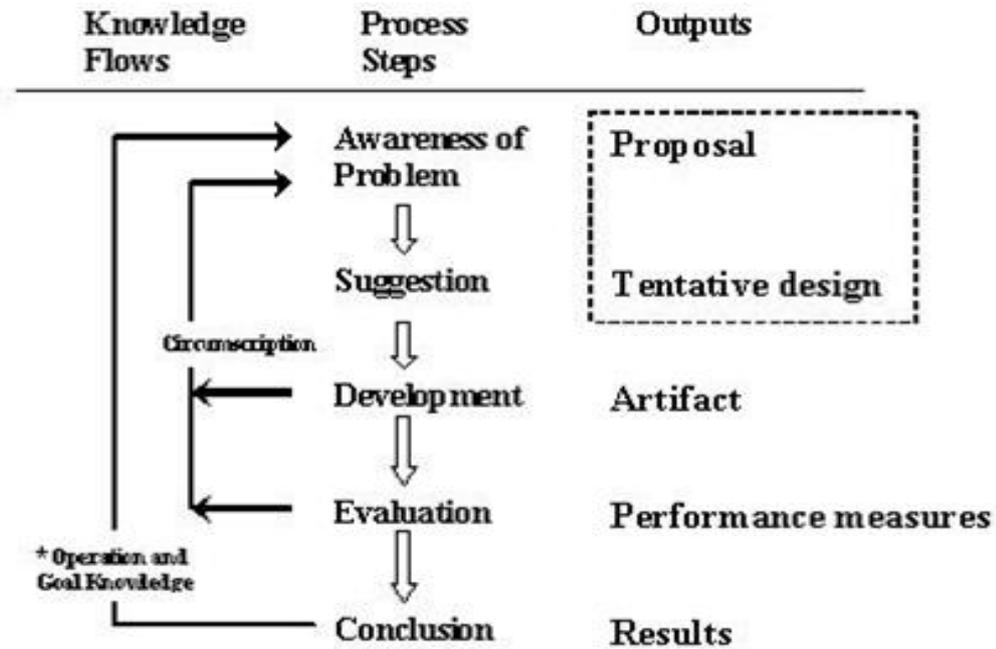


Figure 4-1. The General Methodology of Design Science Research  
(Adapted by Vaishnavi and Kuechler, 2004)

Each of these steps is carried out independently of the others; however, the product of each is fed to the next in the process. A more specific description of how these five steps interact and how they are applied to this research is provided next.

#### 4.3.1.1 APPLYING THE DSR CYCLE TO THIS RESEARCH

In order to understand how this mapping is accomplished, it is beneficial to examine the five DSR cycle steps of Figure 4-1 and revisit the seven guidelines described in the previous subsection, in order to explore how our research approach follows through them.

**Awareness of Problem.** This research has explored current practices in healthcare, and specifically in medical visualization with a focus on pain, for the purpose of identifying any deficiencies that might exist. As such, a problem has been identified that concerns the insufficiency of the current practices in efficiently visualizing the pain experience. In addressing this problem, this research has employed the second

guideline – *the research relevance* – and produced a technology-based proposal that is described in chapter one.

**Suggestion.** By employing the sixth guideline – *design as a search process* – a thorough review of the literature related to the identified problem has been performed (chapters two and three), with the purpose of discovering established theories and techniques related to pain assessment and visualization. Based on the above findings, their improvement in the form of a technology-based solution has been suggested, and an initial tentative design has been proposed as a product of this second step, described in chapter five that follows.

**Development.** As we have already discussed, the core of design science research is to produce a viable artefact. In doing so, it is vital that the first (*Design as an Artifact*) and fifth (*Research Rigor*) guidelines need to be employed. As such, the design of the technology-based solution proposed in the previous step has been mainly *instantiated* over two interrelated iterations, namely A and B, by employing a well-established software development methodology (see section 4.4); the former produced an initial instantiation based on the findings identified in the first two steps of the DSR cycle, and on the user requirements identified by interviewing patients and clinicians alike involved in the first case study. This has been then evaluated against a cohort of potential users presented in this first case study, who identified the need for an enhanced design that would be based on the evaluation results. This improved design has been realized to the final instantiation in accordance to the performed evaluation, as well as to the user requirements identified from interviews with patients and clinicians involved in the third case study, all of which took place during the latter iteration. Chapter five deals with the design and implementation aspects discussed above.

**Evaluation.** The developed artefact has consequently been evaluated for its utility, quality, and efficacy (according to the third guideline – *Design Evaluation*) in addressing the problem and the limitations identified at the beginning of the process. Based on the description of the purpose of this step, the evaluation is performed in accordance with specific metrics (*functionality, completeness, consistency, accuracy, performance, reliability, and usability*) suggested by Hevner et al. (2004). Based on the above discussion, the artefact's evaluation - by employing well-established evaluation methods, as suggested by the fifth guideline (*Research Rigor*) - has been carried out based on three real-life case studies (chapters six to eight) that would explore its completeness in terms of *acceptability, its functionality*, its performance in terms of *efficiency, its usability, and its accuracy in terms of feasibility*.

**Conclusion.** At the final step of the DSR cycle, the results of the above process have been presented and discussed in a variety of audiences (e.g. conferences, peer-reviewed journals) during and after the end of the research, as suggested by the seventh guideline – *Communication of Research*. Furthermore, during this last step the contributions of the current research to the studied discipline have also been provided and made clear (according to the fourth guideline – *Research Contributions*), presented as part of the research discussion and conclusions described in the ninth chapter.

### 4.3.2 DESIGN SCIENCE RESEARCH OUTPUTS

With regards to the discussion so far, we can understand that the visible output of design science research is the artefact (Blum, 1996). However, it appears to be quite vague in the literature what an artefact precisely is. Already established as a technological innovation, March and Smith (1995) followed by Hevner et al. (2004) further classify the artefact as:

## CHAPTER FOUR – RESEARCH APPROACH AND METHODOLOGY

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1. A *construct*, which forms the vocabulary of a domain based on which the specialized language of a discipline is also formed, which is then used to describe problems within this domain;
2. A *model*, which uses the constructs in order to represent a real-world situation, such as the defined problem and its solution. Natural scientists, for example, often use the term model as a synonym for theory. In design science research though, a model is regarded as a visual utility;
3. A *method* that constitutes a set of specific steps (such as an algorithm or a guideline) that could be used to solve problems and perform certain tasks. They are based on a set of underlying constructs (language), as well as a representation of the solution space (model), or;
4. An *instantiation*, which is the implementation of an artefact with the use of all the above. They are used in order to demonstrate the feasibility and effectiveness of the artefact in its environment. Table 4-2 summarizes the above discussion.

Table 4-2. Classification of the Artefact

	<b>Output</b>	<b>Description</b>
<b>1</b>	Constructs	The conceptual vocabulary of a domain
<b>2</b>	Models	A set of propositions or statements expressing relationships between constructs
<b>3</b>	Methods	A set of steps used to perform a task – how-to knowledge
<b>4</b>	Instantiations	The operationalization of constructs, models and methods.
<b>5</b>	Better theories	Artifact construction as analogous to experimental natural science

Moreover, it can be also argued that design science research offers more than just a visual output to the knowledge base of a domain. On the contrary, it also provides the basis for creating new and interesting knowledge (Table 4-2 above). To this end, as discussed by Puroo (2002), unlike the conventional research methods whose visible output is mostly theories, facts, laws, and assertions, in design science research the

output is merely concerned with a) the implementation of an artefact and b) “*the production of interesting (to a community) new knowledge*” that will also be able to eliminate in a degree the intellectual risk faced in a typical design method (Vaishnavi and Kuechler, 2004). Therefore, the IT artefacts designed and produced are not simply natural, universal, or given, but they are designed according to the interests, values, and assumptions of researchers, prospective users, and developers from whom the knowledge is acquired (Purao, 2002).

### 4.3.2.1 RELATING THIS RESEARCH RESULTS TO DSR OUTPUTS

Following the same rationale, in a previous subsection we demonstrated that the main output produced within our research approach so far is an artefact in the form of an instantiation of the technology-based proposed solution. However, it is imperative for the nature of this research to also indicate the existence of several more outputs that our developed artefact has produced, and further to describe how these outputs are linked to the DSR’s outputs previously described.

**Constructs.** This research attempts to provide to the healthcare community an artefact that will be sufficient to overcome the limitations that exist with regards to pain visualization. We will know that this work has been successful when the aforementioned community believes that employing this artefact would indeed improve the current practices. In doing so, we have identified several specific metrics in the previous subsection that would allow us to measure whether the artefact fulfils its intended purpose. These metrics represent the underlying constructs in developing our solution.

**Models.** Keeping the above constructs in mind, another output that our research has produced is a *conceptual* model that could be employed when prospective research efforts involve measuring the feasibility of 3-D visualization techniques in the development of future technological solutions (i.e. artefacts) for healthcare.

## CHAPTER FOUR – RESEARCH APPROACH AND METHODOLOGY

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**Methods.** The aforementioned model has been used in the context of this research to evaluate our proposed solution. The evaluation and the set of steps used to perform it - described in chapters six to eight – represent a proposed method that could be used as a guideline in the effective evaluation of innovative healthcare application within a wider spectrum.

**Instantiations.** As we have already discussed, the main result of this research has been the implementation of a visual instantiation that has been presented in the form of a software application.

**Better Theories.** This research by definition does not attempt to develop any new or better theories. Instead, the experiences gained throughout this research could be explicitly used in order to improve current research efforts within the same domain. Simply put, this research could contribute to improving existing theories, but not to constructing new and better theories. The latter is outside the scope of this work.

To summarize the discussion presented in the previous two subsections, the following Table 4-3 has been created that provides a graphical representation of how the DSR cycle, the seven guidelines of artefact building and evaluation, and the DSR outputs have been put together to address our research problem.

## CHAPTER FOUR – RESEARCH APPROACH AND METHODOLOGY

Table 4-3. Mapping of DSR Cycle to the Seven Guidelines and the DSR Outputs

Guideline	DSR Cycle Step	DSR Output
Problem Relevance	Awareness of Problem	Constructs
Design as a search process	Suggestion	Methods Models
Design as an Artifact Research Rigor	Development	Instantiation
Design Evaluation Research Rigor	Evaluation	Better Theories
Research Contributions Communication of Research	Conclusion	

### 4.3.3 WHY DESIGN SCIENCE RESEARCH?

To address the above question, it is essential to realize that any research output should demonstrate a clear contribution to the area of the designed artefact. However, it is argued that the output of design science research (i.e. artefact) is in a manner different than the output of the generally accepted notion of research (i.e. knowledge and theories), in the sense that no further knowledge is offered to the studied area besides the artefact (Purao, 2002). For this reason, it is considered beneficial to provide an enhanced view of the overall output of design science research and it is necessary to realize that it is about more than just artefacts. In fact, design research offers two more types of research contributions in addition to the artefact, based on the novelty, generality, and significance of this designed artefact (Purao, 2002). Specifically, it further contributes:

- A. **Reproducible Knowledge.** A creatively developed and appropriately evaluated novel artefact consists of constructs, models, methods, or instantiations that often extend and improve the existing knowledge base. For

example, design algorithms, innovative information systems, or problem and solution representations are such artefacts. This situation is often represented by concepts and abstractions in the form of reproducible knowledge that the artefact illustrates.

**B. Methodologies and Theories.** Finally, the development and use of novel artefacts provides us with an understanding of how we can support or control the phenomenon of interest (emergent theory). In plain words, emerging theories about supporting a phenomenon are also contributions of design science research.

To this end, by embracing Purao's (2002) argument, the author supports that owing to the significant contributions of design science research - described as the improvement of theories and the implementation of artefacts to realize these - *design science research can be adopted as the most suitable research approach for our purpose, as it combines both aspects of research and design.*

### **4.4 ARTEFACT DEVELOPMENT: WHICH METHODOLOGY?**

Our discussion up to this point has attempted to make very clear that the visible output of this approach is an artefact, which in our case has been decided to be mainly in the form of a software application, as described in the previous section. Accordingly, the discussion that follows in the next subsections will mainly focus on the development aspects of the aforementioned software application, and specifically on the need to employ a suitable software development methodology that acts as the prerequisite for the actual implementation described in chapter five.

But, why is such a methodology important? To answer this question it is best to first consider the following definition of System Development Life Cycle (SDLC). According to Satzinger et al. (2005), SDLC is defined as "*the process of building, deploying, using, and updating a system*". The purpose of a software development

methodology in the context of the above definition, therefore, is to provide the guidelines for the successful management of the SDLC.

### 4.4.1 INTEGRATING A METHODOLOGY INTO THIS RESEARCH

The system development life cycle involves a significant number of different software development methodologies that support its success. Boehm (1988) and much later Sommerville (2011) have both attempted to provide an overview of the most important, which is presented in Table 4-4 that follows.

Table 4-4. Summary of Software Development Methodologies  
(Compiled after Boehm, 1988 and Sommerville, 2011)

Methodology	Pros	Cons
Code and Fix	Suitable for small software	Expensive to maintain code
Waterfall	Well-documented	Lack of flexibility
Spiral	Improves Waterfall model	Subjective risk assessment
Rapid Prototyping	Ensures user satisfaction	Limited testing
Incremental Delivery	Satisfies critical requirements for immediate use	Limited user feedback
Reuse-oriented	Reduces cost and risks	Requirements compromise may lead to poor functionality
Object-oriented Programming	Easier to adapt to change	Lack of object organization
Extreme Programming	User part of development process	Not widely used

The above table, however, only constitutes a summary of the most commonly used software development methodologies. For the interested reader, a more detailed description of the most important, currently in use methodologies is provided in Appendix A.

For the aim and purpose of this research, although the Waterfall model remains the most common software life-cycle paradigm, our primary focus to assess the impact of 3-D visualization technology to the assessment of pain necessitated **rapid**

**prototyping.** This choice accounts primarily to the nature of this methodology that provides the ability to engage in a process (Figure 4-2) of quickly developing an initial version of our software and immediately evaluating it with potential beneficiaries (i.e. pain sufferers). As such, feedback in the form of modifications and improvements that satisfy the complex characteristics of their pain will be received, and then added as improved features and functionality to the next version of the software, until a final satisfactory version of the prototype is produced.

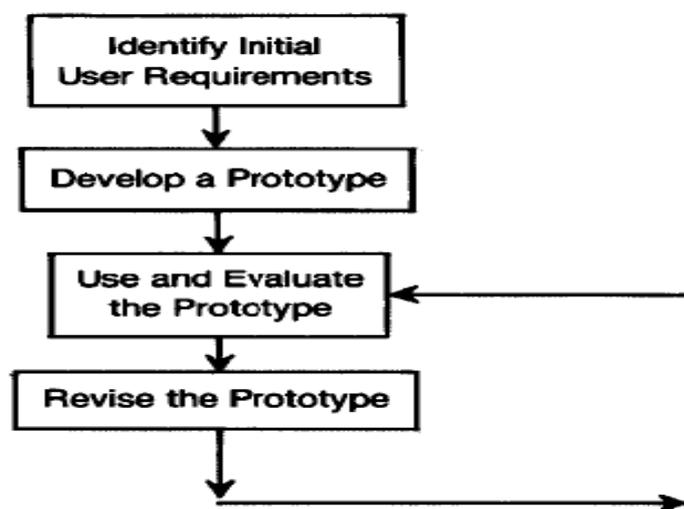


Figure 4-2. Rapid Prototyping (Adapted by Alavi, 1984)

Evidence from the literature seems to similarly support the ability of rapid prototyping to enhance software functionality in order to meet user requirements. In a review study launched by Gordon and Bieman (1995), 39 published case studies of rapid prototyping were analyzed for the purpose of identifying whether this methodology was effective in developing a satisfying software product. The analysis was performed based on the level of improvement (whether it was increased or decreased) that the rapid prototyping process has offered to six software attributes – ease of use, user needs, number of features, performance, design quality, and maintainability. In support of our anticipation that rapid prototyping will facilitate the development of an effective artefact, the results of the study show that this

methodology was successful in improving all of the six aforementioned software attributes in 33 of the 39 cases.

In light of the above study, the suitability of rapid prototyping in the software development process seems to have been established. But, the essence of the developed software lies within the purpose that it was implemented to serve – that is, whether the produced artefact improves with its performance the specific task for which it was created. Petzold et al. (1999) have attempted to address the above concern with their work on exploring the application of rapid prototyping in medicine, a study which is consistent with the nature of this research.

In summary, the aim of this study was to examine the clinical use of rapid development products in terms of improving the quality of planning and simulation in surgery. As such, this methodology has helped in this specific case to reproduce objects from a 3-D medical image as a physical object that could be felt and looked at by the surgeon. The results obtained indicate that these objects developed using rapid prototyping were very well suited for their intended use within the aforementioned context.

The same positive outcome is anticipated that rapid prototyping methodology will facilitate to be produced for the purpose of this research. To this end, it is considered to be the most suitable software development methodology for the context of this work, and is therefore employed in implementing our artefact.

### **4.5 RESEARCH STRATEGY**

As a final discussion in this chapter, a brief description of the research strategy that will be followed in terms of data collection, artefact evaluation, and data analysis will be provided in the subsections that follow.

**4.5.1 DATA COLLECTION METHODS**

Data collection is a necessary step for the research progress irrespective of the research methodology followed, as it enables you to extract the required information from the research participants. Typically, this information is collected by adapting different research techniques from within the wider spectrum of two research methodologies that co-exist with design science research in the IS discipline – namely, *qualitative* and *quantitative*. Such an adaptation is consistent with Minger’s (2001) suggestion of combining research methodologies together in order to focus on different aspects of a certain research topic, and therefore better understand it.

In retrospect, both qualitative and quantitative methodologies consist of several techniques for gathering information, summarized in Table 4-5 below.

Table 4-5. Qualitative and Quantitative Data Collection Techniques  
(Adapted by Roth, 1998)

<b>Data Collection Techniques</b>	
<b>Qualitative</b>	<b>Quantitative</b>
Observation	Surveys
Participatory research	Demographics
Interviews	Statistical analysis
Diaries: self-reporting	Anthropometrics
Ethnography	Structural testing
Experiential sampling	Standardized tests
Cultural inventory	Experiments

As proposed by this table and following Goede and De Villier’s (2003) rationale, qualitative research provides the flexibility and freedom to explore the phenomenon in depth, the main aim being to understand the phenomenon. On the contrary, quantitative research attempts to explore and understand the studied phenomenon by

remaining in a way objective and neutral, through the use of experimental methods and reliance on mathematical and statistical models (Roth, 1998).

To this end, considering the nature of this research that involves a direct interaction with participants during most of the design science research cycle steps, starting off with the interpretive perspective seems as the most appropriate approach, as suggested by the philosophical assumption adapted for this research (see Appendix A). Therefore, qualitative techniques will be adapted as they will enable us to better identify the users' thoughts, feelings and impressions. Based on them the problem area can be thoroughly understood and the proposed artefact's objectives can be successfully fulfilled. These data collection techniques would allow us to come up with the necessary user requirements needed to design and develop our novel artefact, as well as to facilitate its subsequent evaluation.

In retrospect, during the first step of the DSR cycle a study through the literature relevant to the research area was performed. This has built an essential basis for the rest of this work, as it has provided an overview of the different processes of how pain is assessed that will help us clarify the research problem.

As the research develops through the next three steps, due to the subjective nature of pain, the need of subjective data collection techniques should be used, such as self-reports. Specifically, participant self-reporting in the form of questionnaires and interviews, as well as observation while using the developed artefact, will be the techniques employed for the purpose of data collection within the first four steps or phases of the cycle of this research.

### **4.5.1.1 CONSTRUCTING THE INTERVIEW AGENDA**

Gathering data about the perceptions of clinicians and patients is of significant importance to the efficient design and development of the artefact, as they constitute

the main stakeholders that would potentially use it. This was the main motivation for initiating the artefact design process with the employment of interviews.

The writing of the interview questions was conducted on the basis of the information and the findings derived from the review of the literature described in chapters two and three, as these would serve as a guide in determining what the main stakeholders think would be of importance to the intended purpose of this research. In retrospect, the literature review findings were divided into two categories; '*general information about pain assessment and visualization*' and '*specific information to pain assessment and visualization*'. These were then put together and used to form the first part of the interview agenda presented in Appendix B that would be used to gather the necessary user requirements for the artefact. Responses to these initial interview questions would also be used as an aid to develop the questions for the second part of the interview agenda (see Appendix B) that would later on be employed to evaluate an aspect of the artefact (see chapter six).

The interview questions within the aforementioned agenda were constructed by using an exploratory approach due to the small number of participants involved in the design and development process of the artefact. As such, the questions were designed in an *open-ended* format that would allow the participants to answer them in their own words and could reveal their thoughts, concerns and perceptions about pain and the potential use of visualization to measure it, without restraining them to specific possible answers. Broadly speaking, these questions could be placed in one of the following three categories: a) *general technology background*, b) *current pain assessment practices*, and c) *artefact-related perceptions*.

The interviews would be performed with teams of clinicians and patients that agreed to participate in this research (see chapters five and six), and they would be recorded and transcribed. While interviewing, the questions would be asked during an

informal discussion, and therefore, follow-up questions/clarifications would be provided, if necessary. In the transcription process, privacy and confidentiality of the participants and their responses should be highly regarded; therefore, their names would be replaced with codes (e.g. P1 for participant 1).

Finally, the analysis of the interview findings would be based on the transcription results and would only involve the responses given by the participants to the initial and follow-up questions. It has to be noted at this point that no qualitative analysis software (e.g. NVivo) would be used to do the analysis, as it is anticipated that it would not produce any meaningful results due to the small number of the participants involved. As such, it was considered as more appropriate that the analysis would be performed using conventional pen and paper, which could be used to address the relatively small amount of data that would be produced by the interviews. The findings of this analysis would be then used to draw conclusions, and inform the design and evaluation processes.

### **4.5.2 ARTEFACT EVALUATION METHOD**

According to the positivist perspective of the philosophical paradigm that will be employed in this work, the researchers following this approach often make use of quantitative techniques in their research, such as experiments, surveys, etc. that usually involve numerical information. As we have also justified in the same subsection, the interpretive perspective is an approach that will similarly be followed in this research, shifting occasionally to the positivist perspective; therefore, our evaluation will not be performed by only engaging qualitative research techniques, instead a combination of both qualitative and quantitative methods will be employed.

The justification for this comes from the nature of our research problem that involves the study of an information system (i.e. our artefact) within an organization (i.e. healthcare provision), which is the very definition of IS research. According to

Myers (1997), several qualitative methods exist that are particularly well-suited to IS research, with *case study* being the most commonly used. Briefly, Myers defines case study as an ‘*empirical enquiry that investigates a phenomenon within its real-life context...*’.

To this end, the artefact evaluation will be performed with a number of evaluation surveys and case studies (presented in chapters six to eight), which will be carried out within real-life contexts that would consist of our study participants. Finally, on a whole, we would describe the research approach adapted in this work as design science research combined with qualitative and quantitative techniques and methods. We will be using, thus, a combination of natural and design sciences, something that has been characterized as the best useful way of improving IS research.

### **4.5.3 DATA ANALYSIS TECHNIQUES**

The final activity in this research will be the analysis of the data collected during the evaluation. This analysis is going to be based on extensive reading of the findings, something that besides enabling us to thoroughly understand the nature of the question and phenomenon under research also maximizes the avoidance of preconceived concepts that could easily distract us from this problem.

To be more specific, the analysis is going to be based on extensive reading of the data, something that, besides enabling us to thoroughly understand the nature of the question and problem, also maximizes the avoidance of preconceived concepts that could easily distract us from this problem. However, it can be difficult to extract relevant information from questionnaires and interviews; as such, different quantitative techniques, such as statistical analysis and standardized tests will be employed to more accurately analyse the findings. To this end, Predictive Analytics Software (PASW) v18.0 was decided to be used for the analysis stage. PASW is software developed by SPSS, Inc. in Chicago, Illinois, and is perfectly appropriate

for the analysis of data extracted from the instrumentation that we will be using for our data collection and evaluation.

### **4.6 SUMMARY**

In this chapter, the research approach employed to address the limitations with respect to the visualization of pain has been discussed. In the process of choosing and justifying design science research as the best suitable research methodology for this research, the difficulties that exist in identifying the most appropriate research methodology have been highlighted in section 4.2. The chapter then provided a detailed description of the characteristics of design science research and how it is mapped to this research in the sections that followed, and finally summarized with the presentation of the software development methodology employed to address the research problem, and the research strategy used to support it. The chapters that follow deal with demonstrating the application of the software development methodology in practice (chapter five), and show the exploitation of the research strategy in real-world contexts (chapters six to eight).

## CHAPTER FIVE

# ARTEFACT DESIGN AND IMPLEMENTATION

### 5.1 OVERVIEW

In this chapter, the research methodology and approaches discussed in the previous chapter have now been taken a step further by putting them into practice for the purpose of producing this research's artefact outputs. As such, work has now focused on the design and implementation of the artefact, which will be demonstrated in the following sections by employing the software development methodology (Rapid Prototyping) discussed in the previous chapter. This was undertaken over two interrelated iterations, during which the design and implementation took place, as discussed in the third step of the DSR cycle (see subsection 4.3.1.1).

Accordingly, the chapter begins with the discussion of design and implementation issues relative to the first iteration. The initial user requirements are identified in the section that follows, and the artefact's design and implementation process is subsequently described. The discussion of the first iteration concludes with the presentation of a walkthrough on using the developed artefact. The chapter then continues with the discussion of the second iteration, where a refined version of the artefact's design and implementation process is described, and it concludes with the presentation of a second walkthrough relative to the refined artefact, as well as a summary of the aforementioned discussion.

## **5.2 ITERATION A: INITIAL DESIGN AND IMPLEMENTATION**

The first version of the prototype was designed during the primary iteration by taking into consideration two main inputs: 1. *the findings identified in the first two steps of the DSR cycle*, and 2. *the user requirements derived from interviews with patients and clinicians* that would be involved in its evaluation. The implementation was then carried out based on the design produced, and its first evaluation was consequently performed (see chapter six).

### **5.2.1 DESIGNING THE PROTOTYPE**

Accordingly, findings from the review of the literature have shown that the process of assessing a patient in pain heavily relies on the collection of medical information such as medical history, pain factors, and type and location of pain. However, this whole process is approached by using paper-based methods in a person-to-person basis; as such, it is not always a quick and efficient way to collect the necessary information, especially if you consider the fact that very often patients in pain may face difficulties in visiting, for instance, a hospital. Therefore, allowing such patients to record the information when and where needed is a more effective and flexible approach to the aforementioned issue.

#### **5.2.1.1 THE NEED FOR A MOBILE SOLUTION**

More specifically, because of the complexity and sensitivity of pain problems, every sufferer needs individual treatment options. However, unavoidable situations such as queues at hospitals or practitioners' individual places of treatment cause type 2 (e.g. abdominal pain, chronic pain, etc.) patients, who are not considered as urgent cases, to have to wait excessively long, in order for their health-related information to be collected (Garcia et al. 1995).

However, conditions such as the above do not allow an effective and efficient use of health information that would provide both parts with the necessary means for pain assessment and treatment. Although, the rapid acquisition and distribution of such information is definitely a priority, most of the times, the professionals responsible for such activities often operate under tight time constraints. Therefore, health-related information collection and allocation in an effective and systematic way must be balanced with the fact that they need to attend to all patients as promptly as possible (Warren et al. 1993).

Because of the enormous impact of the aforementioned conditions, there have been efforts (Gomez et al. 2002; Lin et al. 2006; Serif and Ghinea, 2005) to guide the patient's assessment and monitoring outside clinics in a way that health-related issues can be efficiently manipulated and used in a timely manner, since time and space constitute barriers between health care providers and their patients, and indeed, among health care providers themselves. One of these directions has been to empower the patient to become a better stakeholder in the management of pain by allowing an anytime, anywhere collection of medical information, in the anticipation that it would overcome the current health-related information limitations discussed so far.

Finally, findings from the first two steps of the DSR cycle have also demonstrated that collection of medical information is dependent upon the use of 2-D approaches, as paper-based methods are, to visualize the pain experience, and for which the effectiveness is highly questionable as has already been discussed in previous chapters. As such, the consensus of the literature and research so far, seems to indicate the need for a mobile approach to the above process, which would exploit the advantages of 3-D in visualization that have been described in subsection 3.2.1.

### 5.2.1.2 IDENTIFYING THE USER REQUIREMENTS

The second stage of the design process consists of the user requirements that would complement or even refine the aforementioned findings. For the purpose of collecting them, in subsection 4.5.1 of the previous chapter we have justified that qualitative data collection techniques will be employed. As such, interviews were constructed (see Appendix B, Part 1) and were carried out focusing on two different, but interrelated, directions: a *professional* and a *patient* one.

For the former, interviews were conducted in collaboration with four clinicians from the Rheumatology Department of the Northwick Park Hospital, London, who would potentially use the system. Interviews with these stakeholders were held in order to define the desired requirements of the prototype. In particular, interviews focused on the deficiencies of the existing pain assessment approach and areas of opportunity for the 3-D approach to possibly exploit. In brief, the identified professional requirements were to:

- Be able to collect information regarding pain characteristics;
- If possible, enhance the 2-D pain drawing to a more realistic version;
- Monitor the intensity and spreading of pain during the day;
- Be easy to use;
- Support privacy of medical information

Accordingly, for the latter, interviews were also held with eight patients who suffered from pain, all recruited from the hospital mentioned above and from the Hillingdon Independent Wheelchair User Group. The most important findings from this data collection were two: first, the need for an approach that would provide the functionality to record pain characteristics; and second, with respect to the second

requirement identified from the interviews with the clinical staff, the patients were asked if a 3-D approach as an alternative to the current 2-D pain drawing would be beneficial, with the majority of them agreeing with this statement.

As such, the user requirements identified seem to be consistent with the findings of the research conducted during the first two steps of the DSR cycle. Accordingly, to summarize the above discussion, the prototype requirements identified were to:

- 1) Provide a 3-D model of the human body that would provide a more natural perception of the real-world environment;
- 2) Provide navigational controls enabling the ability to zoom, rotate, drag for depth perception in accordance to the first requirement;
- 3) Allow pain characteristics such as location, type, and intensity to be recorded;
- 4) Allow individually selectable regions of the body in accordance to the third requirement;
- 5) Use colour to represent different types of pain in accordance to the third requirement;
- 6) Provide the patient with the ability to input pain data ubiquitously and upload it to a central hospital server;
- 7) Provide a handheld solution for data collection in accordance to the sixth requirement

**5.2.1.3 THE DESIGN PROCESS EXPLAINED**

The design of the prototype has consequently been based on the requirements presented above. As such, the prototype would represent an approach that combines a 3-D adaptation of the 2-D pain drawing, with the possibility for the user to directly navigate and select the type and location of pain on the 3-D mannequin.

In addition, it will also provide the capability to the user to support the 3-D visualization of pain with the collection of specific, pain-related medical data (e.g. personal details, pain factors, and pain intensity) in a questionnaire format. All the collected information will then be saved to a backend database for further analysis and preview. Finally, the saved information will be accessible by a clinician, as they will be securely uploaded and be available from a server. Figure 5-1 shows an overview of the system process discussed.

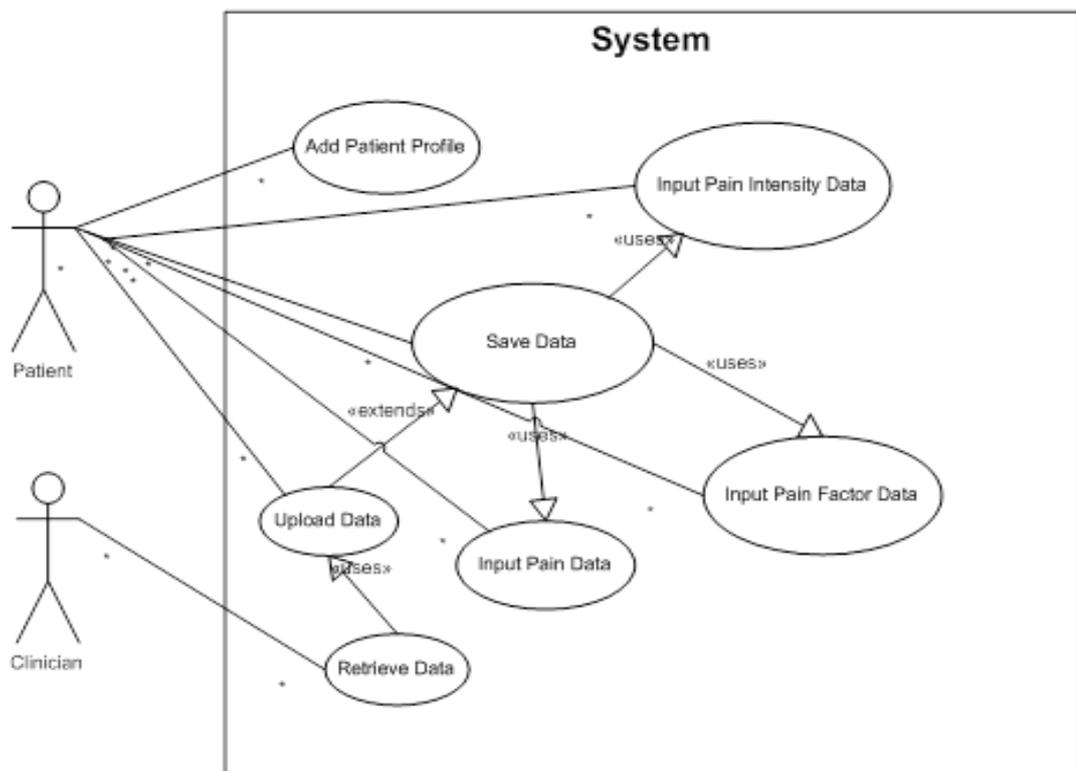


Figure 5-1. System Use Case Diagram

At this point, it is important to clarify that from the above prototype functionalities described, only the 3-D visualization of pain characteristics is of interest to the nature of this research. To this end, aspects such as the wireless functionality and the recording of pain-related information have not been taken into consideration as mandatory aspects when evaluated the prototype through the case studies that will be described in the chapters to follow. Nevertheless, for the remaining of this chapter, the complete design and implementation of the software solution will be described for a complete picture of the prototype.

By consulting the above figure, the algorithm that would realize the above functionalities could be described as follows:

- 1) Patient connects to the system;
- 2) Patient enters pain data;
- 3) Patient saves data to a local database;
- 4) Local database receives and records the data;
- 5) Patient uploads the data from the local database;
- 6) Server receives and saves the data to its database;
- 7) Clinician requests for the data;
- 8) Server responds with the transmission;
- 9) Clinician receives and displays the data;
- 10) Procedure ends

From this algorithm, we can derive the initial prototype architecture that consists of 4 main building modules (see Figure 5-2), the *User-interface*, the *3-D pain visualization application*, the *database*, and the *hospital web/database server*.

### **User Interface**

This module will allow the user to interact with the 3-D pain drawing, and it will be responsible for providing information (pain type, location, intensity, etc.) to the other modules. It will consist of five to seven screens, depending on whether the user uses

the application for the first time or uploads the data. Specifically, it will have an introduction, a registration, a pain factors, a pain intensity, and a pain drawing content screens in the specific order mentioned, as this information recording was requested by both clinicians and patients. The sixth screen will be the one where the user creates his/her profile the first time of use, and the seventh a screen where s/he can upload the saved data.

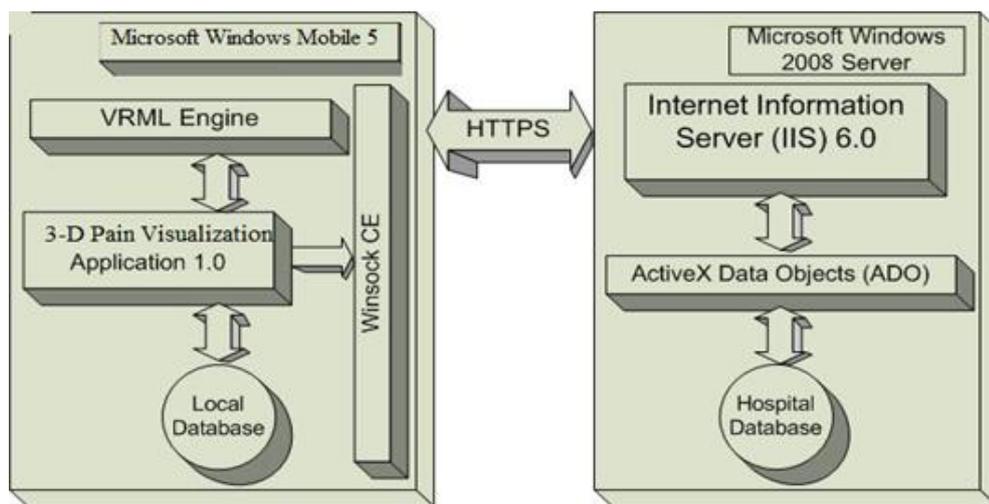


Figure 5-2. Initial Artefact Architecture

### 3-D Pain Visualization Application

This application constitutes the underlying functionality that the user interface module employs to display the aforementioned series of screens. As such, it consists of a pain questionnaire that collects information regarding a patient’s personal data for demographic purposes, as well as information concerning factors that worsen and relieve pain, the kind of treatment received, and the intensity of their current pain at the time of measurement in seven predefined by the clinicians body parts (*back, neck, buttocks, legs, arms/shoulders, feet, hands*), taken via a VAS.

The most important part of the application, however, is the 3-D pain drawing that offers the pain visualization functionality. The 3-D pain drawing was developed in a standing posture, with its body surface been segmented into six specific regions, namely *head and shoulders, torso, arms, hands, legs, and feet*, according to the clinicians involved in the research. On these six regions, clinicians suggested that the

patient could visualize the location of the pain using four, color-coded, basic types of pain (*numbness, pain, pins and needles, and ache*) that the s/he could select from, by manipulating the mannequin to the most suitable- to describe the pain - position on the 3-axis, using zoom-in and out functionality.

**Local Database**

The collected information described in the context of the previous module would then be saved to a local database (Figure 5-3). It has to be noted, however, that, with regards to the 3-D functionality, even though data input is mainly done on the 3-D mannequin, the data that are saved are not pictorial, but mainly numerical/textual (location of pain—each body region had a unique text identifier, type of pain – each type had an Red Green Blue (RGB) numerical value, and time/date of input). As such, database sizes are kept relatively small and can, therefore, be more efficiently used e.g. in uploading or transmitting the information over the internet. Figure 5-4 shows how the interaction takes place between the three modules.

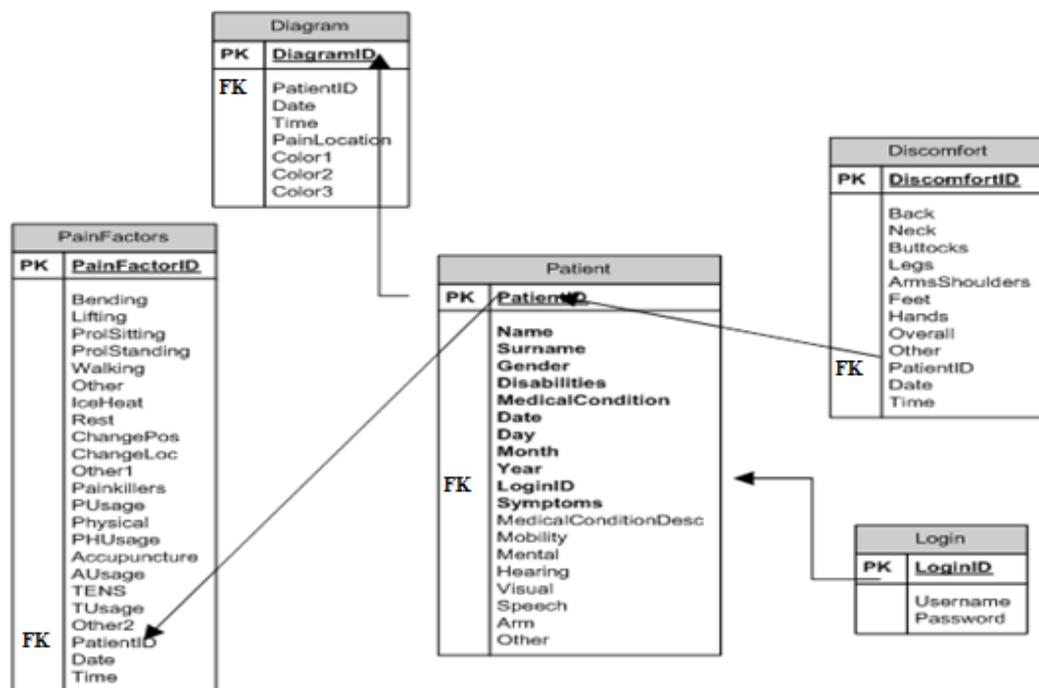


Figure 5-3. Database Relationship Diagram

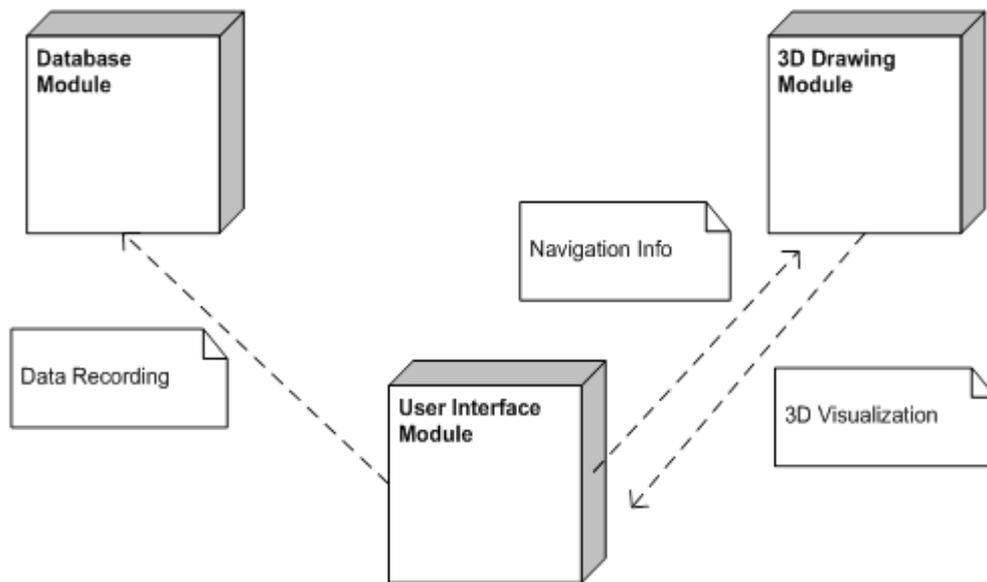


Figure 5-4. Interaction Between the Three Modules

### Hospital Web/Database Server

When the medical information collection has finished, the data can then be wirelessly uploaded from the local database to the hospital server's database using this final module of the prototype design architecture. The process of uploading is based on a user authentication technique with a username/password tuple, which, if passed, the server receives the data and saves it to the hospital database, where it will remain until a clinician requests them for assessment.

The wireless transmission is based on the three-tier wireless system model shown in Figure 5-5, which was chosen because this component-based architecture simplifies the implementation, and provides reusability and scalability to the system by keeping the components independent from each other.

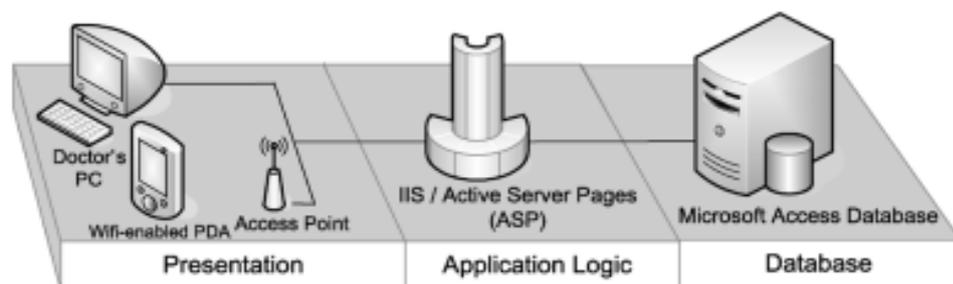


Figure 5-5. Three-tier Wireless System Model

Figure 5-6 further shows a sequence diagram describing the interaction between these three tiers. With the below sequence diagram, by exploiting the approaches discussed in the research methodology chapter, the initial design of the prototype has been concluded. In the next section, a discussion of the implementation decisions employed in order for the artefact to be developed will be similarly provided.

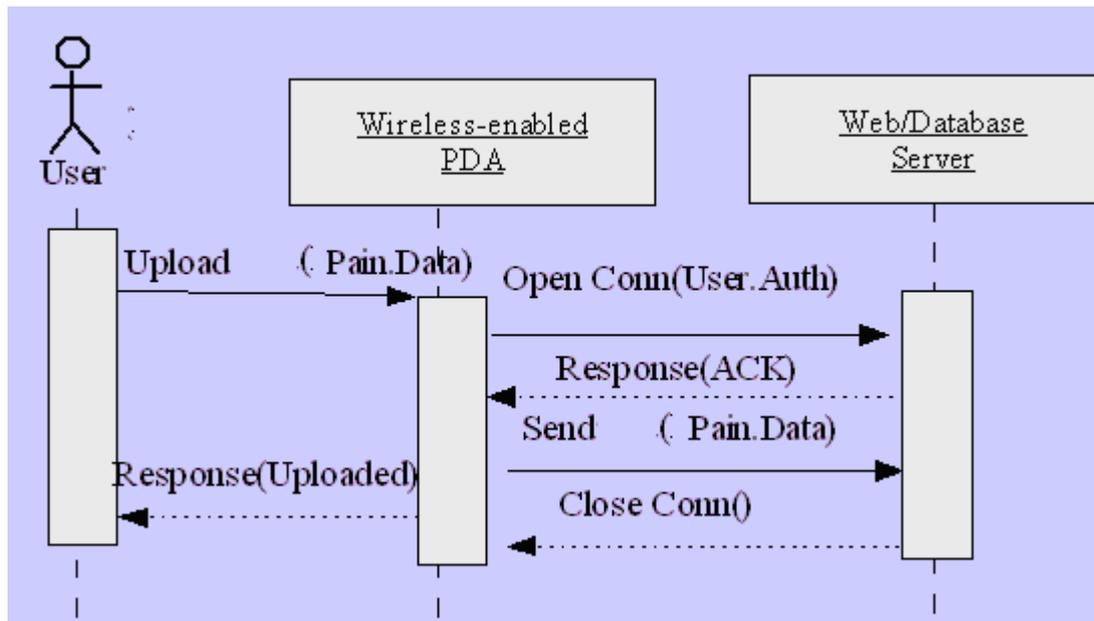


Figure 5-6. Sequence Diagram of Interaction Between the Three Tiers

### 5.2.2 IMPLEMENTING THE PROTOTYPE

Knowing the overall structure of the prototype, as derived through the design discussion provided in the previous section, the artefact has then been implemented based on this design by employing the following software and hardware specifications.

#### 5.2.2.1 DELIVERY HARDWARE PLATFORMS

According to the design and implementation requirements identified, the prototype should be able to provide the patient with the ability to collect pain data ubiquitously through a handheld solution that would offer flexibility in the data collection.

## CHAPTER FIVE – ARTEFACT DESIGN AND IMPLEMENTATION

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To this end, the 3-D pain application was implemented on an HP iPAQ hx2400 Personal Digital Assistant (PDA) (Figure 5-7) with 16-bit touch-sensitive transfective Thin Film Transistor (TFT) Liquid Crystal Display (LCD) that supports 65,536 colours. The display pixel pitch of the device is 0.24 mm and its viewable image size is 2.26 inch wide and 3.02 inch tall. It runs Microsoft Windows Mobile 5.0 operating system on an Intel 520 MHz PXA270 processor and contains 64MB standard memory as well as 128MB internal flash ROM. The reason a Microsoft Windows-based PDA was chosen is because it was, at the time of development, a more popular platform than its main competitors Palm OS and Symbian, or Google's Android and Apple's iOS.



Figure 5-7. Screenshot of the PDA

Accordingly, the hospital web/database server has been implemented on an Intel Core Duo running at 2.4 GHz, with 3GB RAM and a 250GB hard disk, and with a Netgear DG834PN 108 Mbps RangeMax ADSL Modem Wireless Router to be used for the wireless transfer.

### 5.2.2.2 DELIVERY SOFTWARE PLATFORM

In order to implement the prototype on the above hardware, the selection of the appropriate software was also necessary. So, for the PDA pain visualization application, Visual Basic .NET within Microsoft Visual Studio 2008 was considered, a software environment that allows for smart device development.

The 3-D pain drawing was developed from a previous model by *Cyberware, Inc.* (1999). This Cyberware model was adapted, and then manipulated and extended to meet our needs of a 3-D pain drawing. This was then imported in the PDA application by using the functionality of Parallel Graphics Cortona Software Development Kit (SDK), an Application Programming Interface (API) that facilitates the development of 3-D-enabled applications by using VRML, and then displayed using the Parallel Graphics Cortona3D Viewer (Parallel Graphics, 2011).

VRML provides the technology that integrates two or three dimensions, text, and multimedia into a coherent model. It is a technology that has the ability to easily build 3-D objects using a format similar to the HTML's tags. One of the most important functionalities of VRML is the ability to allow objects in the world to move and to allow the user to interact with them.

It has to be made clear at this point that VRML, which is essentially the same as its successor X3D, was selected over other technologies (e.g. Java3D, WebGL) for two main reasons: firstly, VRML demonstrates high compatibility in developing applications for mobile platforms via the Parallel Graphics Cortona plugin (see above). Secondly, it enables the porting of the developed 3-D object from a mobile to a desktop application and vice-versa through minimal changes and reprogramming.

The following is a brief overview that describes the major features of VRML, as taken from Web3D organization's official website.

- **Scene Graph Structure**

VRML describes 3-D objects and worlds using entities called *nodes* that include various types such as geometry, appearance, and sound.

- **Event Architecture**

VRML defines an *event* or message-passing mechanism by which nodes in the scene graph can communicate with each other.

- **Sensors**

*Sensors* are the basic user interaction and animation primitives of VRML.

- **Scripts and Interpolators**

Script nodes can be inserted between event generators (typically sensor nodes) and event receivers. Scripts allow the world creator to define arbitrary behaviours, defined in any supported scripting language.

- **Prototyping: Encapsulation and Reuse**

VRML includes a prototyping mechanism for encapsulating and reusing a scene graph (the PROTO statement).

- **Distributed Scenes**

VRML includes two primitives that allow a single VRML world definition to span the WWW e.g. the Inline node and the EXTERNPROTO statement.

Finally, the local database on the PDA has been implemented using Microsoft Access.

The web/database server has been implemented using the Windows 2008 Server operating system and Internet Information Server (IIS) 6.0, with an Open Database Connectivity (ODBC) service to the Microsoft Access database. For the wireless transmission, Winsock CE 3.0 (Windows CE Sockets) have been used, while all

information is sent through Wi-Fi Protected Access–Pre-Shared Key (WPA-PSK) encrypted radio broadcast. At the software level, the information privacy is maintained by the use of 128-bit Secure HyperText Transfer Protocol (HTTPS). In addition to all of the above, to prevent identity theft, a rotating-password approach is utilized, which requests five random characters of a predefined 16-letter password, and creates a unique keyword combination for every transfer.

### 5.2.2.3 APPLICATION WALKTHROUGH

In order to realize how the design and implementation discussion has been instantiated into a real-life artefact, the following walkthrough will be provided.

Hence, the first screen presented when the prototype initialises is the *Introduction*. This screen has been divided in an upper area where the information is displayed, and the *menu* part of the lower area with several system choices based on our User Interface module. Before any pain data can be collected, the user has to first create his/her profile by tapping on the *New Patient* button (Figure 5-8), which in its turn initialises the database and takes the patient to the *Registration* screen.



Figure 5-8. Introduction Screen

## CHAPTER FIVE – ARTEFACT DESIGN AND IMPLEMENTATION

Here, the patient enters information about the username/password preference, and then by clicking “OK” s/he is taken to the *New Patient profile* screen where his/her personal details and medical information such as symptoms, disabilities, and medical conditions are recorded in the local database (Figure 5-9), as requested by the clinicians. In this screen, we can also see the control part of the lower area with the two buttons enabling interaction with the application. The same structure applies to all developed screens, something that creates an easy to use and navigate graphical environment.

The figure consists of four screenshots of a graphical user interface for patient registration and profile creation. The top-left screenshot, titled "Registration", shows a form with three input fields: "Please enter your desired username:" (containing "joe"), "Please enter your desired password:" (containing "\*\*\*\*"), and "Please re-enter your desired password:" (containing "\*\*\*\*"). Below the fields are "OK" and "Cancel" buttons. The top-right screenshot, titled "New Patient Profile", shows a form with fields for "Date:" (9/3/06), "Name:" (Joe), "Surname:" (Downing), "Gender:" (Male), and "Date of Birth:" (7, 6, 1974). A "Symptoms:" text area contains "painful aches". The bottom-left screenshot, titled "New Patient Profile", shows a form with a dropdown for "Does the patient have any disabilities?" (Yes), a list of disability types with checkboxes (Mental Illness, Hearing Impairments, Visual Impairments, Speech Impairments, Arm Problems, Other Impairments), and a dropdown for "Does the patient have any significant" (Select One). The bottom-right screenshot, titled "New Patient Profile", shows a form with checkboxes for "Speech Impairments", "Arm Problems", and "Other Impairments", a dropdown for "Does the patient have any significant medical conditions?" (Yes), and a text area for "If yes, please list the medical condition/s s/he has:" containing "diabetes". A "Save" button is at the bottom.

Figure 5-9. Creating a New Patient Profile

Following the patient profile creation, the patient is again taken to the *Introduction* screen, from where s/he can login or exit the application by tapping on the *Login* button, where s/he is then requested to enter his/her username/password tuple. Upon successful login, the patient is then requested to provide more specific details regarding his/her pain factors and discomfort level, as also requested by clinicians, which together with the previous mentioned recorded information, fulfil the respective requirement identified. Thus, in the screen following login, the factors that worsen and relieve the pain, as well as the medical treatment and their associated usage frequency are requested, based on predefined by the clinicians options (Figure 5-10).

Figure 5-10. Pain Factors and Medication

After saving the information, the next and final screen that completes the pain questionnaire before the 3-D pain diagram, requires the patient to enter his/her pain discomfort level for the seven predefined body areas and give an overall body discomfort level. Moreover, s/he can mention any other areas not listed, all performed by using a VAS scale between 0 and 9 that has been implemented using scrollbars, as also requested by the clinicians (Figure 5-11).

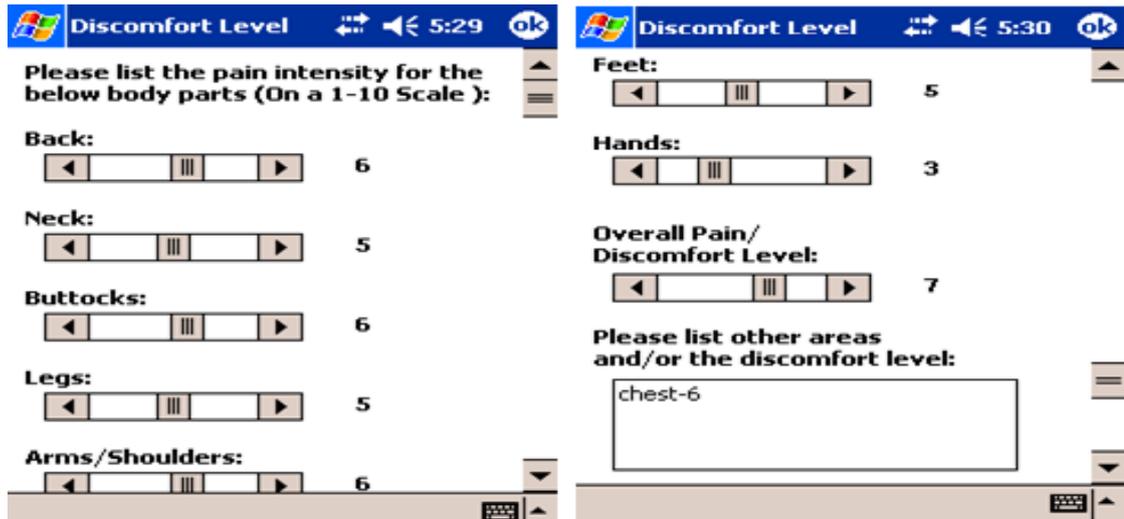


Figure 5-11. Pain Discomfort Level

By tapping on the *Next* button, the patient is taken to the last screen of our application, where the *3-D pain drawing* module is displayed. Here, the patient can select the pain from the four predefined by the clinicians types (Numbness, Pain, Pins and Needles, and Ache), using the four buttons representing them based on a colour format (Red for Numbness, Blue for Pain, Yellow for Pins and Needles, and Green for Ache), as again requested by the clinicians for better and clearer displaying abilities (Figure 5-12).

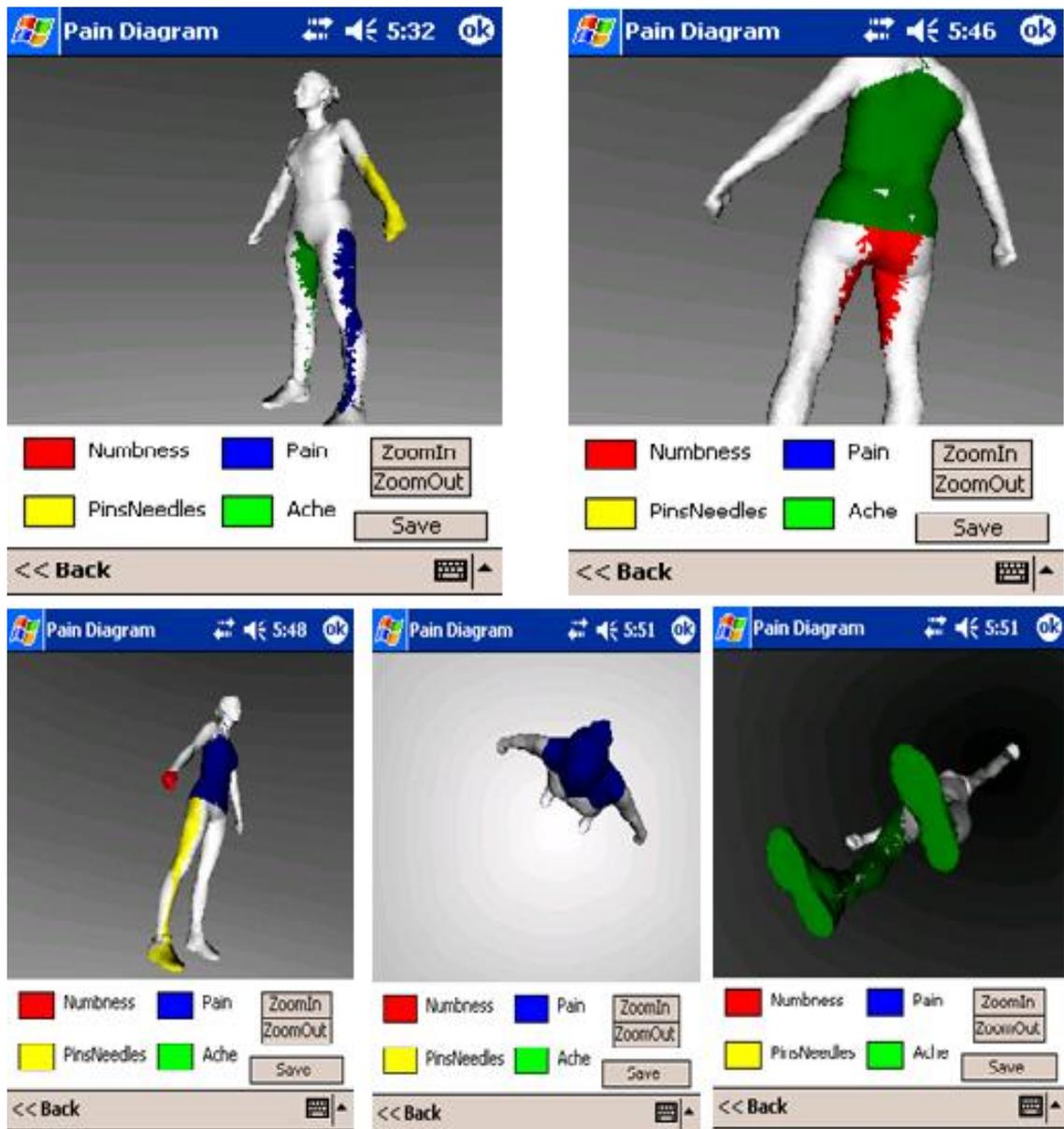


Figure 5-12. 3-D Pain Drawing

Having selected the pain type, the patient can then select the pain location on the 3-D pain drawing from the six regions it was divided into. This pain location can be selected by easily rotating the mannequin based on the 3-axis using the PDA stylus. In addition, the patient can also zoom in or out using the two relevant buttons on the screen, for depth perception purposes. So, by tapping on the screen, it colours any of the regions mentioned, visualizing the pain type and its location on the overall body. The patients can add or remove as many pain types and locations as they want. If a

## CHAPTER FIVE – ARTEFACT DESIGN AND IMPLEMENTATION

mistaken pain indication was given, the user can delete it by clicking again on the selected pain type and then on the 3-D body.

When the pain information data collection process has finished, the patient can then click the *Save* button and save the pain location, type, as well as the time and date of the selection to the local database, where all the data previous to the pain diagram have also been saved (Figure 5-13).

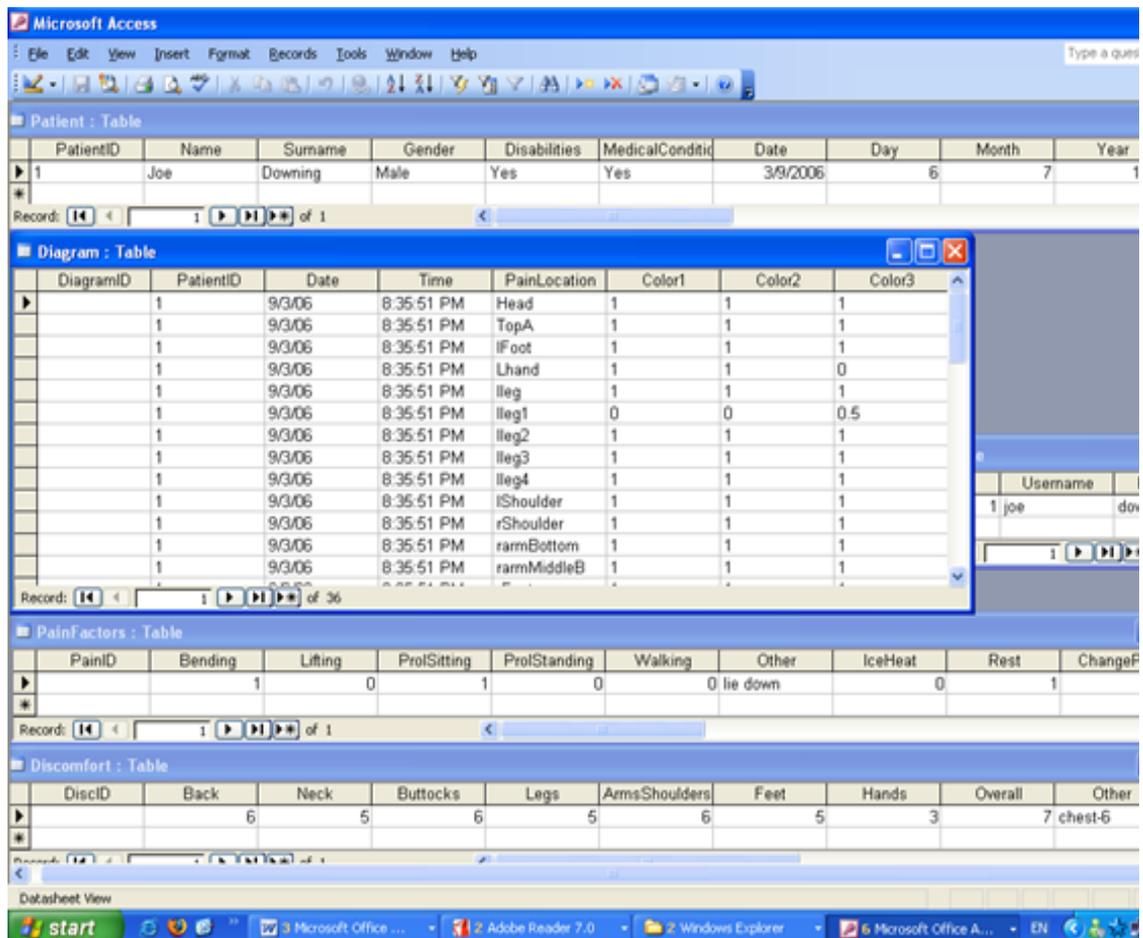


Figure 5-13. Application's Local Database

After the necessary saving of pain data, the patient is returned to the *Introduction* screen from where s/he can choose to upload the data to the server.

### 5.2.3 END OF ITERATION A

At the conclusion of the first iteration of the artefact design and implementation, a working prototype has been produced, as demonstrated from the previous section, which has then been fed to the next phase of the Rapid prototyping methodology, the *Use and Evaluation*. As such, case study one that is presented in chapter six describes the evaluation of the built prototype with a specific user cohort, from which several insightful results and suggestions for improvement of the prototype have been derived. These are similarly fed to the next phase of the employed software development methodology – *Revise the Prototype* – that is represented by a second design and implementation iteration, for the purpose of addressing the aforementioned evaluation results.

### 5.3 ITERATION B: SECOND DESIGN AND IMPLEMENTATION

The evaluation results derived from the first case study, for which a detailed discussion will be provided in the next chapter, indicated the need for a refinement in two aspects of the 3-D pain drawing. Moreover, in addition to the refinement input, this second iteration similarly takes into account the necessary for the design user requirements. Accordingly, interviews were also performed with clinicians and patients alike that would be involved in its next evaluation. The final implementation was then carried out based on the refined design produced, and its third evaluation (the second evaluation described in chapter seven is irrelevant to the design and implementation) was consequently performed (see chapter eight).

#### 5.3.1 DESIGNING THE REFINED ARTEFACT

As such, the final version of the prototype has been designed in this second iteration by taking into consideration the need for a) *a more fine-grained subdivision of the 3-D pain drawing from the six regions to regions that would more accurately represent the painful sites*, and b) *the use of colour to code **multiple** pain types for a particular*

*body region*, unlike the current version that codes only one pain type for a particular body region that is not realistic if the multidimensional nature of pain is considered.

### **5.3.1.1 DEFINING ADDITIONAL USER REQUIREMENTS**

To keep with best practice in achieving the prototype aims, the refined design of the application was also conducted in collaboration with three clinicians and a team of six patients, this time from the Spinal Cord Injury Unit of the Royal National Orthopaedic Hospital, London, who would potentially also use the prototype. In accordance to this research's methodology approaches, interviews with these stakeholders were held in order to define new or refine existing user requirements. To this end, expanding on the requirements initially identified in the first iteration, the derived requirements were to:

1. *Be user friendly*. It should be extremely friendly and very easy to use and understand, as the clinical staff and patients might not be IT-oriented;
2. *Record pain characteristics*. It should provide the functionality to record pain information also for various aspects of the daily patient's life (e.g. personal care, physical activities, treatment) on top of the already established pain characteristics (pain location, type, intensity, time of input), all in the form of a questionnaire;
3. *Provide improved visualization*. It should encompass a 3-D representation of the human body, as an improved version of the 2-D pain drawing. This would provide navigational controls (zoom, rotate and drag) and the ability to allow individually selectable regions of the body that could be highlighted in order to represent different types of pain, in accordance to the first group of patients and clinicians;

4. *Be accurate.* The model should be able to also represent different body postures, which typically reflect a patient's everyday life, and enable selection of body regions that most closely reflect a patient's topology of pain;
5. *Be implemented on a laptop or PC.* A special requirement derived was that the application be developed on a laptop or a PC, instead of a PDA that has been used so far. The reason was mainly that patients suffering from mobility impairments are likely to interact more easily with the application if it is presented on the larger screen of e.g. the laptop, and a mouse (as opposed to the PDA's stylus) is also used.

### **5.3.1.2 THE REFINED PROTOTYPE ARCHITECTURE**

The user requirements discussed above have revealed three important findings. Firstly, the purpose and underlying structure of the prototype have not been considered as necessary to change and have remained the same as in subsection 5.2.1.3. As such, the prototype would still provide a 3-D pain drawing and the capability to collect pain-related medical information that would be saved and later transmitted to a server for the clinicians to consult.

Secondly, the need for extra functionality on top of the aforementioned capabilities was also revealed, which would reflect more activities, and further, be closer to reality and the natural environment of patients.

Finally, the third finding was that clinicians and patients alike agreed that it would be more beneficial to replace the PDA platform with a laptop or PC. Hence, being consistent with the need for mobility, as discussed in subsection 5.2.1.1, the new design has been carried out with a laptop as the delivery hardware platform.

To this end, the refined prototype architecture remained essentially the same as before, with the four main building modules still being the *User-interface*, the *3-D pain visualization application*, the *backend database*, and the *hospital web/database server*. Considering, however, that the server is the only part of the architecture that has not been affected by the change of hardware platform, only the first three modules that have will be discussed next. Figure 5-14 shows a high level approach to the refined prototype architecture.

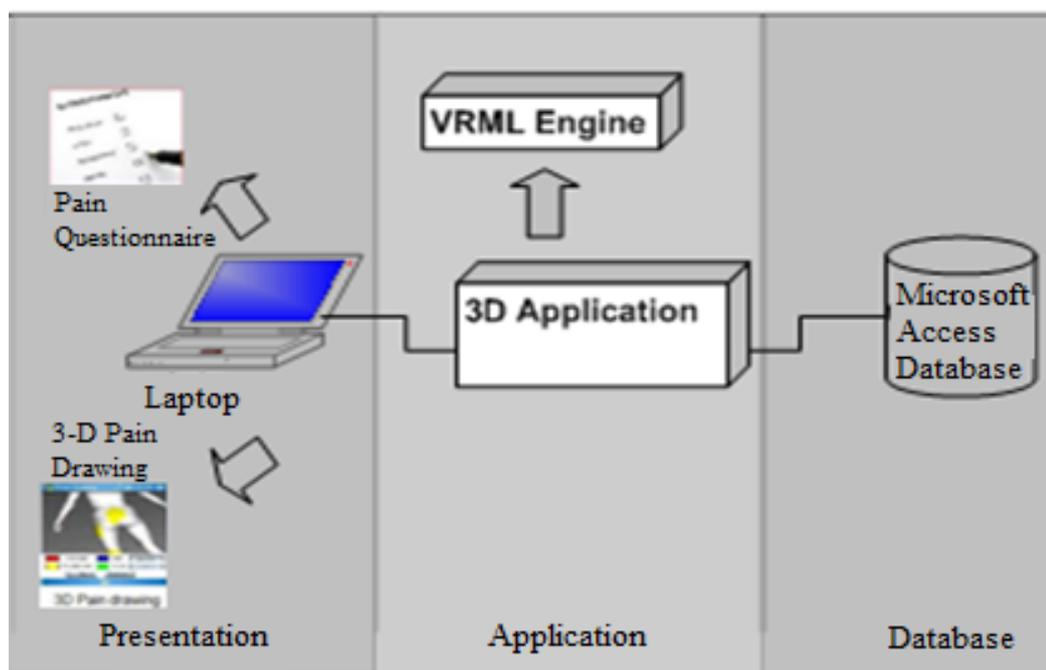


Figure 5-14. The Refined Prototype Architecture

### User Interface

The purpose of this module remains the same, with this being to allow the user to interact with the 3-D pain application's functionalities. The screens that are displayed are also the same, the difference noticed, however, is the number of them that has now been initially reduced to three to improve any complexity in use, with the screens being seven if the user uses the application for the first time or uploads data.

### **3-D Pain Visualization Application**

Similarly, the underlying structure of the application itself has also not been changed. To this end, the questionnaire is again the main component used to collect information regarding a patient's personal data, factors that worsen or relieve pain – but this time in relation to physical activities and personal care as the new requirements suggested - the kind of treatment received, as well as the intensity of their current pain at the time of measurement in the seven predefined body parts.

As in the previous design, the most important part of the application is the visualization ability of pain. Using again the Parallel Graphics' components, our application displays the 3-D pain drawing whose surface was now segmented into more clinically appropriate regions, with respect to the user requirement for the need for more accuracy, and the refinement input for better subdivision of the body. This segmentation, therefore, was performed in three levels: *level 1- least detailed division of the body in regions; level 2- moderate division; level 3- most detailed division*, for more freedom in selecting the level that best reflects painful sites.

Moreover, based on the need for using the initial colour coding to now represent multiple pain types for a particular body region, we also included the enhanced functionality of being able to further choose a combination of these pain types to more accurately highlight pain. Finally, in accordance with the user need to reflect a patient's everyday life, the ability to also select between three different body postures (*besides standing, also sitting and lying*) was also incorporated. Finally, the user still has zoom-in and zoom-out buttons for manipulating the mannequin for depth-perception, whereas rotations are now implemented through mouse input.

### **Backend Database**

The obtained information are similarly recorded in the database architecture of Figure 5-3, however, to reflect the patient population that the evaluation has been performed with, as well as to address the new user requirements and refinements, it was necessary that some changes had to be made in the structure of the database tables, in order to accommodate the new information. For instance, a new field named ‘*Posture*’ had to be included in the ‘*Diagram*’ table that would save information regarding the user-selected posture.

Finally, the transmission of data is again based on the three-tier wireless system model shown in Figure 5-5, with the Wi-Fi-enabled PDA having been replaced by a laptop with wireless functionality. Nevertheless, if no wireless transmission is possible, the data could still be uploaded using conventional networking methods. As a last remark, the interaction between the three tiers remains the same as the one shown in the sequence diagram of Figure 5-6, with the only difference being again the presence of the laptop instead of the wireless-enabled PDA.

### **5.3.2 IMPLEMENTING THE REFINED PROTOTYPE**

The implementation decisions for the refined prototype design were essentially the same as the initial discussion of the implementation aspects provided in subsection 5.2.2. Nevertheless, the hardware and software platforms employed in this second iteration will be similarly discussed in the subsections that follow.

#### **5.3.2.1 DELIVERY HARDWARE PLATFORMS**

Based on the refined design discussion, the final version of the prototype has been developed on a Sony Vaio laptop consisting of an Intel Core 2 Duo Processor with Microsoft Windows Vista as the operating system, running at 2.10 GHz. Moreover, it had 3 GB RAM and a 250 GB hard disk, while the display ability of the laptop

consisted of a 15.4” Liquid Crystal Display (LCD) screen with a resolution of 1280 x 800 pixels.

### **5.3.2.2 DELIVERY SOFTWARE PLATFORM**

The refined 3-D pain application was now implemented by combining Microsoft Visual Studio 2008, a software package that offers the ability to build Windows applications, and the functionality of the Parallel Graphics’ components presented in a previous discussion. Finally, the local database on the laptop has been again implemented using Microsoft Access, whereas the server has remained the same.

### **5.3.2.3 REFINED PROTOTYPE WALKTHROUGH**

As in the previous iteration, it would be beneficial to similarly see by walking through the refined prototype, how it has been instantiated into software that addresses the requirements set.

In retrospect, the interaction starts with initially creating a patient profile by registering the patient user, prior to any pain characteristics data being collected. This is achieved by clicking on the *New Patient* menu item that is under the *Patient* menu in the *Introduction* screen. As a result, the database is initialized and the user is taken to the *New Patient Profile* series of screens, where setting up a username/password pair and filling the questionnaire in with background information such as personal details, symptoms, type of injury, as well as any significant medical or impairment conditions (Figure 5-15), are typically required.

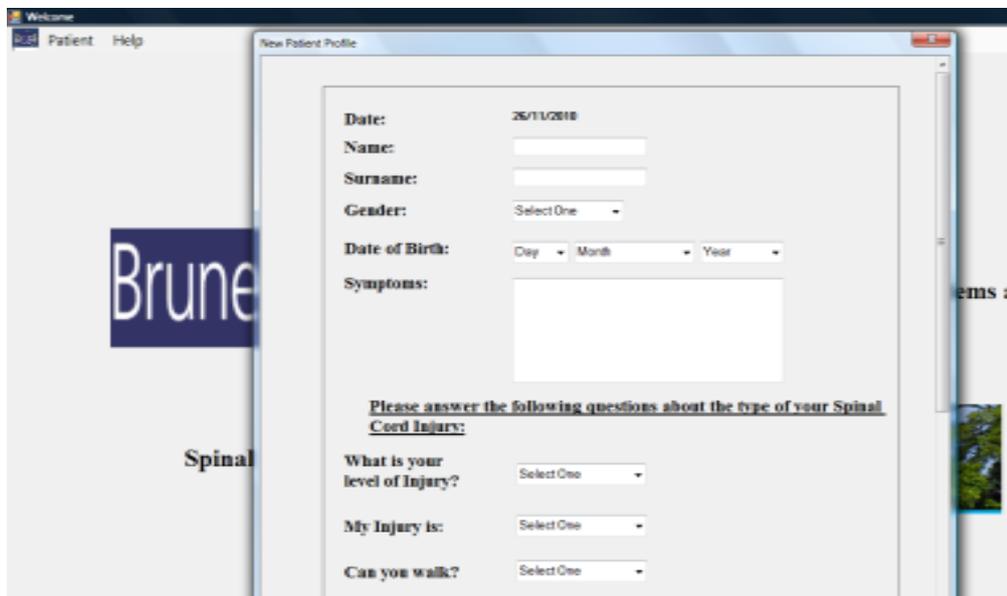


Figure 5-15. Introduction (Up) and New Patient Profile (Down)

The screen that follows requires the clinician to enter more specific pain information with regards to a patient’s pain factors and treatment received. In particular, the system prompts the clinician to specify from predefined lists by the clinicians themselves, the factors that worsen the pain in relation to physical activities (e.g. prolonged sitting and/or lying) and personal care (e.g. dressing, bowel care), as well as the factors that may usually offer relief from any pain (e.g. rest, change of position). In addition, the treatment received (e.g. painkillers, physiotherapy) is also recorded next, after which the user can save the information and proceed with the collection of pain information (Figure 5-16).

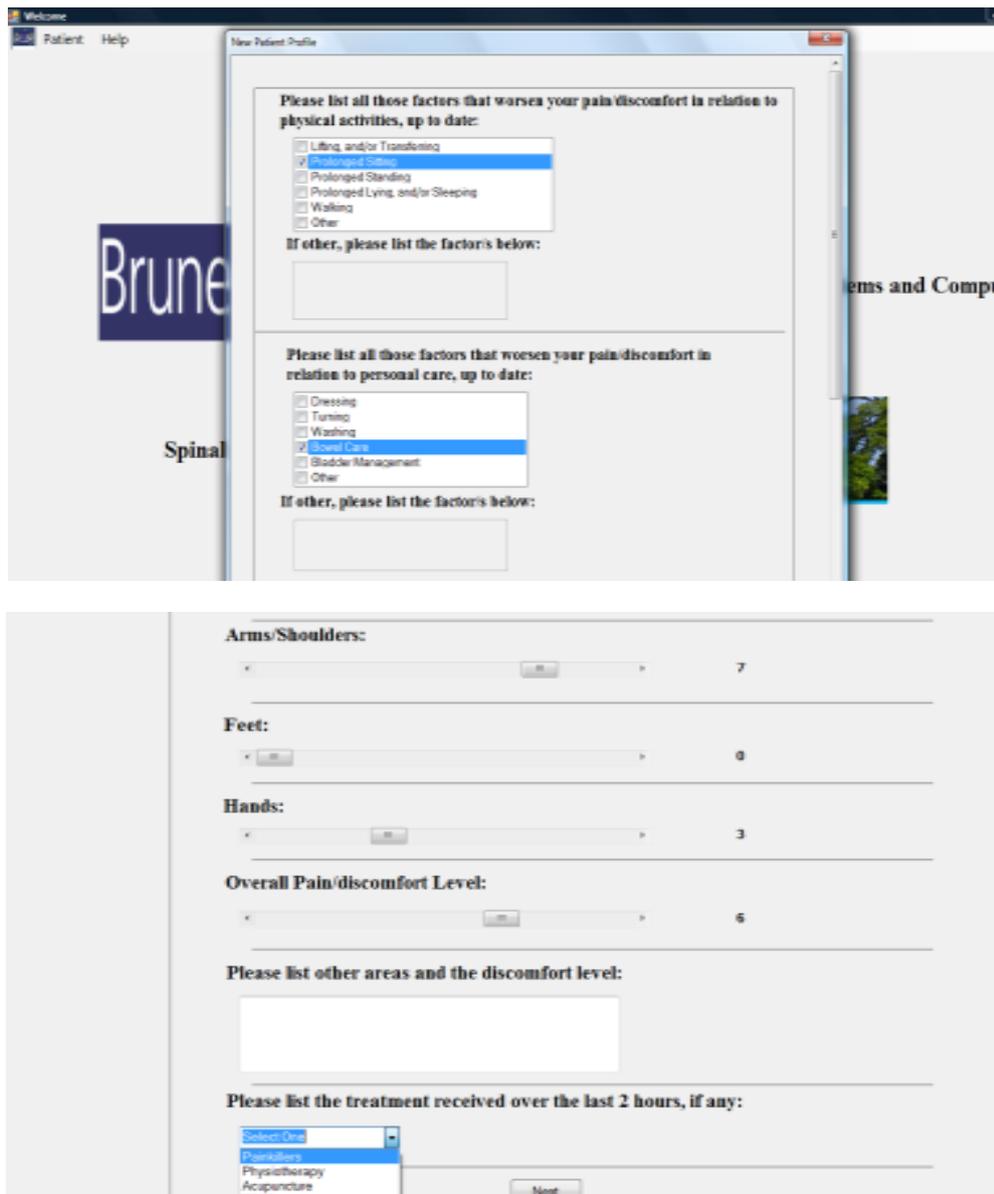


Figure 5-16. Pain Factors (Up) and Discomfort (Down)

With the patient profile created, the patient (or the clinician acting on behalf of the patient, if necessary due to extreme mobility impairments), can log in to the application from the *Introduction* screen by clicking on the *Login* menu item under *Patient* menu. Upon authentication, the user can then score the pain intensity for the seven clinically predefined body parts. In addition, the user can also provide information regarding any treatment received over the last two hours, as well as specify any other painful body areas with the corresponding intensity level (Figure 5-

16). By clicking next at the bottom of the screen, the user can proceed to the 3-D pain drawing screen (Figure 5-17).

While in this screen, the ability to choose between the three postures (*standing, sitting, lying*) and select a better region division of the human body (*Level 1, Level 2, or Level 3*), is provided through the *Mode* and *Level of Detail* drop-down lists, respectively. In order to visualize the pain, the user can select from the four basic types (*numbness, pain, pins and needles, and ache*), but also from a combination of them, all predefined in the menu in the middle of the screen. Each pain is represented by a different colour.

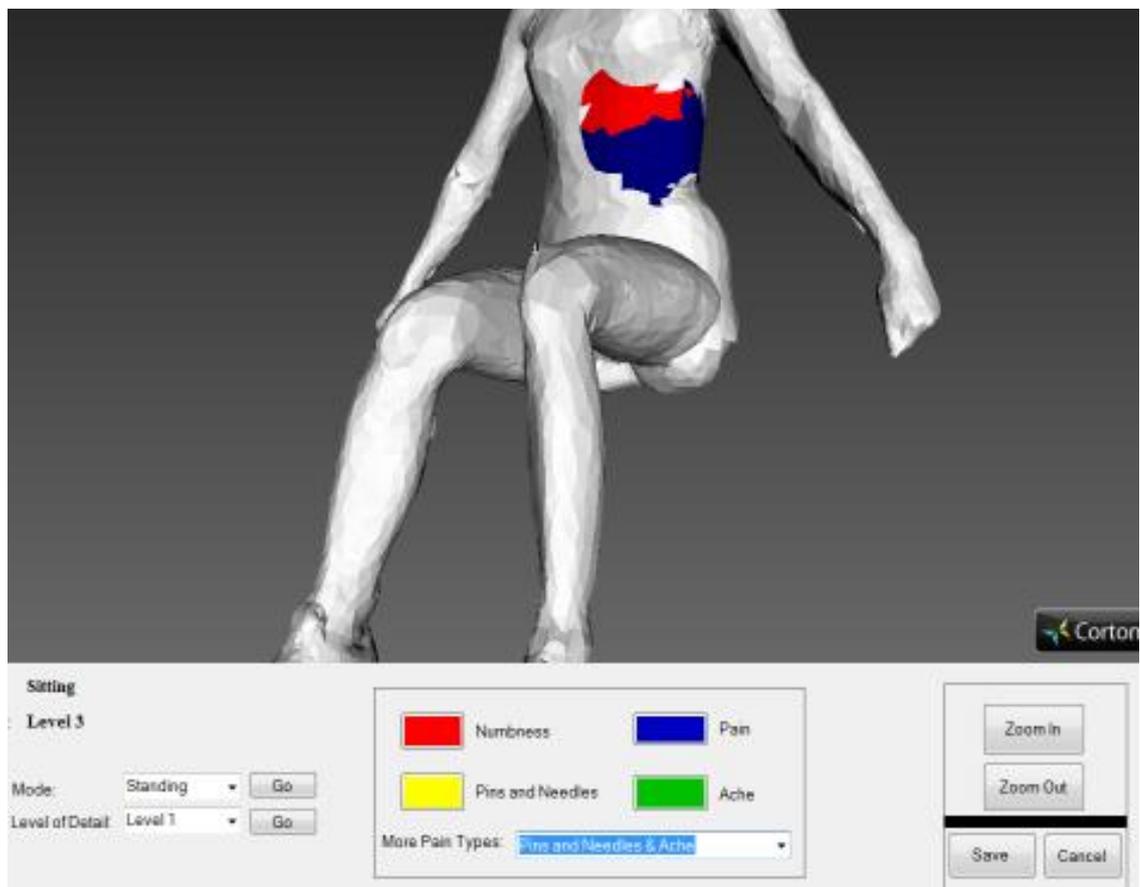


Figure 5-17. The Refined 3-D Pain Drawing in the Sitting Posture

Following the selection of the pain type by clicking on the corresponding colour, the user can manipulate the 3-D pain drawing through the mouse and the *zoom in/out* buttons to the required body part, and indicate the type of pain by simply clicking on

it. If a mistaken pain indication was given, the user can delete it by clicking again on the selected pain type and then on the 3-D body. At the end of the pain information inputting, the user can click on the *Save* button and the application saves it on the local database and returns to the *Introduction* screen.

### 5.4 SUMMARY

This chapter has presented the two iterations that were performed in accordance to the Rapid Prototyping development process in order to design and implement this research's artefact. In specific, the user requirements necessary to establish the design, and consequently the implementation of the prototype have been explored with respect to both iterations' purpose. Next, the designs of the prototype have been described as carried out during the process of the two iterations, and the implementation decisions for the development have been then presented for both. As a final point in this chapter's discussion, the walkthroughs for both versions of the prototype have been similarly presented in order to gain a significant amount of understanding of their functionalities, prior to proceeding with a detailed discussion of their evaluation process.

In retrospect, the following three chapters will present the evaluation process of the prototype that was carried out within three real-life case studies. In accordance with the fourth step in the DSR cycle, the prototype has been evaluated against several specific metrics that include the *acceptability*, *functionality*, *efficiency*, *usability*, and *feasibility* aspects of the developed software. As such, the first and third case studies have explored the acceptability and functionality, as well as the usability and feasibility, respectively. The efficiency was measured in the second case study.

However, in the context of the current chapter we have seen that the results of the second case study have not been used in the design and development process. The reason lays in the nature of this case study, whose purpose has not been to evaluate

## CHAPTER FIVE – ARTEFACT DESIGN AND IMPLEMENTATION

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functional aspects of the artefact, but rather to address concerns with respect to the nature of pain and the applicability of the prototype, which do not constitute inputs for improvement. Unlike the second though, the results of the first and third case studies have been utilised from the two iterations, as we have already discussed. All these case studies will be presented in the three chapters that follow.

## CHAPTER SIX

# CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK PAIN

## 6.1 OVERVIEW

A large number of the adult population suffers from some kind of back pain during their lifetime. Part of the process of diagnosing and treating such pain is for a clinician to collect information as to the type and location of the pain that is being suffered. Traditional approaches to gathering and visualizing this pain data have relied on the simple 2-D representations of the human body, described in chapter two, where different types of sensation are recorded with various monochrome symbols. Although patients have been shown to prefer such drawings to traditional questionnaires, these pain drawings can be limited in their ability to accurately visualize pain.

The focus of the work described in this case study is to demonstrate how 3-D visualization technology could be employed as an alternative approach towards the augmentation of the 2-D pain drawing with respect to its ability to visualize back pain. Specifically, this case study will attempt to address the practicality and the functionality of the 3-D pain drawing prototype in visualizing back pain as perceived by its direct stakeholders – medical staff and patients – respectively.

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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Accordingly, understanding of back pain is introduced in the next section, and current approaches and limitations in visualizing its characteristics are subsequently discussed. The methodology undertaken to evaluate the developed 3-D artefact is presented next, and the chapter concludes with the presentation and discussion of the results of this case study.

### **6.2 UNDERSTANDING BACK PAIN**

It is estimated that during any one year, up to half of the adult population (15-49%) will have back pain at some stage in their life (Burton et al. 2006). Besides being uncomfortable and affecting day-to-day life on a personal level, it also has a considerable effect on society, as well as on the health budgets and national economies of countries (Frank and De Souza, 2001; Vaughn et al. 1999).

#### **6.2.1 PREVALENCE AND IMPACT OF BACK PAIN**

Back pain is considered to be a worldwide experience that appears to be a problem for most of the western and industrialized societies. According to Borenstein (1997), the lifetime prevalence of back pain is more than 70% in most industrialized countries, affecting 20% of the population in the United States per year. A survey performed by the Department of Health indicates that the relative numbers in Britain reach 40% of the adult population, 5% of which have to take time off to recover (cited in Ghinea et al. 2004). Studies have also revealed that most people experience back pain at some time in their lives, usually beginning between ages of the 30 and 40 years, with men and women being equally affected (Koelink, 1990).

The impact of this condition is such that back pain alone cost the UK economy about £9090 million in 1997 and 1998, with between 90 and 100 million days of sickness and invalidity benefit paid out per year for back pain complaints (cited in Serif and Ghinea, 2005). Moreover, in 2008, Backcare published figures indicating that the

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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NHS in the UK spends more than £1 billion on back pain related costs per year, with the equivalent figure for the United States being \$50 billion per year. As a result, back pain is considered to be second only to the cold as the most common disease in humans. Furthermore, together with heart disease, arthritis or other joint disease, backache is one of the most common causes of morbidity, disability, and perceived threat to health (Koelink, 1990).

### 6.2.2 UNDERLYING CAUSES

Unfortunately, according to Vaughn et al. (1999), the available medical information only provides partial success in diagnosis and treatment of back pain with only 15% of the patients obtaining an accurate diagnosis of their problem. This partial success is due to the complexity of the back, where the main causes of pain could result from reasons such as strains and minor injury rather than serious injury, and could originate from doing a wrong sort of movement to muscle and spine abnormalities. In addition, back pain can also be triggered by injury to back muscles or spinal discs during lifting with improper load handling (Frank and De Souza, 2001; Parker et al. 1995).

Nevertheless, evidence from the literature about the biomechanics of back pain suggests that in essence the causes of back pain still remain unclear. However, studies in the field (Wong and Deyo, 2001) have shown that the most common causes of back pain can be divided in three major categories, namely *musculoskeletal*, *systemic*, and *visceral*, detailed in Table 6-1 below.

Analysis of these studies has shown that 98% of the cases are musculoskeletal in aetiology, with the remaining 2% being due to systemic conditions, referred visceral pain, or psychological and social factors. Furthermore, Adams et al. (2002) suggest that the joints and the spinal discs are indeed the leading sources of back pain with

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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pain originating from the joints accounting for some 10-15% of patients, and pain coming from spinal discs causing more than 40% of the cases.

Table 6-1. Major Causes of Back-pain (Compiled after Wong and Deyo, 2001)

Type	Cause
Musculoskeletal	<ul style="list-style-type: none"><li>- Muscle spasm</li><li>- Ligament strain</li><li>- Disk herniation</li><li>- Compression fracture</li><li>- Spondylolisthesis</li><li>- Spinal Stenosis</li></ul>
Systemic	<ul style="list-style-type: none"><li>- Malignancy</li><li>-Spondyloarthropathy</li><li>-Infection</li><li>-Dissecting abdominal aortic aneurysm</li></ul>
Visceral	<ul style="list-style-type: none"><li>-Renal</li><li>-Endometriosis</li><li>-Dysmenorrhea</li></ul>

### 6.3 VISUALIZATION OF BACK PAIN: STATE-OF-THE-ART

In spite of the above discussion, the assessment of this medical complaint remains notoriously difficult. In fact, as with most types of pain, back pain is difficult to assess, since the only information that can be used is suggestive descriptions from the patient. However, chapter two has highlighted that this patient self-reporting may be a challenge for clinicians to understand, mainly because these patients may have developed psychological and emotional problems as a result of suffering with pain, resulting therefore in biased communication of their experience. This problem is further exacerbated as, in some patients, the psychological problems may have actually caused some of the back pain by adding stress to the body, or the stress of the back pain may have caused psychological problems (Uden et al. 1988). The subjectivity of pain has been described in more detail in chapter two; nevertheless, its appearance in back pain assessment justifies the recurring discussion identified in the literature and the need for immediate action.

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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In retrospect, one of the first steps that are traditionally undertaken by patients in a back pain clinic is the completion of a medical questionnaire, which is intended to identify the location and type of pain being experienced. Specifically, in most cases, the only visual aid to assist medical staff with their assessment is the 2-D pain drawing discussed in chapter two. Previous research (Wiltse and Rans, 1975) on methods of efficient assessment of back pain had indicated that the Hypo-chondriasis (Hs) and Hysteria (Hy) scores of the MMPI were the best prognosticators for disc-disease. However, the study performed by Ransford et al. (1976) similarly showed that pain drawings were also a good indicator of Hs and Hy scores, and thus, could effectively be used in the treatment and management of back pain.

Building on the work of Ransford et al. therefore, a significant amount of research efforts have been identified in the clinical literature to evaluate the performance of the 2-D pain drawing in the visualization of pain. Ohnmeiss et al. (1995) by using the pain drawing have determined that the pattern or the type of pain indicated were related to the presence of herniated disc that was identified by CT/discography, while Takata and Hirofany (1995) have demonstrated the ability of the pain drawing to differentiate between three groups of patients with distinct pain patterns, making it a considerably useful method for predicting the outcome of treatment.

More recently, work has focused on determining the correlation that might exist between 2-D pain drawing modalities and other pain assessment methods (such as the ones described in chapter two), with the results indicating that such pain modalities are often correlated to pain and other functional variables (Grunnesjo et al. 2006). As a step further, Lin et al. (2006) have employed the 2-D pain drawing as part of a web-based decision support system that was developed to assess the patient's information and recommend a diagnosis.

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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All of the studies described above have provided sufficient evidence of the ability of the 2-D pain drawing as an aid in the process of visualizing and assessing pain. Nevertheless, a general paucity has been identified in the literature with regards to research on improving the pain drawing's capabilities in accordance to its beneficial usage for back pain. Moreover, coming back to the discussion held in chapter two, any pain information nowadays is still mainly gathered through the use of interactive interviews by highly skilled medical personnel, supported by various paper-based questionnaires and the 2-D pain drawing. However, notwithstanding its advantages, the 2-D pain drawing has its limitations as the 2-D representation constitutes a limited dimension representation of the medical information, potentially resulting in a time-consuming process with possible irrelevant medical data collected that can lead to a report that obscures important information.

In these conditions, we intend to employ the digitized 3-D pain drawing described in chapter five, in the anticipation that, firstly, it will increase the ease with which patients visualize their own back pain experience, and secondly, such an approach will provide an attractive opportunity for enhancing interaction between the clinician and the patient in a more perceivable way to the natural environment. Nonetheless, in our research, it was felt important that 3-D visualization technology should not be applied to the problem for the sake of it, but that any new approach should be more intuitive than existing approaches, and just as usable.

### **6.4 METHODS AND MATERIALS OF THE CASE STUDY**

The aim of this case study is to investigate the effect of the developed 3-D pain drawing in the visualization of back pain. To this end, we specifically targeted two research questions (research questions i. and ii. in chapter one) within the context of this work:

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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1. How is the introduction of 3-D technology *perceived*, and what is the level of *acceptability* of the 3-D pain drawing for the visualization of back pain by the medical staff in everyday practice?
2. What are the patients' perceptions with regards to the *functionality* characteristics of the 3-D approach in terms of its ability to ease the process of visualizing the back pain experience?

In order to address the first research question, the 3-D pain drawing will be evaluated with the medical staff involved in this research as they constitute the most appropriate evaluators for assessing the acceptability aspect within everyday clinical practice. Accordingly, the most suitable way to explore the functionality - as defined above - of the 3-D pain drawing is to form an evaluation with potential users of the prototype, who in our case are individuals who suffer from some type of back pain.

### 6.4.1 INSTRUMENTATION

The instrumentation used for this case study consists of the PDA that runs the 3-D pain drawing prototype (Figure 6-1), described in chapter five, a wireless router that could be used, if desired, to upload the medical information, and one evaluation questionnaire that will be filled by the users.

This questionnaire is constructed in a way that it will include eight questions that define the functionality aspect of the evaluation, and which users will have to answer by recording their opinions on a 5-point Likert scale, where 5 corresponds to the most positive response and 1 to the most negative (see Table 6-3). Finally, interviews will be similarly employed, as a means of obtaining the necessary views and opinions of the medical staff when assessing the acceptability of the 3-D pain drawing in the clinical practice (see Appendix B, Part 2).

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

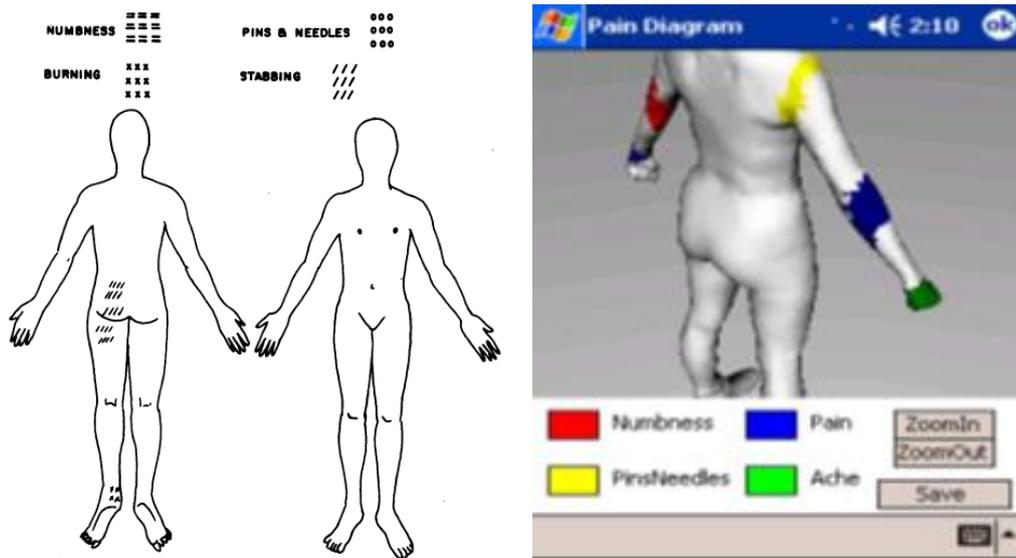


Figure 6-1. The 2-D (Left) and 3-D (Right) Pain Drawings

### 6.4.2 DESCRIPTION OF PARTICIPANT GROUPS

This case study involved two participant groups in the evaluation with respect to the two research questions defined in subsection 6.4.1. The former consisted of four clinicians who were asked to review the prototype for its acceptability. One was a back pain specialist; another was a palliative care specialist, both from Northwick Park hospital, in London, with the prototype also being evaluated by two physiotherapists from the same hospital as above. The only selection criterion was that the clinicians had considerable experience in assessing back pain using the 2-D pain drawing.

Accordingly, the latter consisted of 45 back pain patients (26 males, 19 females, mean age 46.1 years) who evaluated the prototype for its functionality between June and August 2008. Out of these, 13 were patients at the Rheumatology Clinic of Northwick Park Hospital and volunteered to take part in the case study. The remaining 32 participants were members of the Hillingdon Independent Wheelchair User Group, who also volunteered to participate. A summary of both groups is shown in Table 6-2 below.

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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Table 6-2. Participant Groups

<b>Participant Groups</b>	
<b>Medical</b>	<b>Patient</b>
One Back-care Specialist	13 Patients at a Rheumatology Clinic
One Palliative care Specialist	32 Members of a Wheelchair User Group
Two Physiotherapists	

The only inclusion criterion in this case was that participants had to experience back pain during the period of the case study. It was also optional, but desired, that they had broadband access at home and allowed us to install a wireless router over the evaluation period (although wireless connectivity is not necessary for pain data upload, it was considered beneficial in order to evaluate this aspect of our prototype).

### **6.4.3 PROTOCOL AND ALGORITHM**

As with all consecutive case studies, informed consent was obtained prior to initiation of the evaluation with both participant groups. Having two research questions in this case study, the evaluation consisted of two respective parts; firstly, the 3-D pain drawing prototype was assessed for its acceptability by the medical staff described in the previous section over a period of one day in the London hospital where the medical staff was employed at. Considering that the aim of this first evaluation was not to explore whether the prototype was functional with respect to visualizing back pain, the aforementioned participants were each walked through the prototype application by the author, while at the same time were also interviewed regarding their opinions, comments, and suggestions for its capability to be used in everyday clinical practice. Each session lasted approximately 40 minutes.

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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Accordingly, the second part evaluation with the back pain patients was carried out over a period of one day at each participant's premises. With respect to the second research question of this case study, the functionality of the 3-D pain drawing prototype was next investigated, with patients this time using the application themselves, unlike the first evaluation with the medical staff. Specifically, patients were asked to record their back pain information on the 3-D pain drawing at three set times a day (first thing in the morning, noon, and before going to bed) in accordance with the suggestions of the medical staff involved in this case study. In this way it was ensured that a sufficient amount of times of use would be achieved prior to been asked for their perceptions about its functionality at the end of the one-day period. Each set time lasted approximately 25 minutes. At the end of the day, patients had the option to upload the recorded information to the hospital server, and they were asked to complete the evaluation questionnaire of Table 6-3. Finally, participants were also asked to note any other comments they might have had in respect of the developed application.

### **6.4.4 DATA ANALYSIS**

The data obtained from the aforementioned evaluations consisted of information collected from the interviews with the medical staff, and the results of the evaluation questionnaire distributed to the patients. Analysis for the former was performed by reviewing the interview data (whether they were comments, suggestions or opinions) and deriving information that would address the research question regarding the acceptability of the 3-D drawing. While the aim was to simply obtain the subjective views of the medical staff, no specific content analysis was sought due to the small participant group, which produced data that were easily extracted and analysed without the need for such advanced methods (see subsection 4.5.1.1).

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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Along the same lines, analysis for the latter was carried out in terms of both descriptive statistics and a graphical representation of the questionnaire findings, by employing the PASW software.

Table 6-3. Functionality Evaluation Questionnaire

Question	Mean	St. Deviation ( $\sigma$ )
Q1. How effective did you find the controls to navigate the 3-D model?	4.24	0.83
Q2. How would you describe the overall layout of the interface?	4.31	1.00
Q3. Were the tool tips helpful?	4.29	0.89
Q4. Was the use of the color notation clear?	4.29	0.94
Q5. It is important to be able to record my pain on a PDA.	4.38	0.86
Q6. It is useful to be able to log pain data across time.	4.40	0.78
Q7. It was difficult to input pain data on a PDA.	2.07	0.75
Q8. Process of transferring data from PDA to the main database could be easier	1.98	0.72

The results of the aforementioned analysis were then interpreted to identify whether the findings could address our second research question with respect to the 3-D pain drawing's functionality as perceived by the patients.

### 6.5 EVALUATION RESULTS

Accordingly, the results of the two evaluations of the prototype are presented in this section in the order of the evaluation performed. As such, the feedback from the medical staff involved in this case study is firstly presented, followed by the findings that would allow us to gain an understanding of how functional the 3-D pain drawing was by back pain patients are similarly demonstrated.

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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### 6.5.1 CLINICAL EVALUATION

As has been highlighted before, this evaluation was performed to ascertain whether this approach to pain visualization could be used in practice, by professionals with considerable experience in the use of existing 2-D pain drawings. In general, all clinicians surveyed approved of the visual appearance of the prototype, and suggested that it would be usable and practical in a clinical environment. Nevertheless, they also provided a number of interesting observations on limitations and improvements that could be made.

The back pain specialist noted that the 3-D interface covered almost all aspects of existing pain drawings. He was impressed by the level of detail and navigation control. However, he did note that users with disabilities might find it difficult to interact with the PDA. While he was “excited” by the possibility of patients collecting their own data, especially at set times of the day (and thus, being able to remotely monitor the progression and type of pain, vis-a-vis the prescribed medication/treatment), he did highlight that *1) users should be given appropriate training* and *2) appropriate personnel and facilities should be made available to interpret this wealth of data*, otherwise it would ultimately be a futile exercise.

These concerns were also echoed by the palliative-care clinician, who was, however, impressed by the opportunity that the application gave patients to become better stakeholders in managing their pain. Moreover, he was also of the opinion that even though the tool did not provide a diagnosis as such, it could have important and beneficial psychological effects on patients eager to record their pain diaries.

Finally, both physiotherapists interviewed had no concerns with the practicality of the prototype, but did suggest that *1) the feet should point downward rather than be in a standing position* to allow for ease of marking and analysis and *2) in future*

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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*versions of the prototype could be consider having a more fine-grained division of the mannequin body surface.*

The physiotherapists were impressed by the potential ability of the prototype for anytime, anywhere data collection, and hinted that even if the prototype would have had usability issues, in practice, most patients would overlook this, as the convenience factor associated with it would outweigh such considerations—for one, there would be less hospital visits.

### **6.5.2 PATIENT EVALUATION**

Much along the same lines of the views of the medical staff, the results obtained from the patient evaluation were positive and in line with our expectations that individuals with back pain would approve the ability of the 3-D pain drawing to visualize their pain characteristics.

In retrospect, patients found the color notation clear, and found it easy to navigate and control the 3-D pain drawing used in the PDA application ( $\sigma = 0.94$  and  $0.83$ , respectively) as shown in Figure 6-2. These results with respect to the developed interface are especially encouraging ( $\sigma = 1.00$ ), since the majority of the users were wheelchair patients, many of whom wore glasses, and whose condition was compounded by other disabilities (such as motor ones).

Strongly positive results were also obtained with respect to the ability of the prototype to record pain data anywhere, anytime, and especially, with the fact that it allows the patient to show clinicians how their pain varies across the day ( $\sigma = 0.78$ ), in this respect, the trend confirming earlier results (Serif and Ghinea, 2005). Furthermore, patients generally disagreed with statements regarding the difficult of data input and upload ( $\sigma = 0.75$  and  $0.72$ , respectively) as shown in Figure 6-3.

CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D  
VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

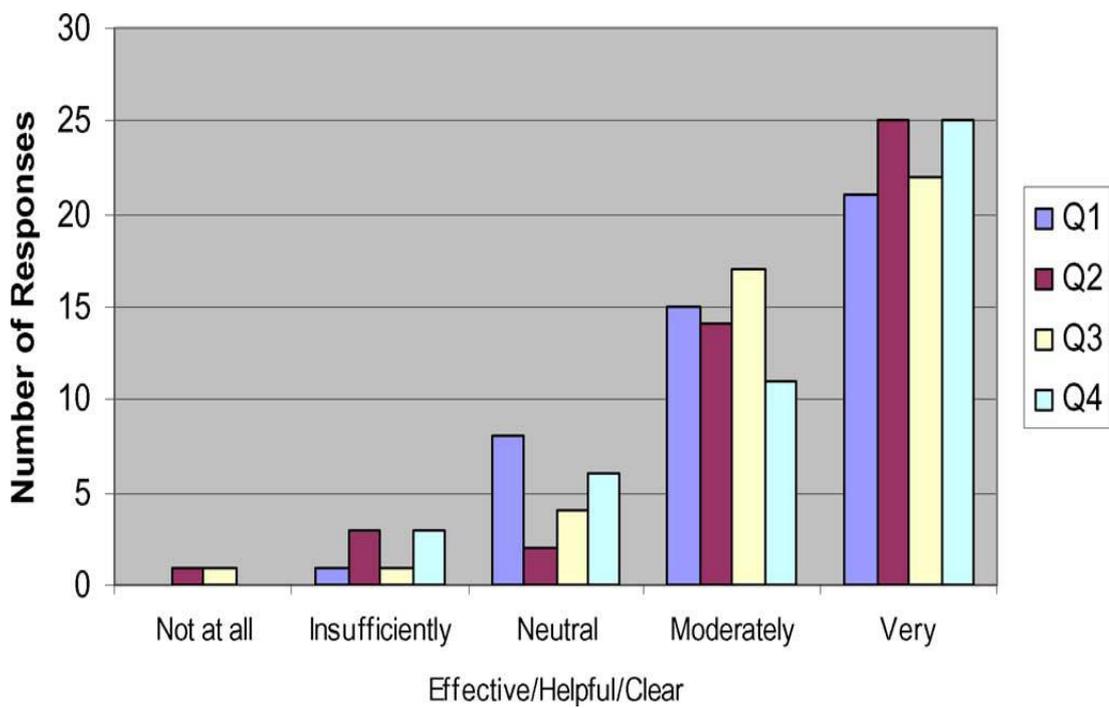


Figure 6-2. Histograms of Responses to Questions 1-4

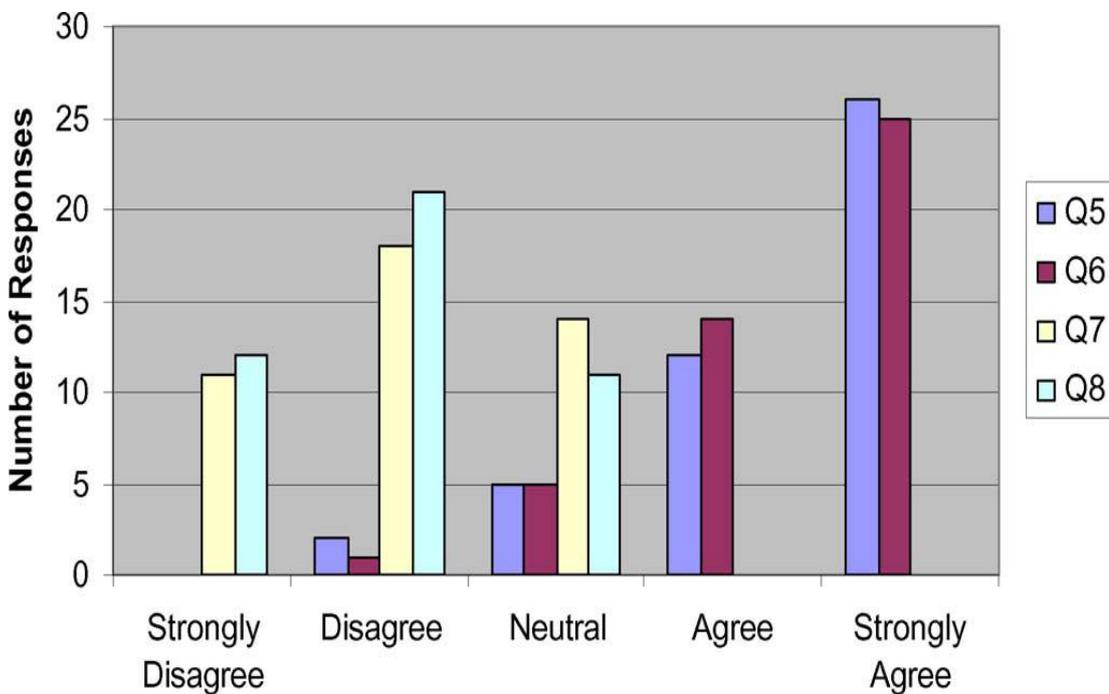


Figure 6-3. Histograms of Responses to Questions 5-8

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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In support of the findings, patients also made some interesting comments when evaluating the prototype:

*“The application allows me to correlate more closely the pain I am experiencing with the activities that I had been doing . . .”* The patient then remarked that, as a result of self-monitoring of how activities impacted his/her pain levels, s/he could manage the pain much better by reducing those activities that led to intense pain.

Another patient remarked:

*“The software made me realize that I was taking my medication at the wrong time of the day . . .”*

This observed discrepancy between medication intake and experienced peaks of pain, as well as a better understanding of the link between activities undertaken during the day and pain intensities and patterns in the end resulted in the patient reducing his medication (strong analgesic) by 25%, with no deterioration in the pain levels encountered. Indeed, the reduction of medication intake as a result of self-monitoring of pain was not a singular observation, as this was reported by five other members of our case study group.

Yet another patient highlighted:

*“Being able to rotate, zoom-in and out makes me feel that I have a much better control of my pain . . .”*

This observation seems to show that even though pain levels of the individual in question had not necessarily decreased as a result of the developed application, at least it offered him a perceived leverage of control over his suffering, as it allowed for an improved interaction with the 3-D pain drawing, on which he could better pinpoint his pain characteristics. Indeed, as remarked earlier, surveyed users were most enthusiastic about the ability to log data and its variation in time.

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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In rounding off the analysis of patients' comments, it was particularly pleasing to obtain a statement to the effect that:

*“ . . . 3-D on a PDA allows me to accurately pinpoint any location I choose. Now, I would never go back to 2-D (pain drawings) again.”*

Lastly, it must be remarked that, from the additional written and oral comments that have been received, the general trend was that patients were enthusiastic about the functionality of the 3-D pain drawing, with the only suggestion for further improvements being a finer division of the body mannequin, so that pain locations could be better pinpointed and the possibility of having more than one type of pain for each selected body region.

### **6.6 SUMMARY**

This case study has presented how 3-D visualization technology could be employed, and what are the effects of such an approach in the visualization of back pain. The two evaluations performed revealed particularly encouraging results, with patients appreciating the advantages that self-monitoring of pain offers in managing this complex phenomenon, while clinicians especially liked the ability of the 3-D pain drawing to remotely monitor pain. Moreover, both patients and clinicians indicated positive views toward the developed interface, platform, practicality, and functionality.

The results reported in this case study have also raised interesting comments and suggestions for improvement that constituted valuable feedback for the refinement of the prototype, which would then be used in the consecutive case studies that are described in the following chapters. Chief of these is a more fine-grained subdivision of the 3-D mannequin in regions that would more accurately represent the painful sites, as well as the use of colour to code multiple pain types for a particular body

## CHAPTER SIX – CASE STUDY ONE: BRINGING 3-D VISUALIZATION TO THE ASSESSMENT OF BACK-PAIN

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region. Special consideration should also be given to the subjectivity of pain that seems to make its appearance in most pain cases. All these constitute parts of the two next case studies.

Finally, the work presented here is, of course, prototypical; nevertheless, it has shown that the new approach is a promising development in this area of medical visualization and has been positively received by patients and clinicians alike.

## CHAPTER SEVEN

# CASE STUDY TWO: 3-D VISUALIZATION TECHNOLOGY AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

## 7.1 OVERVIEW

The previous case study has pointed out several important remarks as a result of the evaluations performed on the developed 3-D pain drawing within the back pain context. While most were suggestions for improvement that were addressed in the second software development iteration (see chapter five), the most considerable that was revealed was the subjective nature of pain, for which there is still an on-going debate in the literature with respect to finding more effective ways of dealing with this aspect.

In view of the above concern, this case study demonstrates how 3-D visualization technology could be employed to visualize the pain characteristics efficiently, so that an improved understanding of whether this reported pain is truly a product of subjective self-reports or is indeed fairly justified, could be obtained. The aforementioned approach has been evaluated for validity under two criteria: first, participants had to be a cohort of individuals who suffer from some type of medical condition that involves some pain; and secondly, this cohort had to consist of individuals with a type of mobility impairment, who are characterized by the severity and presence of pain. It also has to be mentioned at this point that the selection of a variety of medical conditions for the evaluation, unlike the previous case study where

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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only back pain was examined, was justified by the universal incidence of the subjectivity aspect, which typically appears whenever pain is present, irrespective of the underlying clinical condition.

Accordingly, this chapter begins with an overview of current approaches and concerns to pain visualization with regard to the mobility impaired population. Specific attention is given next on the effort to communicate successfully the subjective pain experience, and a review of the most important methods that could be used for this purpose, in addition to the 2-D pain drawing, is presented. The methodological approach employed to evaluate the 3-D pain drawing and address the subjectivity of pain is subsequently discussed, and the chapter concludes with the presentation and a summary of the findings.

### **7.2 PRESENCE OF PAIN IN MOBILITY IMPAIRED PEOPLE**

Amongst the significant percentage of the population suffering from some form of painful condition, it seems that there is a trend for pain to be very common for many mobility impaired people (Harms, 1990; Samuelsson et al. 2001). This group of individuals usually find themselves suffering from particularly severe pain, often deteriorated due to their reliance on wheelchair support that presupposes prolonged sitting and reduced physical activity.

In a study carried out by Gibson and Frank (2005), 26% of Electric-Powered Indoor or Outdoor (EPIOC) wheelchair users in the UK admit to pain or discomfort when sitting in their chair at four months after delivery. This figure rises to 46% at two years, an indication of increasing pain due to prolonged sitting. Similarly, results of another study indicate that pain was a common problem in the studied group with a reported frequency of always (12%), everyday (33%), several times a week (17%), sometimes (30%), and very seldom (8%) (Samuelsson et al. 1996).

### 7.2.1 VISUALIZING PAIN: APPROACHES AND CONCERNS

Despite the huge amount of money and resources spent, the assessment of this medical complaint remains notoriously difficult, with sporadic success in assessing pain efficiently. Previous chapters have highlighted that this challenge typically stems from the multidimensional nature of pain, which typically involves physiological, as well as emotional qualities (see also Mannion et al. 2007). As a result of this heterogeneity, the available medical methods only provide partial success in the assessment of this chronic condition. According to the literature, there are mainly two important factors, which could affect this partial success in assessment, namely:

1. The limited ability of the current assessment methods to *visualize* pain efficiently, and;
2. The insufficient *communication* of pain to clinicians

It has already been established in previous discussions that the most important tool currently in use to visualize pain is the 2-D pain drawing. In retrospect, the 2-D pain drawing has been thoroughly examined in the clinical literature as a means of visualizing pain originating from a variety of medical conditions, in keeping with this case study's first selection criterion mentioned in section 7.1. The consensus seems to indicate that the pain drawing is considered to be a valuable and useful tool in identifying pain location and sensation type, with most of the studies pointing to patients consistently completing it (Ohnmeiss, 2000; Takata and Hirotsu, 1995).

Nevertheless, in light of the several drawbacks that the 2-D pain drawing was identified to have, for the purpose of this case study the developed 3-D pain drawing that has been evaluated in the previous case study has been adopted for this work. The reason for this decision is that it has shown to be of practical use in visualizing

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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pain better, as well as in demonstrating consistency in its functionality, addressing in this way the first factor identified above. As such, 3-D visualization technology has been shown to have a positive effect in better visualizing pain, however, its effect on addressing the subjectivity of pain is yet to be examined.

### **7.3 COMMUNICATION OF PAIN**

Although the pain drawing as a pain visualization tool is widely considered to be valid as discussed both in the literature (Ghinea et al. 2008; Ohnmeiss, 2000; Ransford et al. 1976), as well as in the previous case study, there seems to be considerable debate as to whether visualization as a result of the pain drawing alone is sufficient to communicate the pain to a clinician, and, indeed, of determining whether someone really suffers or not from pain (Haefeli and Elfering, 2006; Jamison et al. 2004; Lee, 2001; Mannion et al. 2007; Mooney et al. 1976; Ohnmeiss, 2000; Serif and Ghinea, 2005).

In chapter two it was highlighted that, typically, patient self-reporting is the most reliable indicator of the existence and intensity of pain (Kendall et al. 1996). However, by revisiting our discussion about the subjective nature of pain, self-reporting was also found to be subjective by definition, since patients that self-report pain may have developed psychological or emotional problems due to the fact that they have to deal with such pain.

In retrospect, the pain drawing used for pain visualization is also considered to be subjective in nature, since it constitutes the direct indicator of a patient's self-reporting of pain. Moreover, Jamison et al. (2004) also found similar results in their study about the use of the pain drawing in identifying real or imagined pain. Specifically, 228 pain drawings were randomly shown to medical staff for the purpose of identifying the existence of pain in the participant who filled them. From

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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these, 114 were from patients in pain, whereas the other 114 were from healthy individuals. The results of this study suggest that although an accuracy of 68.9% was achieved, subjective assessments of pain drawings alone are not sufficient in determining whether someone really suffers or not from pain.

To this end, the need for the establishment of a reliable objective pain visualization method has been identified, which would ideally *complement* the aforementioned subjective visualizations in more accurately assessing patients' subjective pain indications as communicated through the 3-D pain drawing. To the best of the author's knowledge, to date there are no accurate and reliable methods that can be used to visualize pain objectively and efficiently, an opinion also supported by Kendall et al. (1996).

### 7.3.1 CURRENT OBJECTIVE PAIN ASSESSMENT METHODS

The clinical literature contains a variety of methods which have been extensively described and exploited in order to acquire objective measurements of pain (Harcourt et al. 2003), with these being mainly related and limited to physical body functionality measurements. To this end, several *physiological* and *neurological* examination tests (Table 7-1) that address the aforementioned aspects are usually considered for objective pain measurements (Bertilson et al. 2007; Malliou et al. 2005). Unfortunately, according to Harcourt et al. (2003), such objective measures often tend to be less reliable even compared with patient-reported subjective measures (e.g. VAS and pain drawings), usually because of the examiner's lack of ability to "*quantify patient function reliably.*"

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

Table 7-1. Objective Pain Assessment Methods (Compiled after Bertilson et al. 2007 and Malliou et al. 2005)

<b>Physiological</b>		<b>Neurological</b>	
<i>Range of Motion</i>	Measure active, extension, ventral/lateral flexion and rotation of the torso	<i>Sensibility to Pain</i>	Measure pain sensation in 10 body areas
<i>Shoulder Tests</i>	Measure the shoulder muscles' strength and tension	<i>Strength</i>	Muscle strength is tested in 7 movements
<i>Tenderness</i>	Measure tenderness by exerting mild to moderate pressure on body	<i>Reflexes</i>	Reflexes are tested in 5 muscle groups
<i>Hypotrophy</i>	Hypotrophy is assessed in specific body areas	<i>Nerve Stretch</i>	Testing of the nerve stretching
		<i>Neck compression/traction</i>	The neck is tested for compression and traction
		<i>Straight leg-raising test</i>	Used to evaluate the lower back and thigh muscle activation

Indeed, the issue of reliability of such traditional objective measures applied to pain seems to be a recurring theme in the literature (Kendall et al. 1996). Although physical examinations, as well as laboratory tests and medical imaging techniques are all considered objective measurements, in reality they are also influenced by the patient's motivation, effort, and psychological state (McGregor et al. 1998). What could be done to improve the situation, thus, is to identify an alternative objective assessment method that would ideally minimize the aforementioned risks.

Considering this need for a more reliable objective approach, Mak et al. (2007) in their study have tried to improve the situation by using *Electromyography* as an objective measurement tool to quantify and visualize physical functionalities such as muscle strength and motion in pain patients. Their purpose was to rely more on technological assistive means rather than on a clinician's opinion only in order to objectify physical function, a study that has shown very promising results.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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In light of the established success of this approach to pain communication, several studies have exploited **pressure mapping** - a means of assessing the pressure distribution between a person's thighs and buttocks and the seating surface (Stinson et al. 2008) - as an objective assessment tool on patients with various conditions that involve some form of pain. For instance, the results of the study carried out by Stinson on patients suffering with multiple sclerosis have shown the usefulness of visual pressure maps, especially with wheelchair users. Earlier, Tanimoto et al. (1999) used pressure mapping on patients with spinal cord injuries, with a view to reducing pain originating from pressure sores developed due to inappropriate wheelchair cushions and unsuitable posture. This study has also revealed very positive results with regard to the usefulness of pressure mapping in understanding the pressure distribution, sitting position and sitting balance. Accordingly, Brienza et al. (1996) examined the use of pressure measurements also related to wheelchair cushioning, with again very promising results for the use of pressure mapping on the elderly population regarding the reduction of pain coming from pressure ulcers.

Considering that it does not rely on patient subjective self-reports, the usefulness of pressure mapping to patients suffering from a form of pain is well-established. However, to the best of the author's knowledge no study currently exists in the literature exploring the relationship between the objective nature of pressure maps and subjective experiences of pain in a wheelchair population. Specifically, no study has ever combined the use of pain drawings and pressure mapping's ability to communicate pain more efficiently, for the purpose of visualizing pain, as well as for addressing its subjective nature in patients within the wheelchair population.

## 7.4 METHODS AND MATERIALS OF THE CASE STUDY

Accordingly, the aim of this case study is to examine the benefit of 3-D visualization technology in two ways: first, in addressing the subjectivity aspect of pain that has been proven to exist in most cases, and secondly, in visualizing pain characteristics efficiently. To fulfil this twofold aim, two research questions (research questions iii. and iv. in chapter one) relevant to the context of this work have been targeted respectively:

1. How valuable is 3-D visualization technology in addressing the *subjective* nature of pain, and is there any relationship between the 3-D pain drawing and pressure mapping that could aid in achieving it?
2. What is the capacity of 3-D technology to support patients in communicating their pain to clinical staff, and how *efficient* is the 3-D pain drawing in visualizing such pain for the intended purpose, in respect of its corresponding pressure maps?

For the former, a visual interpretation of the acquired information will be attempted, backed up by analysis of their gradient. With the pressure mapping tool employed in this study it is possible to visualise not only the actual pressures experienced between the person and their seating surface, but also the *rate* of change of pressure between one sensor and the next, i.e. the gradient. The greater the gradient, the more shearing effect there is on the cells of the buttocks, and therefore the greater risk of cell damage and of pain. Thus, pressure gradient can be a primary factor for the development of skin and tissue damage (Brienza and Geyer, 2010). Hence, in addition to the 3-D pain drawing and the pressure maps, the pressure gradient will be similarly employed, due to its capability to provide more clinically relevant information with regards to the changes in pressure and their affect than simply

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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consulting the actual pressure maps. Moreover, a further analysis of the numerical data produced by the pressure mapping equipment will be performed.

For the latter, it has to be initially noted that we define efficiency in terms of the surface area indicated by both methods. We also note that according to *ISO-9241* (Quesenbery, 2001), efficiency metrics include the number of clicks required to complete a certain task accurately. Accordingly, in terms of the 3-D pain drawing's efficiency, fewer attempts ("clicks" on the drawing's body surface) to indicate the pain location is better, since each attempt corresponds to roughly the same amount of surface area being selected. Thus, what we would like to identify is which of the two methods captures more "tightly" (with least amount of surface area indicated) pain data.

### 7.4.1 INSTRUMENTATION

The instrumentation used for this case study consists of the PDA running the 3-D pain drawing adapted from the first case study's evaluation, and a laptop running Microsoft Windows Vista that records the information collected through the commercially available Force Sensing Array (FSA) (VistaMed, Canada) pressure mapping device. The pressure mapping device consists of a sensor mat (16 × 16 array of sensors), a computer interface module, and software that runs on the laptop to record the information from the pressure sensors. The sensor mat was calibrated prior to the beginning of data collection according to the manufacturer's recommended procedure. Last, no specific cushioning or type of wheelchairs was used, as the aim was to identify the relationship between the subjective and objective measures, and not to propose or evaluate any appropriate cushioning or wheelchair.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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### **7.4.2 DESCRIPTION OF PARTICIPANT GROUP**

Nine participants (three females; six males, mean age 62.6 years, range 43–82) volunteered to participate in this case study between November 2009 and January 2010. All were recruited from the Hillingdon Independent Wheelchair User Group, and from the London Borough of Hillingdon council. Their diagnoses varied and included one or more of the following: Cerebral Palsy (CP), Multiple Sclerosis (MS), severe back or hip pain, and arthritis, in consistency with the first selection criterion identified in section 7.1. Further criteria for selection were that the participants have an age of 18 years or greater, be wheelchair users as suggested by the second selection criterion, and experience pain for over a year. From the nine participants, six were found to be eligible to participate (three females; three males), as three of them did not meet the selection criteria. Subsequently, the final mean age was calculated as 59.3 years, with a range of 43–82 years. Finally, the mean pain intensity was 5.14 on a VAS (zero no pain; nine worst pain).

### **7.4.3 PROTOCOL AND ALGORITHM**

Prior to initiation of measurements, informed consent was obtained by each participant along with general and clinical information. Clinical information consisted of their diagnosis, disabilities, and medical conditions, factors that worsen/relieve their pain, medication received, and pain intensity. Subjective and objective measurements were taken in parallel, and started with each participant in turn being asked to take a position on the pressure mat and make sure that they adjusted their posture to their most comfortable sitting position. Once done, an initial pressure measurement was taken to record the pressure when sitting for the first time on the chair. To be more specific, a pressure measurement is taken by placing a pressure mat between the patient's buttocks and thighs, and the seating surface. Subsequently, data computed from the sensors are recorded and displayed on the

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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computer screen in various forms, including a colour-coded contour map, a 3-D grid, and numerical pressure values (see Figure 7-1) (Stinson et al. 2003).

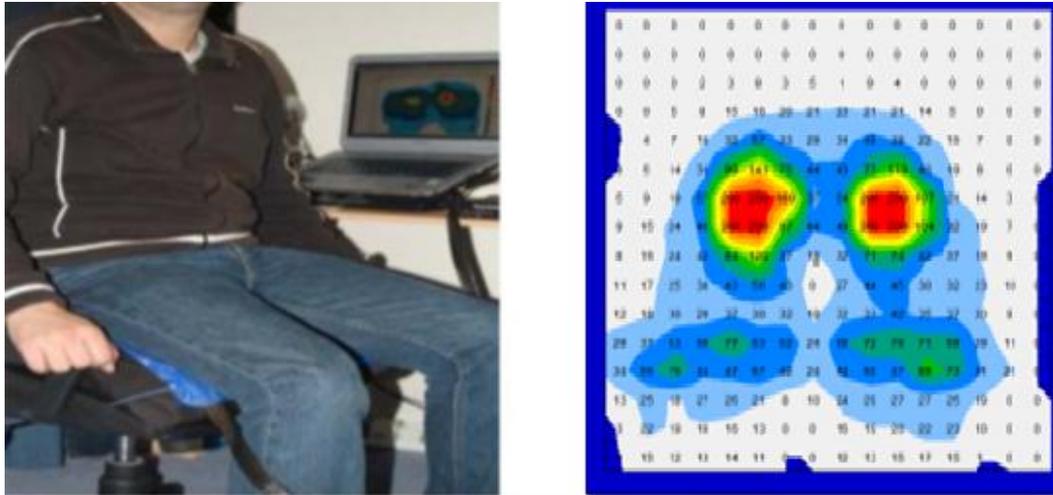


Figure 7-1. Screenshots of the Pressure Mapping Approach

After an 8-minute sitting time on the pressure mat, which was identified as the “*optimal settling time prior to interface pressure recording*” (Stinson et al. 2003), the participant was asked to pinpoint on the 3-D pain drawing the location and type of their pain, while at the same time a final pressure measurement was recorded in parallel with the completion of the 3-D drawing. The initial and final pressure measurements were both taken to identify how pressure escalates after a certain sitting period of time, something that could possibly help us understand if subjective measures are linked to objective ones. Each session had a duration of approximately 25 minutes. After the end of each session, another participant would take a position on the pressure mat, and the protocol was repeated.

### 7.4.4 DATA ANALYSIS

Two sets of data were generated by the measurements: the 3-D pain drawings and the FSA pressure maps. Both being graphical data, the analysis of these two sets of data initially consisted of a visual interpretation, by comparing the 3-D pain drawings to the pressure and gradient maps produced for each of these drawings, in order to

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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examine the relationship between them. It has to be mentioned at this point that the words “*relationship/relation*” are not used throughout this case study in the statistical sense, but rather to describe a connection that might exist between the two data sets, as derived from a visual interpretation. The reason lies in the fact that such a topographical representation and interpretation is very useful in summarizing a patient’s description of the location and type of pain, in way that is interpretable for the clinician. Moreover, it makes it possible to determine whether the pain experienced is of an organic or non-organic nature (Takata and Hirotsani, 1995).

Additionally, further numerical analysis was also performed, in order to identify whether statistical evidence occurred in support of the graphical results produced. The pressure values produced from the mat’s sensors were collected, and these raw data were used to calculate pressure variations by employing the well-established in statistics F-test – a technique typically used to determine changes in variance. Finally, a similar numerical analysis on the 3-D pain drawing and the pressure values was also generated, in order to measure the efficiency of the proposed approach.

### **7.5 EVALUATION AND DISCUSSION OF RESULTS**

The results of the evaluation performed in this case study have identified the existence of relations between a patient’s 3-D pain drawing and the corresponding pressure maps for all six participants of the case study. These relations have been classified as either *direct* or *indirect*. Specifically, the former describes the cases where the pinpointed pain locations on the 3-D pain diagram match the pressure areas identified on the pressure maps, and therefore, the pain reported could be directly indicated by this pressure. Similarly, the latter describes the cases where the pain locations do not tie up with the pressure areas identified, yet the pain reported could be indirectly indicated by this pressure. These relations will be demonstrated in the following section for all six participants by including snapshots of the 3-D pain

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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drawing completed by each participant, as well as of their corresponding recorded pressure and gradient maps.

### 7.5.1 VISUAL INTERPRETATION

The six participants who were diagnosed with severe hip pain, back pain, multiple sclerosis, cerebral palsy and arthritis (see Table 7-2) were identified as having a relation between their 3-D pain drawing and their corresponding pressure maps. Specifically, their subjective and objective measures were either directly or indirectly linked, as can be concluded from a visual interpretation of the data acquired.

Table 7-2. Participants and Corresponding Pressure Values

Participant Number	Participant Diagnosis	Initial Pressure Variance (mmHg <sup>2</sup> )	Final Pressure Variance (mmHg <sup>2</sup> )	p-value
1	Lower back pain	1603.61	3100.77	<<0.01
2	Severe hip pain	1669.38	2100.19	0.033
3	Arthritis	877.56	2123.86	<<0.01
4	Back pain	2354.87	3190.34	0.007
5	Multiple sclerosis	2517.14	1977.77	0.027
6	Cerebral palsy	904.85	1042.78	0.1292

#### Participant 1: Lower Back Pain

Figure 7-2 shows, for example, a direct relation between the 3-D pain drawing and the two pressure maps obtained for the first participant. Similarly, Figures 7-3 and 7-4 show the direct relation between the 3-D pain drawing and the pressure maps obtained for the second and sixth participants, respectively.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

Specifically, in Figure 7-2 we see that in the initial pressure map there was no high pressure when the subject first sat on the chair (high pressure is indicated in the pressure mapping system with the red colour; > 180mmHg; range 0- 200mmHg). Eight minutes later, he pinpointed on the 3-D pain drawing the locations of his pain. At the same time, the final pressure map was recorded. From the 3-D pain drawing, we can see that he experiences ache in his right leg, buttocks, and in his lower back.

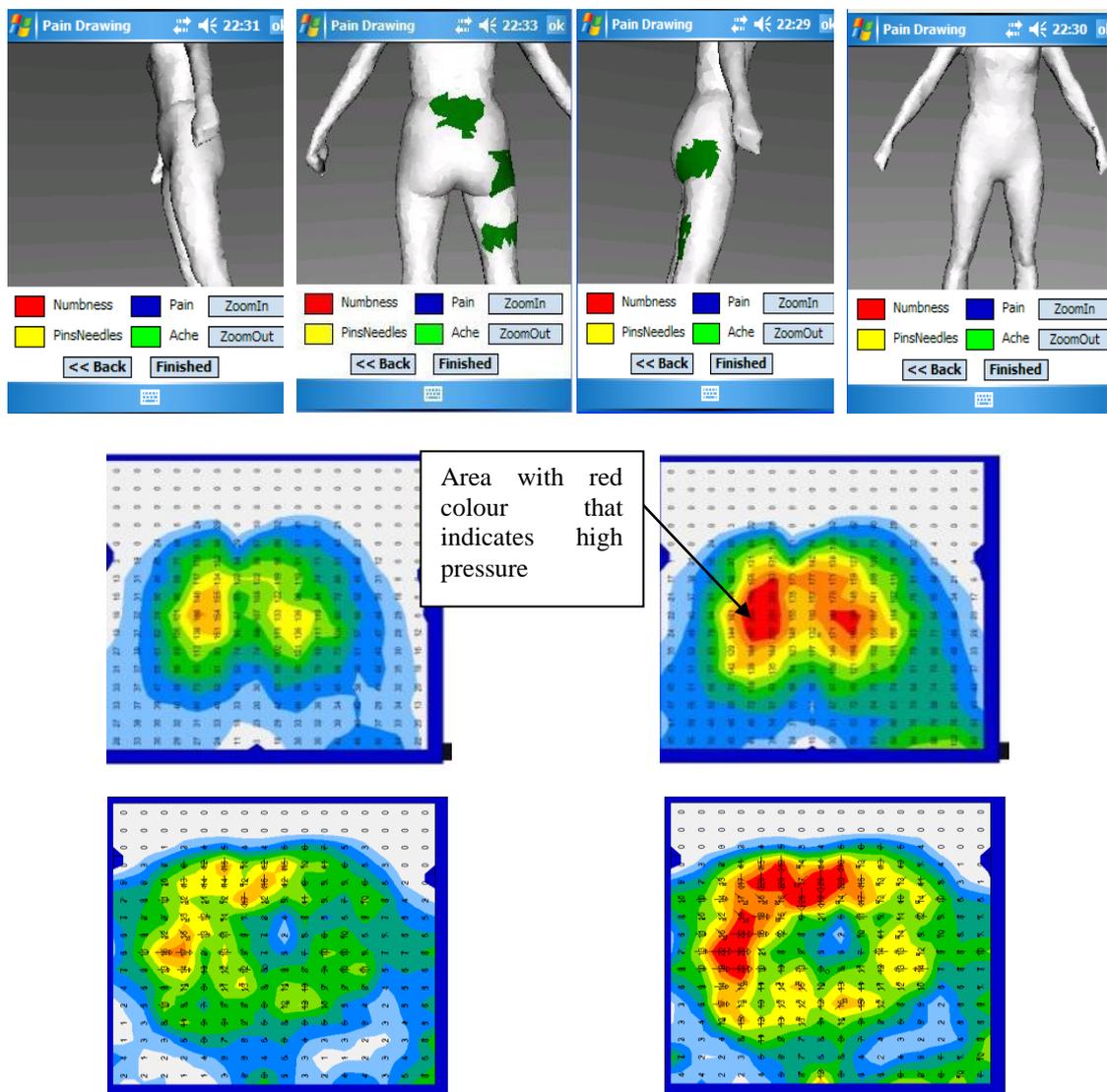


Figure 7-2. 3-D Pain Drawing with Initial (Left) and Final (Right) Pressure (Up) and Gradient (Down) Maps for Participant 1

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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Accordingly, the final map shows an increase over time in pressure on the right side of the buttocks, visually justifying the ache experienced, which could be directly indicated by the increase in pressure while the subject was seating for prolonged time. Indeed, the produced gradient maps (0-20mmHg scale) seem to confirm such a change of pressure, particularly to the right and rear of the buttocks area, in support of the aforementioned statement about the causes of the experienced ache.

Analysis of the numerical data acquired directly as recorded from the pressure sensors was also performed for all six participants. The results of this analysis are presented in Table 7-2, where we can see that a significant difference ( $p < 0.05$ ) was found, by performing an F-test, for the initial and the final pressure variances for the participant with lower back pain, an indication that there is a change in pressure over time, in support of the visual interpretation provided. This confirms Stinson et al.'s (2003) findings that it is best to wait eight minutes to optimise the images, allowing for creep in the individual's tissues and in the seating system itself (mechanical creep in the sensors is compensated for by the pressure mapping software).

### **Participant 2: Severe Hip Pain**

In the same manner, from Figure 7-3 it has to be noted that the participant's initial pressure map was indicating high pressure from the moment she first sat on the chair. Eight minutes later, on the 3-D pain drawing she reported that she is experiencing pain in her left hip and buttocks, as well as ache in her lower back. By examining the final pressure map, we can identify that the pressure surface of her buttocks slightly increases over time, yet the high pressure values remain approximately the same as when she first sat.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

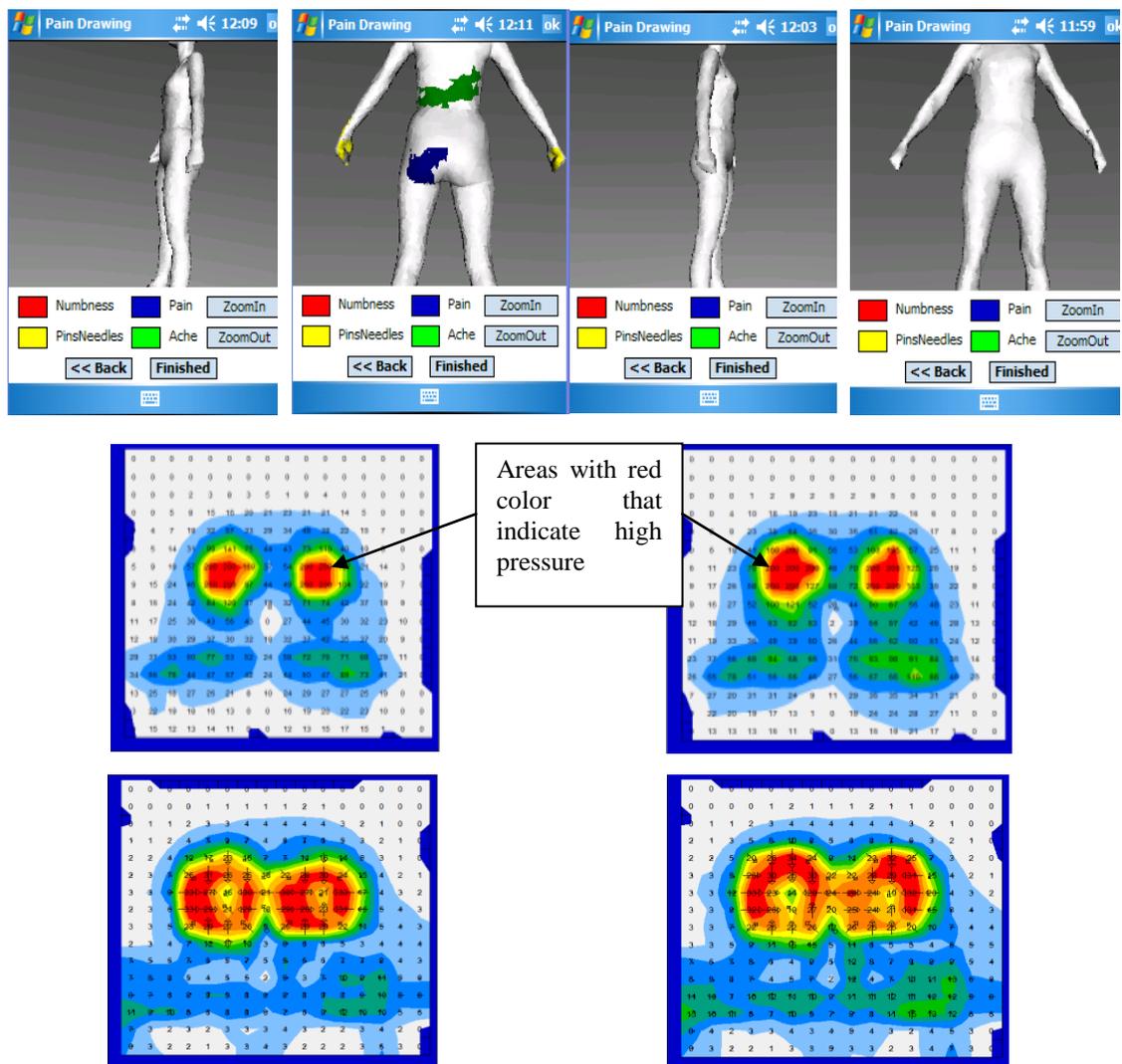


Figure 7-3. 3-D Pain Drawing with Initial (Left) and Final (Right) Pressure (Up) and Gradient (Down) Maps for Participant 2

We could conclude that her pain and ache could be directly indicated by the high pressure produced by seating for any length of time, as indicated by both maps, although measurements of her self-reported pain were not taken at the start. The produced gradient maps (0-30mmHg scale) accordingly confirm this high pressure in the buttocks area by emphasising the great rate of change that appeared, especially towards the right side where pressure seems to be more localized in the final gradient map.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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From Table 7-2, however, we can see that a significant difference ( $p < 0.05$ ) was similarly found, by performing an F-test, for the initial and the final pressure variances for the second participant. This could be an indication of the existence of an increase in pressure over time, something that was not clearly identified by the visual interpretation of the pressure maps alone. Nevertheless, this supports the assumption that pain could be directly indicated by the increased pressure while seating for a prolonged time period.

### **Participant 6: Cerebral Palsy**

Examination of the results presented in Figure 7-4 below seems to reveal another such direct relation for the sixth participant involved in the study. Initially, however, the areas of pressure shown on the pressure maps seemed to not to match directly the sites of pain indicated on the 3-D pain drawing, and particularly the numbness in the wider buttocks area.

Moreover, although no significantly high pressure was reported that could be a more safe direct indication of the presence of such numbness, it is clear that there is a relatively abnormal degree of pressure in the right buttocks area that may be a major factor for the existence of the numbness on the right side due to prolonged sitting and leaning towards the right. Nonetheless, no evidence could be accrued from the pressure maps that could justify the existence of numbness in the wider region of the buttocks.

The respective gradient maps (0-20mmHg scale), however, demonstrate a pressure change from the right to the wider region of the buttocks that was not indicated so clearly by the produced pressure maps. This change could form the evidence required to justify the existence of numbness in the wider buttocks area. The indicated back

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

pain could also be similarly interpreted by the same pressure change illustrated by the gradient maps.

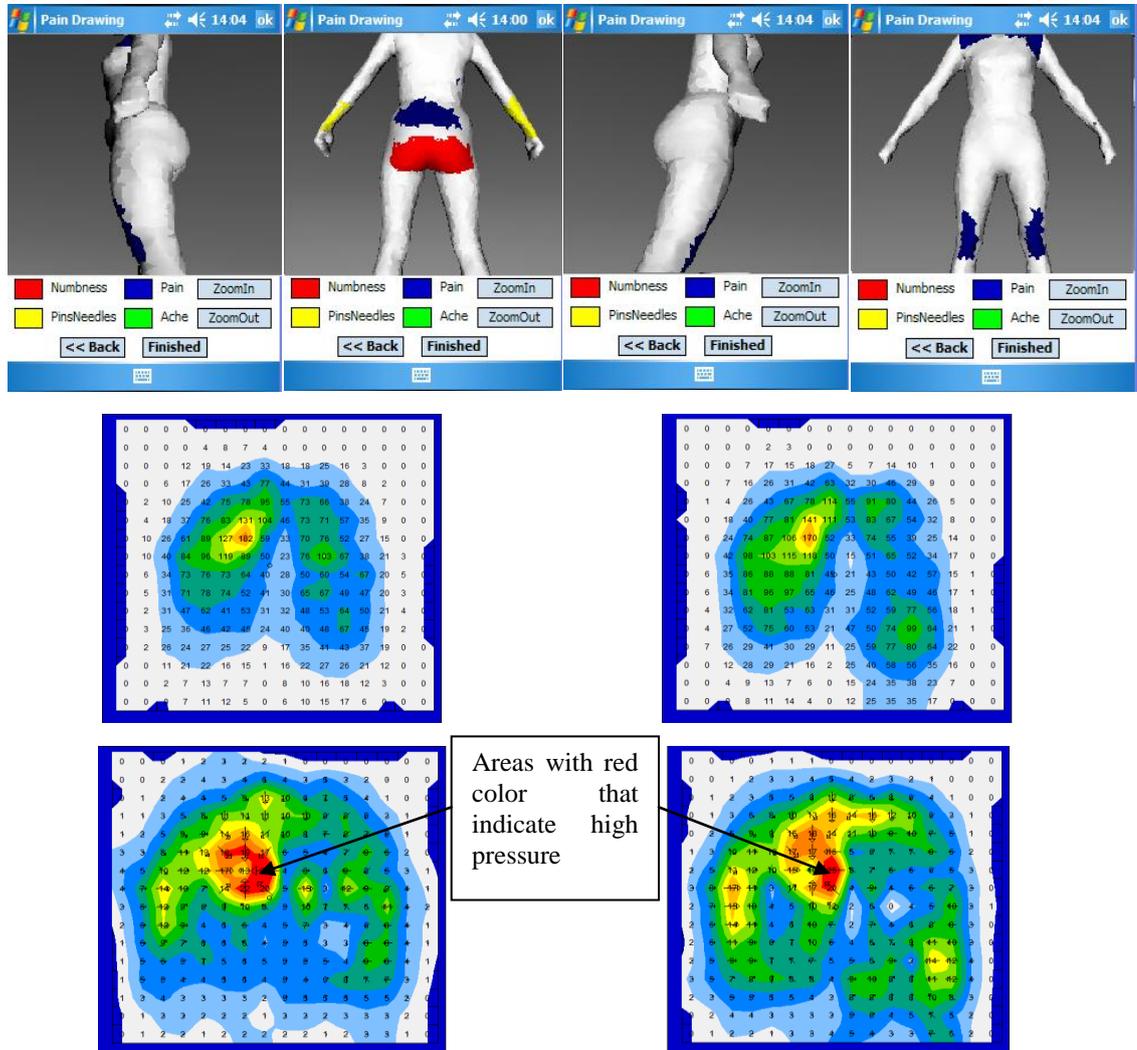


Figure 7-4. 3-D Pain Drawing with Initial (Left) and Final (Right) Pressure (Up) and Gradient (Down) Maps for Participant 6

Further statistical analysis was also performed in order to explore whether the presence of this numbness was a result of a change in pressure over time. Accordingly, the F-test results seem to reveal a non-significant difference ( $p > 0.05$ ) between the initial and the final pressure variances for the sixth participant; as such, such a pressure change could not be a direct indication of the presence of numbness in this particular case.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

Three of the participants who were respectively diagnosed with arthritis, back pain, and multiple sclerosis were found to have an indirect relation between their subjective and objective measures.

### Participant 3: Arthritis

Figure 7-5 shows for example such an indirect relation between the 3-D pain drawing and the two pressure maps acquired from the third participant.

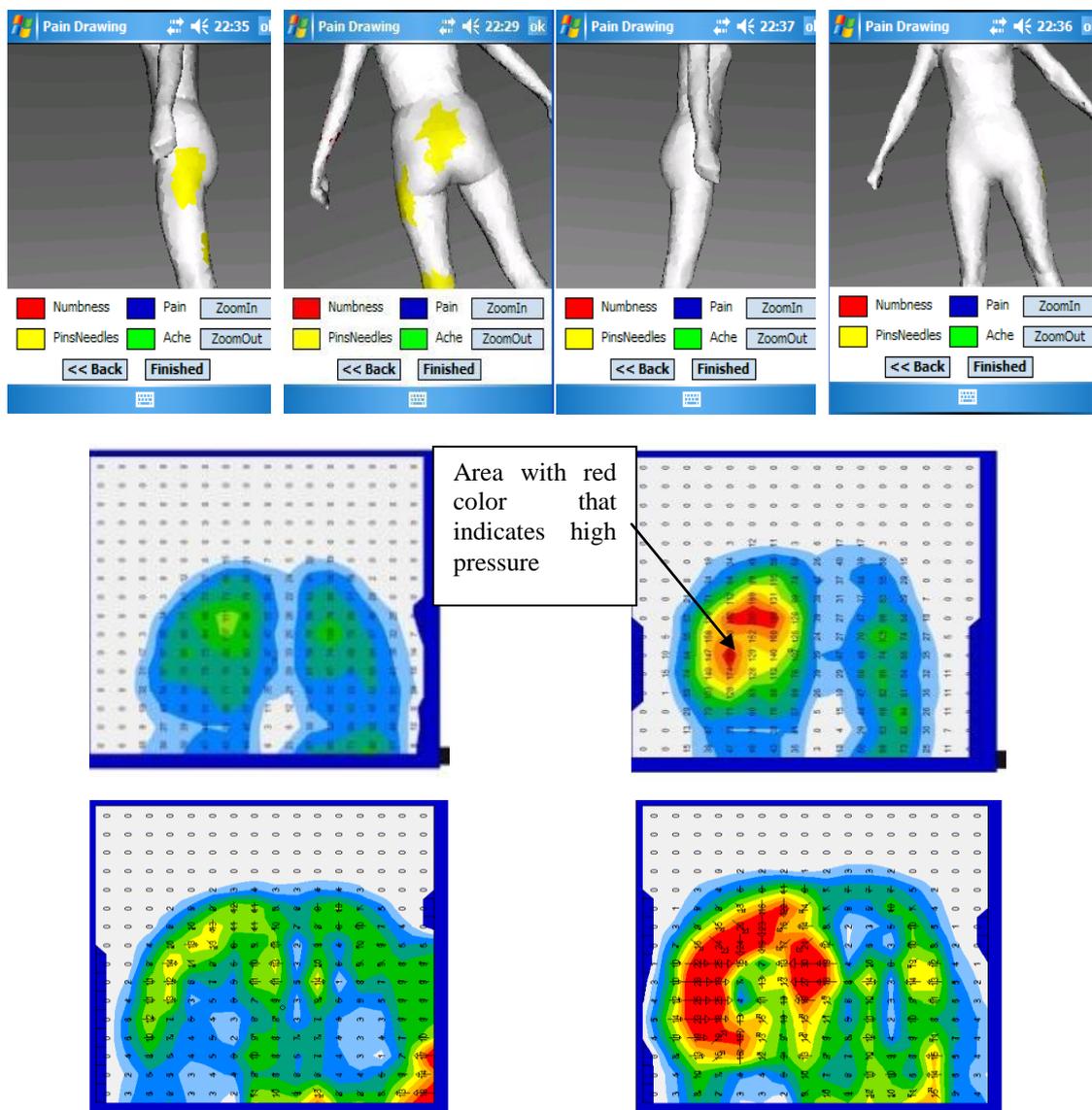


Figure 7-5. 3-D Pain Drawing with Initial (Left) and Final (Right) Pressure (Up) and Gradient (Down) Maps for Participant 3

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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The initial pressure map indicated very little pressure when the patient first sat on the chair. Moreover, pain shown on the 3-D drawing was mainly in the left hip and knee, as well as in the lower back; however, the final map recorded eight minutes later showed high pressure on the right buttocks area. Evidence from the produced final gradient map (0-20mmHg scale) similarly confirms this high pressure on the right buttocks area by emphasising on the significant rate of pressure change that appeared in that region.

Considering the aforementioned information, an indirect relation between the pain locations on the 3-D pain drawing and the corresponding pressure maps seems to exist; nevertheless, in this case, increased pressure in the right buttocks over time does not seem to directly visually indicate the pain experienced in the left side. By consulting the subject though, she let us know that because she experiences pain mainly in her left side, she tends to lean to her right for relief, and that also confirmed the high pressure shown on the final pressure and gradient maps.

Investigation of the specific pressure maps also shows a striking *asymmetry* in the indicated pressure, a finding that could possibly reveal further hidden pain information. In support of the visual interpretation, a significant difference ( $p < 0.05$ ) was found, by performing an F-test, for the initial and the final pressure variances for this participant as well (see Table 7-2), which may also suggest the increase in pressure over time.

### **Participant 4: Back Pain**

Similarly, Figure 7-6 shows the indirect relation between the 3-D pain drawing and the pressure maps obtained for the fourth participant. Again, by observing the figures below we do not clearly see how the pain locations on the 3-D pain drawing directly match with the pressure maps, since high pressure is mainly indicated in both the

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

participant's thighs. Although pain reported on the pain drawing in the left thigh could be indicated by the high pressure on the left side on both pressure maps, no signs of pressure exist in the buttocks that could suggest the reported back pain. Consultation of the corresponding gradient maps (0-20mmHg scale), however, seems not only to justify the high pressure in the thighs areas by emphasising the big change of pressure, but also to reveal pressure changes to the rear that could be an indication of the back pain shown on the 3-D pain drawing, and which were not previously indicated by the pressure maps alone.

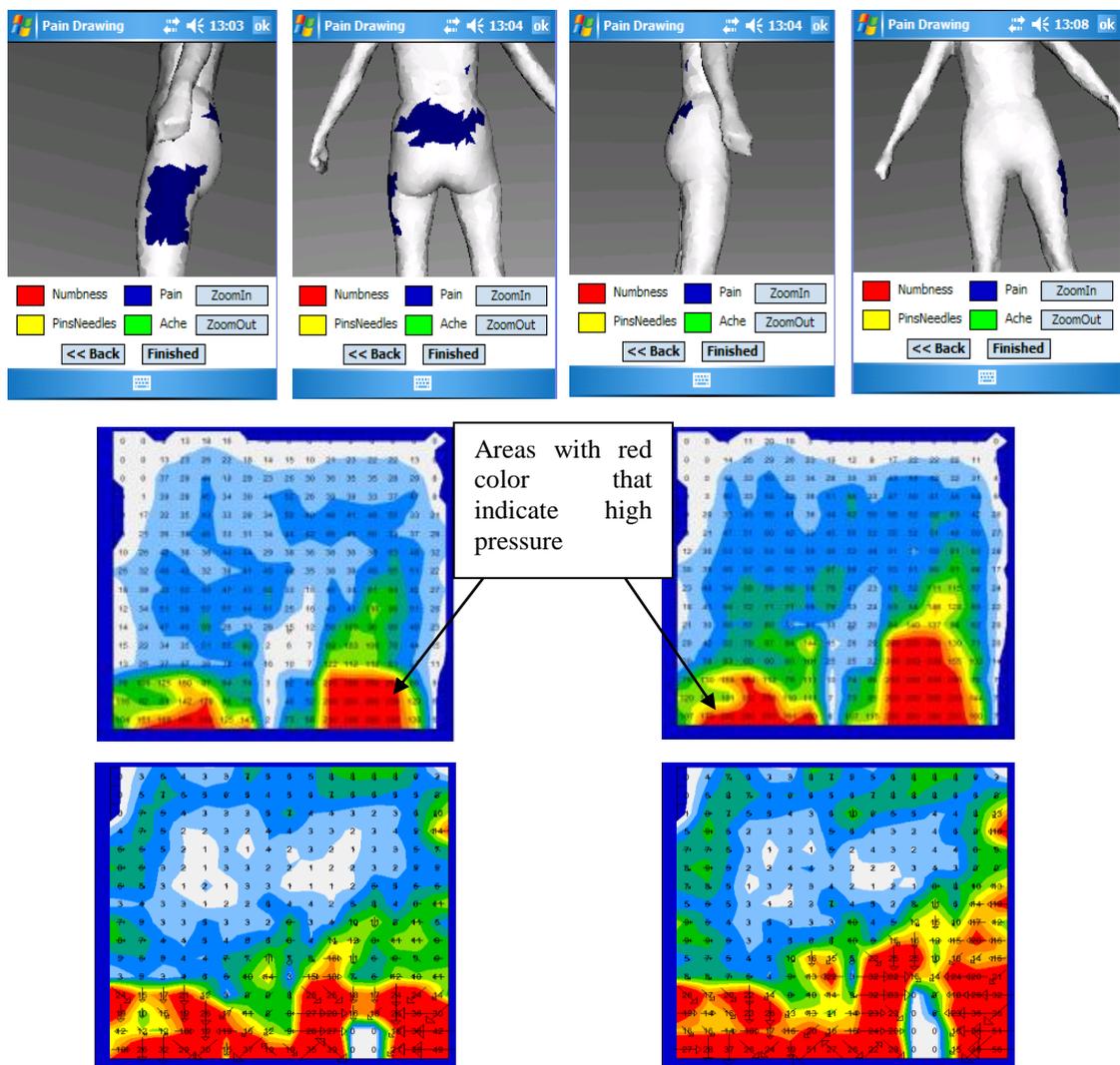


Figure 7-6. 3-D Pain Drawing with Initial (Left) and Final (Right) Pressure (Up) and Gradient (Down) Maps for Participant 4

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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Moreover, along the same lines of the previously mentioned case, certain conclusions could be reached from the produced maps regarding this person's posture and sitting habits, which could in turn lead to identify the possible causes of her pain. Specifically, the participant seems to be leaning forward in her attempts to relieve her pain. This causes high pressure over time, which could also indirectly indicate the back pain expressed, due to the bad posture taken while seating for a lengthy period of time. As before, there is a significant difference ( $p < 0.05$ ) between the initial and the final pressure variances (see Table 7-2), which may also suggest this increase in pressure over time, in support of the visual interpretation provided. Nevertheless, the posture adopted appears to be one to alleviate the back pain, however, it has resulted in high pressures under the thighs, which could also affect venous return and lead to swelling of the feet, etc.

### **Participant 5: Multiple Sclerosis**

Similar are the results of the measurements found for the fifth participant. Specifically, Figure 7-7 shows an indirect relation between the 3-D pain drawing and the pressure maps, which could be a product of two main factors: first, the poor sitting posture of the participant who was suffering from Multiple Sclerosis, and therefore, could not assume an optimal sitting position for the pressure measurements due to his mobility impairment; secondly, the indicated sites of his pain on the 3-D pain drawing that do not match the high pressure in the participant's buttocks area indicated by the pressure maps.

In retrospect, by examining the initial pressure map of the below figure we can see that there was high pressure in his whole buttocks area from the moment the participant first sat. This high pressure remained relatively the same in the final pressure map, but localizing particularly in his right buttocks area. Overly, both

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

pressure maps seem to indicate that the participant was leaning back and right on his wheelchair at the time of measurement.

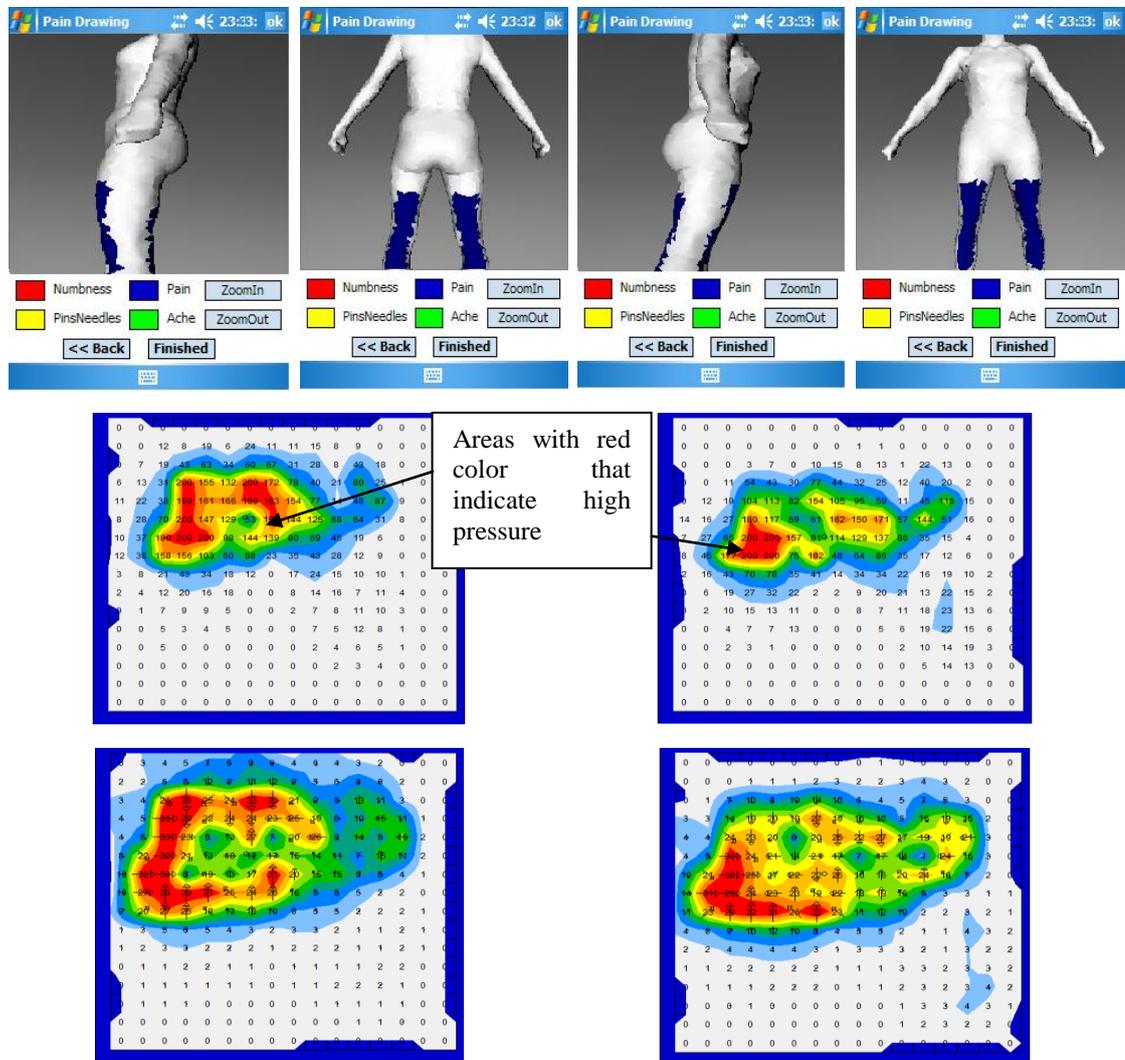


Figure 7-7. 3-D Pain Drawing with Initial (Left) and Final (Right) Pressure (Up) and Gradient (Down) Maps for Participant 5

Further investigation of the rate of pressure change shown on the gradient maps (0-30mmHg scale) confirms the assumption that the participant was leaning towards the rear and right of his wheelchair; however, the pain indicated on the 3-D pain drawing does not seem to match the high pressure areas, as it was mainly reported in the participant's legs instead of the buttocks area.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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A certain conclusion could be assumed from these findings; the participant was sitting in a convenient position for him towards the rear and right of his wheelchair, which was the most appropriate to relieve the pain he was experiencing in his legs. This assumption was also confirmed by the participant himself. Hence, although the above maps do not provide any clear evidence of a direct correlation between pressure and pain in the same area, they do however provide indirectly significant insights about the causes of that pain.

### **7.5.2 PAIN VISUALIZATION EFFICIENCY**

Considering that relationships can exist between the 3-D pain drawing and the pressure maps (as previously discussed), it is also worthwhile to investigate how efficient (in terms of occupying the least surface area) the 3-D pain drawing is in visualizing pain in the context of these relationships. To this end, a comparison between the percentage of the body surface area selected on the 3-D pain drawing to indicate the pain location, and the corresponding percentage of the surface area indicated on the pressure map, was performed to examine which of the two methods better captures pain data more efficiently (see Table 7-3).

For the 3-D pain drawing case, we have previously discussed that the body of the mannequin was segmented into clinically appropriate regions after clinical consultations. The percentage of the surface area was measured based on the number of the selected surface regions indicated by the participant, out of the total number of the regions into which the back side of the 3-D human mannequin body was divided. It has to be noted that we only consider the body regions from the lower back to the knees, as this is where most pain in wheelchair users normally occurs (Kinkade, 2007).

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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Table 7-3. Comparison of Surface Areas

Participant Number	3D Pain Drawing Surface Area Selected (%)	Pressure Map Surface Area Indicated (%) (>80 mmHg)	Pressure Map Surface Area Indicated (%) (>100 mmHg)	Pressure Map Surface Area Indicated (%) (<80 mmHg)
1	13.75	40.30	29.59	59.69
2	17.5	15.34	9.52	84.65
3	15	23.12	17.68	76.87
4	11.25	26.16	21.94	73.83
5	16.25	19.01	14.78	80.98
6	31.25	13.06	4.54	86.36

Given that a pressure map is made up of a matrix of  $16 \times 16$  sensors, a cell associated with a particular sensor is deemed to indicate an area of high pressure if the reading of its sensor is in excess of a specified threshold. Recent research, as cited in Geyer et al. (2001) seems to propose that the specified threshold should not be in excess of 80 mmHg, as this may be the highest figure after which the tissue could be damaged and pressure ulcers might be produced.

Under this assumption, the third column of Table 7-3 presents the fraction of those sensors that indicated higher than the 80mmHg threshold pressure out of the total number of sensors that indicated a pressure reading for each participant. Comparison between the surface area selected on the 3-D pain drawing and the areas that indicated high pressure after the current set threshold suggests that under this threshold condition the former seems to localize data more efficiently in four (participants 1, 3, 4 and 5) out of the six cases. Yet, for one of the remaining the deviation between the relevant figures does not appear to be significant, while for the last one there is a significant difference between the two figures.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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As a step further, the author employed a new threshold of 100 mmHg, which Geyer et al. (2001) further indicate as the maximum pressure value that should not be exceeded. In accordance with the previous comparison, the results expressed in the fourth column of Table 7-3 (the fraction of those sensors that indicated higher than the 100mmHg threshold pressure out of the total number of sensors that indicated a pressure reading) indicate that under the current threshold condition the 3-D pain drawing seems to similarly localize pain more efficiently in three out of the six cases (participants 1, 3 and 4). For the remaining two the deviation increases, but still remains insignificant. The last one, however, appears to stand out even more in this case.

### 7.5.3 ADDITIONAL FINDINGS AND OBSERVATIONS

Overall, the present case study has produced and revealed very promising results with regards to the innovative efforts to combine the advantages of the 3-D pain drawing with the capabilities of the pressure mapping equipment for improved pain visualization. In this respect, some more interesting findings need to be also mentioned that would add more to the value and potential of the described approach.

**First**, the case study was carried out on the basis of Stinson's assumption that the optimal settling time between two pressure measurements is eight minutes (see subsection 7.4.3). The positive nature of the produced results indicate that our findings are consistent with Stinson's assumption; nevertheless, it would be of great interest to examine further the effect of a variety of settling times on this case study's results.

**Secondly**, the post-case study analysis of the results seems to indicate a positive correlation between pain and high pressure in all six participant cases. However, this correlation would benefit from additional investigation, as there have been cases

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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where the sitting position assumed was not the most appropriate due to e.g. mobility difficulties (see participant five) or due to the attempt to relieve pain (see participant three); as such, it would be beneficial to the findings of this case study that future work would test the hypothesis of how pain visualization is affected if high pressure areas would be reduced by adjusting the sitting position and/or setting up the wheelchair seating of the participants more properly.

**Thirdly**, the results of the surface area comparisons presented in Table 7-3 of the previous subsection indicate that, in more efficiently visualizing pain, as the pressure threshold increases, the ability of the 3-D pain drawing to localize pain efficiently decreases. Two main conclusions could be drawn from the above rule:

1. In subsection 7.5.1 it was shown that the existence of high sitting pressure – demonstrated with increases in thresholds in this case – can be an obvious sign of the possibility for the respective existence of developing pain. The present results of Table 7-3 suggest that pressure mapping may be more efficient in indicating/localizing pain in the cases of high sitting pressure compared to the 3-D pain drawing, as the former is very effective in visualizing any high pressures.
2. On the contrary, in cases where the sitting pressure is at low levels (< 80 mmHg; 0 pressure values were not taken into consideration, as they do not denote the existence of pressure) and therefore no assumption could be made about the existence of pain due to this pressure, the 3-D pain drawing may be more efficient in indicating/localizing the existence of pain. The results presented in the final column of Table 7-3 seem to justify this assumption.

**Finally**, a striking finding that has been also derived from these comparisons was that in two of the three cases (participants 1 and 4) in which pain was more easily

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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localized with the 3-D pain drawing, there was a common diagnosis of back pain. Moreover, from Table 7-3 it could be further surmised that an indicated surface area of more than 20% in the 100mmHg threshold could be an indication of the existence of pain, an assumption also supported by Figures 7-1 and 7-6. Nevertheless, although the small sample examined does not allow for large scale generalizations, the results seem to suggest that the 3-D pain drawing may further be an efficient approach in localizing back-related pain, as comparisons to the pressure mapping technique revealed. This assumption constitutes another avenue for future work.

### **7.6 SUMMARY**

The purpose of the work described in this case study was twofold: first, to determine whether relationships between the 3-D pain drawing and the pressure maps exist that could provide considerable insights in the pain subjectivity issue; and secondly, to explore the efficiency of the 3-D pain drawing in visualizing pain, as compared to its corresponding pressure maps. Although both aforementioned methods seem to be clinically useful when used in isolation, they have never been tested together to evaluate if both of these ways of measurement are related.

To this end, with regards to the first research question, the current case study has revealed mixed, yet positive results: while for three of the study's participants a direct link was found between the two methods, for the other three participants this relationship was indirect. These results show that high pressure might not necessarily be a possible direct indication of pain, but could reveal further information pointing to its existence. Nevertheless, it could be argued that the 3-D visualization methods employed for the purpose of this case study offer significant information that could help in addressing the subjectivity of pain better.

## CHAPTER SEVEN – CASE STUDY TWO: 3-D VISUALIZATION AS THE MISSING LINK BETWEEN PAIN AND SUBJECTIVITY

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The efficiency of the 3-D pain drawing in visualizing pain was also justified as part of the second research question, by measuring the ability of the 3-D prototype to better localize pain, using the least possible number of clicks to indicate its location on the body surface. The results indicated that the 3-D approach may constitute a promising method in localizing/visualizing the pain experience, especially in cases where the existence of pain may not be very obvious. However, for the purpose of efficient pain visualization, the results illustrated that both the 3-D pain drawing and pressure mapping could and should be used complementarily. As such, pressure mapping may not be entirely efficient as an objective measurement of pain, and therefore needs also to rely on subjective interpretations, whereas the 3-D pain drawing may benefit from its reliance on pressure mapping.

Nevertheless, the participant group is considerably small, and this does not allow making any large-scale generalizations. However, the pain patterns that exist when combining our proposed methods are obvious even to non-clinicians, which makes it even more imperative that they are also investigated from a clinical point of view. The proposed approach could also benefit from an additional sitting posture that could be provided to represent more accurately the participant's posture at the time of measurements.

Overall, the results of this case study have highlighted the usefulness of the 3-D pain drawing and pressure mapping in visualizing pain more efficiently, as well as the contribution of 3-D technology - through the 3-D pain drawing and pressure mapping – in addressing pain subjectivity. Taking also into consideration the enhanced ability of the 3-D pain drawing to visualize pain better (as demonstrated in the previous case study), it could be surmised that 3-D visualization technology is a promising initiative in the clinical literature for the intended purpose.

CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE  
POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF  
PAIN AMONG THE SPINAL CORD INJURY POPULATION

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## **CHAPTER EIGHT**

# **CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION**

## **8.1 OVERVIEW**

Pain experienced as a result of Spinal Cord Injury (SCI) is a frequent problem in the majority of the SCI population and it is often present in any individual with this kind of trauma. Research on pain has revealed that patients not only experience several types of pain that could prove to be challenging to address, but also that each individual can interpret the same type, location and severity of this pain in different subjective ways, making the need for more effective visualization methods a troublesome effort (see section 8.2).

The two previous case studies have demonstrated the effect that 3-D visualization expertise could have in offering promising opportunities for enhanced visualization of pain resulting from diverse medical conditions such as back pain or arthritis. The same feature benefit was anticipated from employing a 3-D-based approach to be used in SCI pain visualization. As a result, this final case study has focused on investigating the effect of the 3-D pain drawing in visualizing SCI pain. With aspects such as its efficiency, functionality, and acceptability having previously been

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

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established, the prototype in this work has been evaluated to determine if it could be used by SCI patients towards the visualization of their pain characteristics.

Accordingly, the structure of this chapter is as follows: in the next section, a generic overview of pain after SCI and issues regarding its effective assessment are provided. The section that follows discusses the applicability of visualization technology in the assessment of SCI pain, and the methodology employed to evaluate the 3-D approach within this patient group is subsequently provided. Finally, this chapter concludes with the presentation and discussion of the evaluation results.

### **8.2 PAIN AFTER SPINAL CORD INJURY**

Pain is one of the most common and prevalent consequences of SCI that imposes severe implications on patients who have suffered this kind of physical trauma. In fact, according to Spinal Injuries Association (2009), every day in Britain three people are permanently paralysed (approximately more than 1,000 people per year) with the majority of them being between 21 and 30 years old, while in the USA the annual figure of new SCI cases is approximately 12,000 people (MASCIP, 2008).

From this relatively small number of SCI patients, compared to the prevalence of other chronic conditions (e.g. back pain), roughly one-half to two-thirds suffer from some form of chronic pain, and in approximately one third the pain is very severe and disabling (Wang et al. 2004). To be more specific, a summary of results from several studies in patients with SCI (Siddall et al. 2000; Wang et al. 2004) indicates that the average reported estimate of the prevalence of chronic SCI pain is approximately 65%, with roughly one-third of those affected reporting the severity as being greater than 7 in a scale of 10 on a VAS.

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

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Although loss of function is the main consequence of SCI, the symptoms experienced from the presence of such chronic pain could be so severe that it has been reported to frequently interfere with sleep and everyday activities (Felix et al. 2007). To this end, approximately 37% of SCI patients reported that they would like to be relieved from this burden even if they had to trade it with additional loss of bladder, bowel, or sexual function (Siddall et al. 2000).

### **8.2.1 ASSESSING THE SCI PATIENT**

As a result of its incidence, considerable research efforts towards better SCI pain assessment have been reported so far (Haefeli and Elfering, 2006; Lee, 2001). Nevertheless, the majority of them have been criticized in the clinical literature regarding their applicability in assessing persons with SCI (MASCIP, 2008) who are characterized by many different pain types, or in their ability to accurately measure change in pain according to time, posture and activity. For example, asking an individual with SCI a question about pain interference with walking, a common question in many quality of life measures, is not applicable for someone who uses a wheelchair every day (Bryce et al. 2007).

The main reason behind this controversy, however, lies in the multidimensional nature of pain, which is characterized by physical discomfort, and is often influenced by complex qualities associated with psychological and cultural factors (see chapter two). As with the previously examined types of pain, owing to its subjectivity, it is therefore argued, that individuals who have to deal with pain after SCI may frequently experience substantial difficulties when it comes to precisely describe their pain characteristics, as they may have been influenced by the above factors, resulting in different interpretations of the same pain experience.

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

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To this end, considering the heterogeneity of the pain experience also appearing in this patient population, enabling the SCI individual to also visually communicate his/her pain was similarly introduced as a supplementary approach for the rehabilitation of pain for people suffering from SCI.

### **8.3 CURRENT APPROACHES TO SCI PAIN VISUALIZATION**

Since any form of pain is considered as a multidimensional and subjective experience, ensuring that accurate information regarding the pain's characteristics is obtained constitutes an essential step towards the need for more effective pain assessment. As a result, from the discussion so far it has been highlighted that a wide range of valid tools exist today to visualize pain, including psychosocial aspects, functional ability and quality of life. Most, however, are paper-based tools that incorporate one-dimensional measures, such as the VAS, or the 2-D pain drawing.

Due to their established validity, usefulness and acceptance in visualizing pain across various medical conditions demonstrated both in clinical literature (Jamison et al. 2004; Mooney et al. 1976; Ohnmeiss, 2000) and in this work so far, there have also been efforts to utilize the benefits of the pain drawing to the SCI population that is characterized by the severity of this injury. To this end, Samuelsson et al. (1996) have used pain drawings to assess pain and spinal deformity in a wheelchair patient population with the results indicating that pain was found in 84% of the assessed patients. Along the same lines, the pain drawing was employed by Felix et al. (2007) in their attempt to identify and relieve the most disturbing pains reported by patients with a SCI, which often affect the quality of their life. Similarly positive findings were indicated by this study, as it was suggested that in addition to pain intensity, factors such as interference and constancy of pain may indicate pains that are

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

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particularly disturbing to an individual with SCI. Finally, from a different perspective Felix et al. (2010) utilised a quantitative computerized analysis of pain drawings before and after surgery to evaluate treatment interventions in patients with spinal stenosis.

### **8.3.1 THE NEED FOR 3-D VISUALIZATION OF SCI PAIN**

Notwithstanding its reported advantages in SCI pain assessment, it has already been pointed out that the 2-D pain drawing has limitations in its visualization ability. The benefits of 3-D visualization technology also identified in the previous case studies, therefore, have naturally led to the porting of 3-D expertise across the world of SCI.

However, the employment of 3-D technology in SCI is not a recent trend. Work has already focused on the use of 3-D technology in the efforts to reconstruct spinal cord trauma. Thus, Duerstock et al. (2000) have used 3-D computer reconstruction in order to evaluate the pathology of the injury. On the other hand, a 3-D mechanical model of a human lumbar spine segment with the intension to be used in simulation of surgery was depicted in Kakol et al. (2003). From a different perspective, Frank and De Souza (2001), in an experimental study for reconstructing SCI, constructed 3-D virtual images from performing computerized medical scans.

In all cases, 3-D visualization was extremely beneficial because the models produced could be observed from many different viewpoints, while rotation and zooming features were combined to allow observer navigation within the tissue. The same feature benefit was anticipated from employing the 3-D pain drawing to be used by SCI patients in the visualization of their pain.

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

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### **8.4 METHODS AND MATERIALS OF THE CASE STUDY**

In retrospect, the aim of this case study has been to explore the applicability of the 3-D pain drawing in the visualization of pain for the rehabilitation of people with SCI. In achieving the above goal, two research questions (research question v. in chapter one) have been specifically targeted whose investigation would provide significant findings with respect to the effect of 3-D technology in visualizing pain:

1. What is the *usability* of the 3-D pain drawing in accomplishing the above?
2. How *feasible* the 3-D pain drawing is in visualizing patients' SCI pain characteristics?

Overall, *is a 3-D approach a more usable and feasible means of visualizing pain characteristics as compared to methods currently in use?* In doing so, the developed 3-D pain drawing will be evaluated against the well-established 2-D pain drawing. Therefore, to address both research questions, each study participant will be given the chance to use both approaches and, at the end, fill an evaluation questionnaire about the usability and feasibility of using these two approaches for the purpose of recording and visualizing their pain experience.

#### **8.4.1 INSTRUMENTATION**

The instrumentation used for this case study consists of the laptop that runs the 3-D pain drawing application, for which the design and implementation issues were described in chapter five, and two sets of questionnaires that were formed and validated together with the clinical staff involved in the case study. The first is a pain questionnaire incorporated with the traditional 2-D pain drawing that includes questions about general medical information, pain factors, treatment and pain intensity (see Appendix C), whereas the second one is an evaluation survey – for

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

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both the 2-D and the 3-D pain drawing - in which patients are asked to record their opinions about both approaches on a Likert scale of 1 (Strongly Disagree) to 5 (Strongly Agree) (see Table 8-2). Both questionnaires had been piloted at the test site prior to their administration.

### **8.4.2 DESCRIPTION OF PARTICIPANT GROUP**

The participant group consisted of 15 individuals with SCI (7 female; 8 male, mean age 52.3 years, range 28-75) who volunteered to participate in the case study between July and October 2010. This sample represented both new and consecutive admissions at the Spinal Cord Injury Unit in the Royal National Orthopaedic Hospital, in London; 17 potential participants were asked to take part, with two declining. The mean age of the 8 males was 47.3 years (range 28-75), whereas 58 years (range 42-72) was the equivalent for the 7 females. Details of all participants are summarized in Table 8-1.

Their diagnosis varied and included ten patients with traumatic SCI; two had infective causes and one vascular, discal and tumor conditions. The criteria for selection was that the participant has spinal cord-related condition that involves pain, has an age of 18 years or greater and experience some pain during the period of the case study. Finally, the range of pain intensity varied from 0-9, with the mean maximum pain intensity being 8.375 on a VAS, in accordance to the results cited in Siddall et al. (2000) and Wang et al. (2004).

### **8.4.3 PROTOCOL AND ALGORITHM**

Prior to initiation of pain measurements, informed consent was obtained by each participant. A within-subjects design was employed for data collection in this study, where the patients used (in a randomized order to avoid presentation bias) both the 2-

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

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D and 3-D pain drawings to assess their pain. After consultations with the clinicians, it was decided that to satisfy the need for pain measurements over time, the measurements would take place in four points in time over a period of one day for each participant, with an approximately 2-3 hour time difference between them (between 8.30am and 5pm), based on the patients' daily schedule of activities.

Table 8-1. Participant Group

Participant Number	Age	Gender	Diagnosis	Range 'Overall' VAS
1	63	F	Vascular SCI	0-7
2	70	F	Traumatic SCI	0-5
3	41	M	Traumatic SCI	0-5
4	69	M	Epidural abscess	0-2
5	28	M	Traumatic SCI	0-6
6	61	M	Traumatic SCI	0
7	42	F	Traumatic SCI	0-9
8	46	F	Disc prolapsed	0-3
9	32	M	Spinal neurofibroma	0-5
10	75	M	Traumatic SCI	0-4
11	39	M	Traumatic SCI	0-4
12	66	F	Traumatic SCI	0-1
13	72	F	Epidural abscess	0-7
14	47	F	Traumatic SCI	0-9
15	34	M	Traumatic SCI	0-8

Accordingly, the first measurement of the day started between 8.30-9.00am in the SCI unit, with the participant randomly given either the questionnaire with the 2-D drawing or the 3-D application to fill in details about his/her medical background, as well as information regarding pain relieving/worsening factors and treatment

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

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received. The next step was to score the current, at the time of measurement, level of his/her pain intensity, and the recording finished by visualizing on the assigned drawing the type and location of his/her current pain.

The protocol continued for two more measurements in 2-3 hour intervals, and at the end the evaluation questionnaire would be handed to the patient. Each measurement had duration of approximately 25 minutes and, at the end of the day the patient would have used both the 2-D and 3-D approaches twice (the order of use was randomized to prevent order effects).

### **8.4.4 DATA ANALYSIS**

The data generated at the end of the measurements consisted of *a. medical information about the pain characteristics (intensity, pain location, etc.)* and *b. the results of the evaluation questionnaire*. For the former, a medical interpretation was performed by the clinicians involved in this case study, in order to examine the applicability of the 3-D drawing in the assessment of pain, the results of which are not presented here as are outside the scope of this research (for the interested reader, however, please read the second conference publication in the List of Publications, pp. VI). For the latter, both a graphical and statistical analysis was sought by using the specialized software PASW, in order to identify whether statistical evidence occurs in support of the research questions identified at the beginning of section 8.4

### **8.5 EVALUATION RESULTS**

The results obtained from this case study are generally in line with the author's expectations that SCI patients would approve the improved ability of the 3-D pain drawing to visualize their pain experience (see Figure 8-1).

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

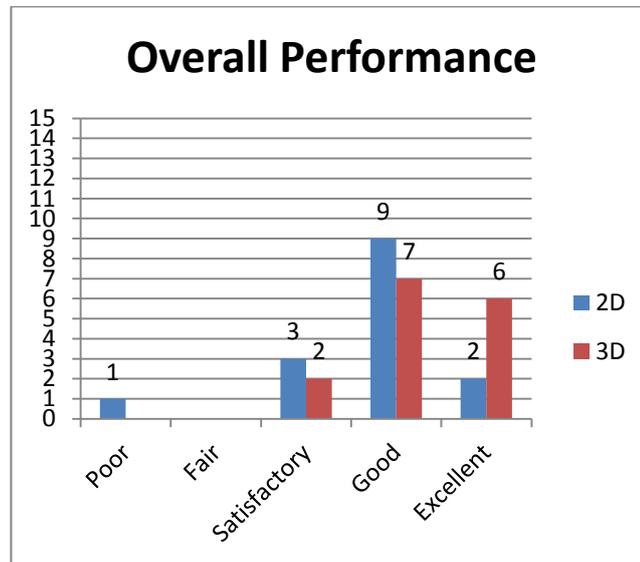


Figure 8-1. Comparison of Overall Performance

To this end, with respect to the first research question, while opinions about the ease of learning and use remained roughly the same for both the 2-D and 3-D pain drawing, the general consensus demonstrated that the process of logging pain information on the 3-D version was relatively more easy compared to its 2-D equivalent, while the importance of doing so, even across time was highlighted in both approaches (see Figures 8-2 and 8-3).

Moreover, performing a paired samples t-test on our results revealed that, while there are indeed no significant differences in opinions about the importance of recording pain information ( $p>0.05$ ), and doing so across time ( $p>0.05$ ), it came as a surprise that while the mean opinion score regarding the ease of learning and use was higher in the case of the 2-D pain drawing, the difference was not statistically significant (Table 8-2). In fact, we expected patients to have more problems learning and using the laptop and mouse than the paper-based approach, considering the age variation and mobility impairments. However, results suggest that patients' perceptions were considerably different than our expectations, as the fact that they found logging pain information on the 3-D pain drawing easier ( $p<0.05$ ), demonstrates.

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

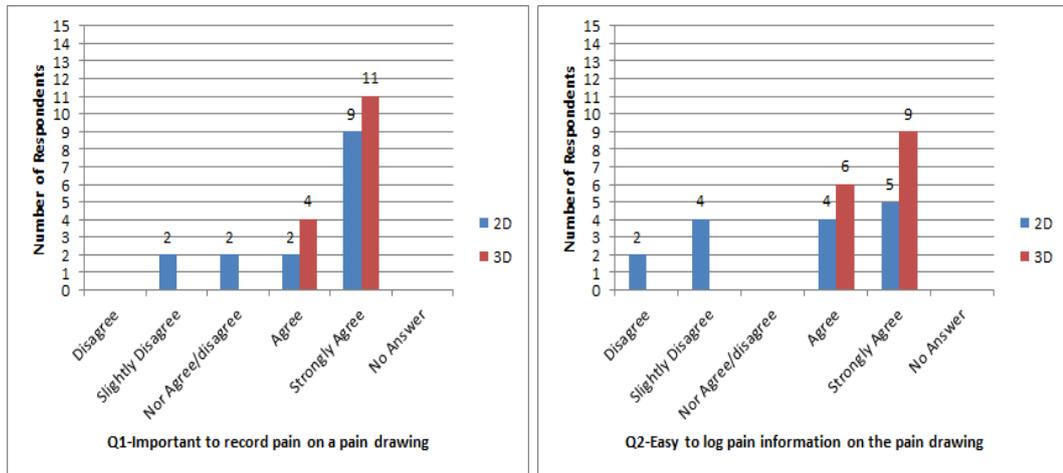


Figure 8-2. Histograms of Responses to Questions 1-2

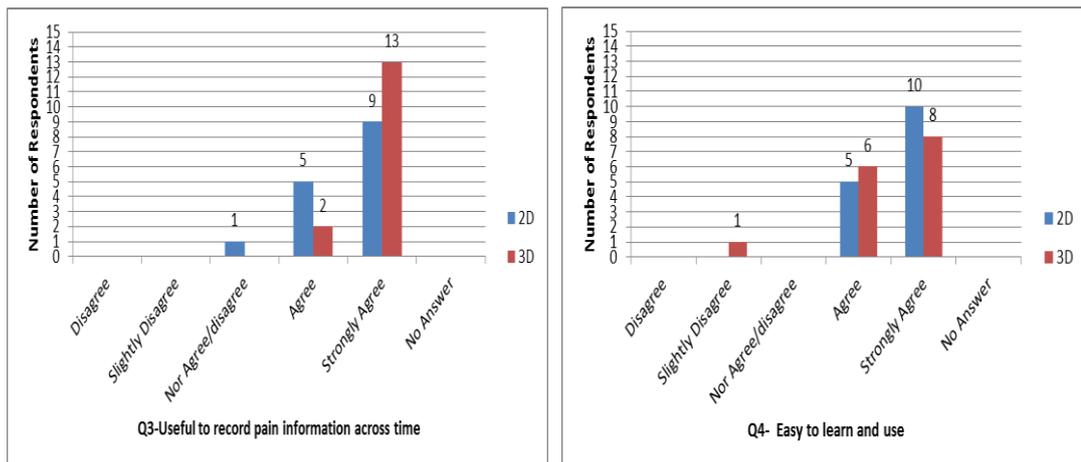


Figure 8-3. Histograms of Responses to Questions 3-4.

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

Table 8-2. Questionnaire and Results

Question	2-D Drawing		3-D Drawing		p-value
	Mean	St. Deviation	Mean	St. Deviation	
Q1. It is important to be able to record my pain on a pain drawing	4.2	1.10	4.73	0.45	0.071
Q2. It was easy to log pain information on the pain drawing	3.53	1.5	4.6	0.5	0.02
Q3. It is useful to be able to log pain data across time, in order to better communicate my pain	4.53	0.63	4.86	0.35	0.055
Q4. The process was easy to learn and use	4.66	0.48	4.4	0.82	0.3
Q5. The use of the pain notations was clear and helpful	3.73	0.59	3.66	1.63	0.8
Q6. Showing the type and exact location of my pain on the pain drawing was easy	2.53	1.24	4.4	0.63	0.0009
Q7. I believe the pain drawing was insufficient to visualize my pain	3.53	0.91	1.33	0.81	0.00000 5
Q8. The overall layout of the interface was clear and simple	3.4	0.91	3.86	0.63	0.06

The results with respect to the second research question regarding the developed interface's feasibility to visualize pain are similarly particularly encouraging (Figure 8-4). Since the 3-D pain drawing was devised to enhance the limited abilities that its 2-D equivalent was offering, it comes as no surprise that patients found that showing the type and *exact* location of their pain on the 3-D drawing was significantly easier than when using the 2-D version ( $p < 0.05$ ) (Table 8-2 above).

In fact, some of the comments made by patients during the evaluation include: “*This is very good and much easier..*” and “*the 2-D drawing was not adequate..*”. Moreover, positive results were similarly obtained with regards to the ability of the 3-D pain drawing to sufficiently record the type of the pain through the use of a colour notation, which patients found to be very clear and helpful. Nevertheless,

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

patients' perceptions suggest that there is no significant preference of color notation over the traditional symbol notation used in the 2-D drawing (Figure 8-4). On the contrary, the mean opinion score was higher in the case of the later, with a small deviation, however, from the mean of the former (Table 8-2). Therefore, the small analogy between the two different ways of pain notation seems to demonstrate the acceptance of color as a means of depicting patients' pain type.

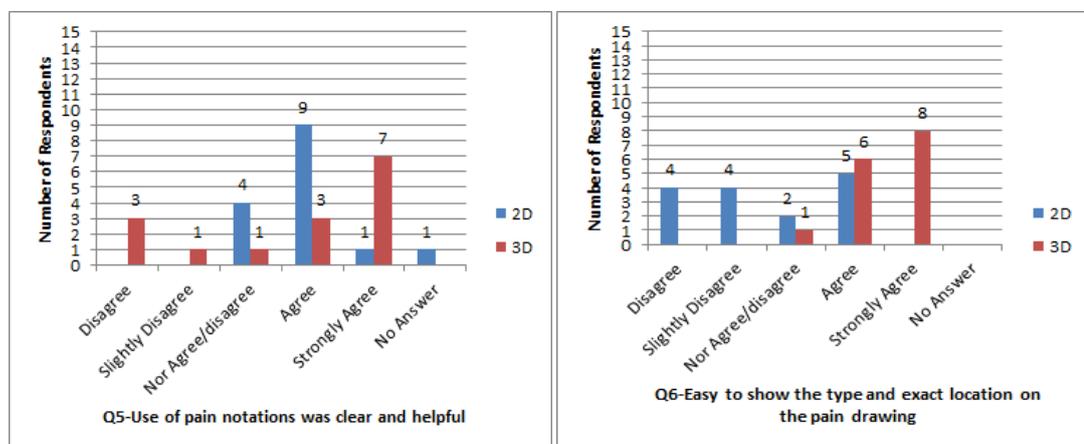


Figure 8-4. Histograms of Responses to Questions 5-6

Lastly, it has to be remarked that the general trend from the evaluation was that patients were enthusiastic about the 3-D pain drawing, generally disagreeing with statements regarding the insufficiency of a 3-D approach to express their pain. In fact, the results highlight the wide acceptability and approval of the 3-D pain drawing's ability to sufficiently visualize their pain experience, as compared to its 2-D equivalent ( $p < 0.05$ ) (Table 8-2). Moreover, the majority of the SCI patients that participated in our study appreciated the advantages of the enhanced visualization ability that our 3-D approach provides by indicating very positive views towards its overall interface layout (Figure 8-5).

## CHAPTER EIGHT – CASE STUDY THREE: EXPLORING THE POTENTIAL OF 3-D TECHNOLOGY IN THE VISUALIZATION OF PAIN AMONG THE SPINAL CORD INJURY POPULATION

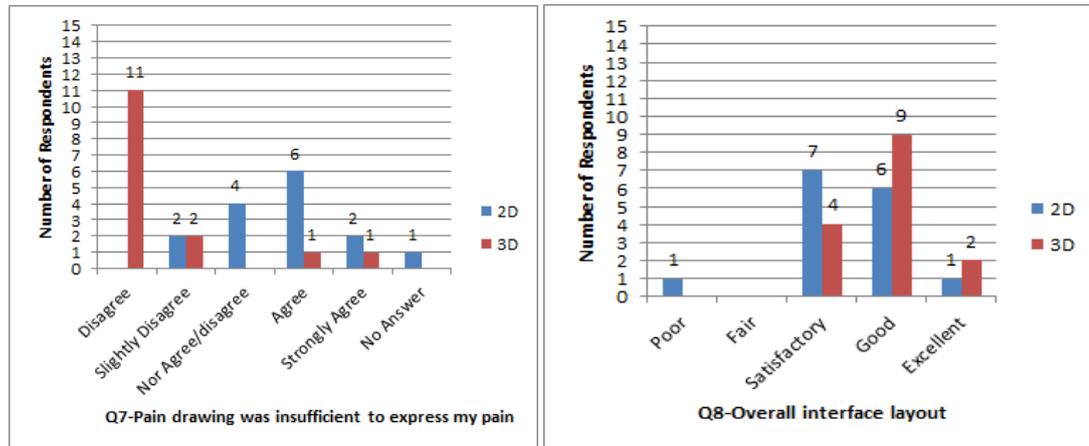


Figure 8-5. Histograms of Responses to Questions 7-8

### 8.6 SUMMARY

With the emergence of 3-D technology, clinical applications that utilize such 3-D expertise could become an important complement for the rehabilitation of pain in people with some form of disability. Accordingly, in this case study an interactive approach that provides individuals with SCI the ability to visualize their pain with the help of a digitized 3-D pain drawing was described. The results indicate that it is feasible to apply 3-D visualization technology in order to assess pain resulting from a SCI, with patients also approving its usability in visualizing their pain characteristics.

Overall, therefore, and in keeping with findings of the previous two case studies, this case study has also demonstrated the applicability, as well as the effect 3-D technology could have in the development of approaches that could be used to support pain rehabilitation. The use of such a technology, thus, creates the possibility for patients to become better stakeholders in the management of their pain, by allowing them firstly to visualize their pain experience in a more perceivable way to the natural environment, and secondly to use this visualization opportunity in order to further understand it.

## CHAPTER NINE

# CONCLUDING DISCUSSION AND REMARKS

### 9.1 OVERVIEW

In the context of the studied research area, this work was motivated by the identified need to contribute in the improvement of the visualization know-hows that are currently present in the medical field of pain management. The review of the relevant literature presented in chapters two and three has demonstrated how existing approaches to pain visualization proved to be insufficient in their capabilities for accurate pain description and are often bound by clinicians' subjective interpretations. The medical staff and patients alike that participated in this research confirmed this impression.

Subsequently, the efforts described in the remaining chapters of this work attempted to address this task by providing and further evaluating an improved, 3-D approach in the anticipation to yield in vivo information about the practicability of visualization techniques in more effectively conceiving the pain condition under study. The results have demonstrated the potential that a 3-D visualization approach offers in vastly improving the assessment and understanding of various pain-related conditions.

In retrospect, this last chapter begins by specifically discussing the achievements and findings of this research in the next section, with respect to the research objectives set in the first chapter of the thesis. Accordingly, the following section discusses the

contributions derived from the research, and this last chapter concludes with the limitations encountered during this work, as well as with the presentation of directions for future endeavours.

### **9.2 RESEARCH ACHIEVEMENTS AND FINDINGS**

This research set out to gain insight into existing available pain visualization expertise, and accordingly investigate the impact and potential benefit that the development of a 3-D technological approach could provide in improving the current practices. As such, a number of issues and concerns - described in chapter one as this research's aim and objectives - were studied, and are subsequently summarized together with their relative achievements in the discussion that follows.

**Objective 1: Identify and explore the research background as well as investigate the research approach that can address the research aim, which can guide us to the development of this work's artefact.** Understanding pain, how it manifests itself in different medical conditions, and what are the most effective ways to combat its immediate consequences have always been attractive challenges for researchers in the field. In that sense, chapter one of this thesis presented the main context from which the aforementioned research concerns derived while explaining the attention and efforts of the healthcare industry in identifying immediate solutions to tackle the pain issue. Collectively, as this constitutes a major problem for healthcare given the vast investing of money and resources, the call for more innovative approaches seemed imperative.

Nevertheless, most of the reported efforts are anecdotal, and it has been shown that there is very much limited research that has attempted the step further to the problem. Specifically, chapters two and three discussed pain in more detail, together with the two main approaches currently in use to accurately communicate pain: generic medical imaging and the 2-D pain drawing. Evidence from the literature suggested

## CHAPTER NINE – CONCLUDING DISCUSSION AND REMARKS

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that neither of them has been successful in effectively visualizing the pain experience/sensation. Although research studies on their applicability have overly produced interesting results, in practice they do have certain limitations. The review of the literature performed highlighted the following main drawbacks:

- Insufficient use of medical imaging (e.g X-rays, MRI, etc.) in terms of visualizing the pain experience;
- Limited visualization ability of the 2-D pain drawing;
- Both are impractical approaches to address all pain conditions;
- Paper-based collection of pain-related information;
- Subjective nature of pain

As such, drawing upon the theoretical backgrounds and the accumulated expertise of the two aforementioned approaches, a Design Science research approach was employed in chapter four that enabled the design and development of an alternative approach – this research’s artefact – that provided improved visualization capabilities with regards to pain characteristics. With the research aim in mind, the qualities and reasoning behind the selection of this research approach as the most suitable to address the objectives were discussed, and the relevant research strategy utilized to instantiate this research was presented. A summary of the research methodological decisions is shown in Table 9-1.

Table 9-1. Summary of Research Approach and Methodology

<b>Research Approach</b>	<b>Philosophical Assumption</b>	<b>Software Methodology</b>	<b>Research Strategy</b>
Design Science Research	Interpretive/positivist	Rapid Prototyping	Qualitative and Quantitative Techniques

A final important point in this chapter was the clarification of the matching between Design Science and Rapid Prototyping with this research’s aim.

**Objective 2: Design and develop an alternative approach to pain visualization that addresses any limitations identified from the review of the research background.** Subsequent to the selection of the most suitable research approach for the purpose of this work, the design and development of the alternative approach was carried out in two interrelated iterations discussed in chapter five. In retrospect, the developed pain visualization solution was implemented by taking into significant consideration both human and medical context aspects that past research seemed to have mostly neglected.

To be more specific on the aforementioned assumption, it is without a doubt that medical imaging and the 2-D pain drawing are both valid approaches to visualization; however, they have been developed as, and currently constitute, generic techniques that can be mostly applied to a variety of medical conditions. As such, they do not take into consideration the specific needs of a particular medical condition that an individual with pain might have. In light of this, the presented artefact was collectively developed by including the human and medical context aspects in the form of user requirements of the pain drawing to be employed. The research results emphasize that this decision seems to have improved the naturalistic interaction with the developed model by offering the capabilities to visualize pain with respect to characteristics tailored to a medical condition under study (e.g. sitting posture for an individual using a wheelchair due to spinal cord injury).

The discussion presented in chapter two of this thesis has also revealed three important issues that the developed approach addressed. The first is solely related to the limited ability of the current 2-D pain drawing to visualize pain. It is a proven fact in the relative literature that the 2-D pain drawing is a valid and reliable approach to pain visualization. Nevertheless, the limited dimension representation that it offers does not comply with the need to visualize a painful condition in a more perceivable to the natural environment way, as it only provides a static view of the

## CHAPTER NINE – CONCLUDING DISCUSSION AND REMARKS

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front and back figures of the human body. Chapter three addressed this concern and demonstrated the high importance of the third dimension to the visualization field. Given the degree of freedom it provides when it comes to viewing a certain object, therefore, the developed 3-D approach, drawing from established knowledge about the 2-D drawing, made it possible to have a layout of the human body that is more consistent with its natural role and shape. As such, the limitations that were imposed by the two dimensions were shifted by the possibility to zoom in the 3-D space, or choose another angle of the human body in addition to the front and back viewpoints.

Secondly, notwithstanding its advantages, the developed 3-D approach does not constitute the exception to the rule that all technological advancements are solely under human influence. As such, any type of resulting interaction between an individual and the 3-D pain drawing is subject to human interpretation that by definition is different and varies from person to person. To put the discussion in the context of this research, in chapter two it was discussed that the visualization of pain is subject to the sufferer's psychological state, as well as being affected by several other environmental variables. This means that the attempt to communicate the pain state through the 3-D approach might not always be representative of the real situation. Realizing the implications of this issue, this research integrated a complementary approach to visualization in the form of pressure maps and attempted to address the problem through the case study presented in chapter seven.

The last issue raised in chapter two was the impractical use of paper-based formats identified in the literature as the main means to store the relative medical information. With the trend in the research community having already been shifted towards the replacement of traditional paper diaries with their computerized equivalents, the nature of this research could not have been different. Along these lines, the design of the artefact was carried out by keeping in mind the specifications of both a mobile and a desktop solution – a PDA and a laptop respectively – on

which the developed 3-D approach would run and store patient pain characteristics. A key ingredient of the development was the inclusion of human and medical context aspects in the process, and results of doing so revealed that both of the aforementioned hardware platforms were identified as being appropriate and fitting to pain sufferers' need for mobility and ease of use, keeping with the advantages of electronic tools discussed at the end of chapter two.

**Objective 3: Evaluate the 3-D approach through real-life case studies with respect to the complexity of pain characteristics and the diversity of medical conditions involving some type of pain.** A key development within the aim of this research was the practical linkage of accumulated knowledge from the fields of pain and visualization with the functionality of the 3-D approach. To this end, the potential of the 3-D pain drawing to improve the visualization of complex pain characteristics irrespective of their resulting medical condition was formally evaluated against the metrics established in subsection 4.3.1.1 over three interrelated real-life case studies.

Specifically, the evaluation included coverage and focus of, initially, low-level aspects regarding the 3-D approach's functionality performed within the first case study that was described in chapter six, and which took place in two different settings involving patients that suffered from back pain. Accordingly, the evaluation continued by examining aspects such as the efficiency and feasibility of the developed approach performed within case studies two and three, respectively. To comply with the need to address the diversity of medical conditions, patients with a wide range of painful conditions (ranging from back pain to spinal cord injury) participated in the evaluation processes that were described in chapters seven and eight. The highest level aspects of the acceptability and usability of the 3-D approach were similarly evaluated in case studies one and three, respectively. All three case studies were carried out in patients' natural settings, with these being either a

hospital or their own premises. In this way, the theory behind the 3-D pain drawing built within this research was brought closer to realistic situations, and practice.

**Objective 4: Establish the reliability of 3-D technology in the visualization of pain characteristics.** The results of the evaluations of the 3-D approach that were performed by the three real-life case studies are the best indicators of providing the right direction in establishing the reliability of 3-D technology in the visualization of pain. It is also important to note at this point that the five questions set in chapter one of this thesis were constituted based on the metrics against which the evaluations were subsequently performed. To this end, addressing these questions by means of the evaluation results will provide us with the insights necessary to examine the fulfilment of the present objective. The discussion that follows, therefore, concentrates around these five questions.

- 1. How is the introduction of 3-D technology in everyday medical practice perceived by the medical staff?* The results from the first case study's evaluation seem to indicate that the clinicians involved highly appreciated the initiative to employ 3-D technology in their everyday attempts to assess patient pain. As the innovation introduced was the enhanced visualization capabilities, it is promising that they have overly valued and approved the 3-D visual appearance of the developed artefact.

Nevertheless, considering that the 3-D approach will be used in a realistic clinical setting, several concerns were also raised (see subsection 6.5.1). However, the positive comments from the medical staff with regards to functionalities such as remote assessment of pain, the opportunity to become a better stakeholder in managing pain, and the important and beneficial psychological effects that it could have on patients, collectively overlooked

these concerns and contributed towards the acceptance of 3-D technological solutions in clinical settings.

2. *What are the patients' perceptions with regards to the functional characteristics of the 3-D approach?* In keeping with the findings of the afore-discussed question, the perceptions of the patients were similarly investigated within the same case study one. The results of the investigation suggested highly positive perceptions, which were in line with our expectations that individuals with pain would approve the ability of the 3-D approach to visualize their pain characteristics.

Specifically, patients indicated positive views towards the developed interface, platform, and practicality of the developed 3-D artefact. In fact, the patient participants found that the basic enhancement functionality aspects of the 3-D approach are a significant improvement to the 2-D pain drawing. The color notation used was characterized as clear, and the navigation and control of the 3-D pain drawing were found to be very easy. Strongly positive results were also obtained with respect to the ability of the prototype to record pain data anywhere, anytime, while, as a patient highlighted, a significant improvement to the accuracy of the pain location is achieved.

3. *How valuable is 3-D visualization technology in addressing the subjective nature of pain?* Accordingly, with regards to the first research objective of case study two that aimed at exploring relationships between the 3-D visualization approach and pressure mapping, the evaluation results produced mixed findings: while for three of the case study's participants a direct link was found between the two approaches, for the other three participants this relationship was indirect. These findings show that high pressure shown through the pressure maps might not necessarily be a possible direct

indication of pain, but could reveal further information pointing to its existence. As such, the question of whether the pain that one experiences is real or subject to psychological factors could be answered by employing 3-D visualization technological means, as the results suggest.

Finally, although various studies have been conducted in the literature (Brienza et al. 1996; Stinson et al. 2008; Tanimoto et al. 1999) that also exploited pressure mapping in the mobility impaired population, their main trend was to reduce any pain originating from pressure sores by suggesting either more appropriate wheelchair cushions, or more suitable postures with respect to the results produced. In contrast, the innovation in this research lies in the fact that, as compared with the aforementioned studies, the intended purpose is to identify the existence of such pain in order to prevent its consequences, rather than reducing it as a result of them.

4. *What is the capacity of 3-D technology to support patients in most efficiently visualizing and communicating their pain to clinical staff?* The relevant answer to the aforementioned question was dealt with in the second case study. Specifically, the efficiency of 3-D technology for the intended purpose was examined by comparing the developed 3-D approach against the already valid method of pressure mapping. To this end, the case study presented produced very promising results, especially regarding the ability of complimentarily using both of the proposed methods to better and more efficiently indicate pain.

The aforementioned efficiency was justified as part of the case study's second research objective, by measuring the ability of the 3-D pain drawing to better localize pain, using the least possible number of clicks to indicate its location on the body surface. The results produced indicated that, overall, the 3-D pain

drawing seemed to more efficiently localize pain data in low pressures, while the pressure mapping equipment was more efficient in the high pressures.

To the best of the author's knowledge, no study currently attempts to evaluate the efficiency of a pain drawing in localizing pain in terms of surface area. Considering the enhanced ability of the developed 3-D pain drawing to better visualize pain, and with regards to this case study's results that revealed its usefulness in more efficiently localizing pain, it could be surmised that it is a promising initiative in the clinical literature for the intended purpose.

5. *Is a 3-D approach a more feasible and usable means of visualizing pain characteristics as compared to methods currently in use?* This question is addressed by the results of the third case study that was performed with a group of SCI patients. Before that, several studies (Duerstock et al. 2000; Frank and De Souza, 2001; Kakol et al. 2003) had suggested some possible areas where 3-D visualization technology could be used in the rehabilitation of patients with SCI. Accordingly, in this case study the 3-D approach was evaluated with people with SCI in terms of the capability to visualize their pain. The evaluation results indicated that it is feasible to apply 3-D technology in the development of approaches that could be used to support post SCI pain rehabilitation.

Indeed, this case study revealed encouraging results, with patients highlighting the ease that they experienced in using, and further logging pain information in the 3-D pain drawing as compared to its 2-D equivalent. This is particularly important considering the age scale of the participants in this case study (28-75 years), which represents the normal patient population in SCI hospital units. This age variation was also demonstrated by their concerns in learning and using the 3-D approach. Nevertheless, it was

assumed that younger patients will not have these same concerns, a condition that is significantly encouraging with respect to the results.

With regards to the feasibility of the 3-D approach to visualize pain compared to its 2-D equivalent, it was found that the 3-D version is significantly more efficient in visualizing their pain type and exact location. Moreover, incorporating color notation capabilities in the process was also suggested to be rather useful, justifying past studies (Ghinea et al. 2008; Malliou et al. 2005) with respect to the use of color for the intended purpose. Overall, according to the results, as well as to the patients' comments, this case study demonstrated that it is possible to apply the use of 3-D visualization technology in order to assess pain resulting from a SCI.

Collectively, the majority of the patients that participated in the three case studies appreciated the advantages of the enhanced visualization ability that 3-D technology provides by indicating very positive views towards its overall interface layout and functionalities. Special attention was finally given by the evaluation participants to the advantages that self-monitoring of pain in managing their medical condition provides.

In retrospect, this research's findings achieved through the case studies described in chapters six, seven, and eight have provided significant insights with regards to the reliability of 3-D technology in the visualization of pain. Addressing the above five questions with respect to these case studies has also contributed to the accumulation of the necessary knowledge to answer the last question under investigation. Hence, although the results produced indicate that 3-D technology can constitute a strong ally in the pain assessment practice, a complete picture of its importance can be attained if we also explore the contributions of this research to the relevant communities.

**Objective 5: Validate and evaluate the research findings with respect to their contribution to the research field under study.** The results accumulated from the case study evaluations constitute the findings of this research. As such, these findings need to be evaluated with respect to the contributions they make to the fields under study, both in theoretical and practical terms. The section that follows addresses the aforementioned discussion and describes how the present objective has been fulfilled.

### **9.3 RESEARCH CONTRIBUTIONS**

Considering the vast impact that pain has in the provision of quality healthcare, the contributions made from this research have been diverse and could cover the most important aspects that fall within the range of theoretical and practical issues of the pain medical field. To this end, the findings of this research are of immediate interest to stakeholders concerned with the provision of healthcare, and of specific value to medical communities and other researchers who are actively involved in the exploration of more effective approaches to the assessment of pain resulting from any type of medical condition. In retrospect, in the following three subsections the contributions of this research with regards to society, science/technology, and healthcare providers, are respectively presented.

#### **9.3.1 CONTRIBUTIONS TO SOCIETY**

The review of the literature has revealed significant improvements towards effective visualization in the medical field. Past methods have been revisited, while new approaches promote the application of visualization technology in various aspects of everyday medical practice. However, the daily reality of pain indicates that the medical community has not yet been successful in overcoming all barriers with regards to the efficient assessment of this common condition. On the contrary, there is accumulating evidence that individuals with pain resulting from any form of

## CHAPTER NINE – CONCLUDING DISCUSSION AND REMARKS

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medical condition are preconceived towards the adequacy of current treatments, especially due to the effect pain has in the quality of their social and working lives.

In fact, Breivik et al. (2006) in their European-scale survey highlighted the significant impact of pain in societal aspects. Specifically, their study revealed that 60% of people were unable to work and around one-fifth lost their job because of pain. The implications of the inability to work in society are enormous. While the cost related to the loss of productivity is substantial, social compensations and retirement pensions for people who are unable to work are similarly increasing. In addition, many people with pain are unable to do a range of daily activities such as sleep, walk, or involve in sexual relations (Breivik et al. 2006). Consequently, the lack of efficient pain assessment approaches provokes social exclusion and isolation for individuals with pain.

To this end, considering that the aim of this research is to support the efforts towards the removal of any pain assessment barriers by developing a novel approach that will offer pain visualization capabilities based on 3-D technological advancements, the overall summarized societal benefits of the present work are threefold:

- ❖ Individuals with pain and discomfort benefit by taking advantage of the possibilities the developed 3-D approach offers for more efficient pain assessment that would improve the quality of their life;
- ❖ Healthcare providers benefit through the adoption of such new technology leading to more adequate delivery of health services (see subsection 9.3.3);
- ❖ Society benefits by avoiding implications related to exclusion of individuals with pain from daily services and activities

Indeed, it is very common amongst individuals with pain not to be able to maintain a satisfying level of social life. People often become very withdrawn since going out

might increase their pain levels, or if they do go out, they might not be able to e.g. dance, or drink alcohol because of medication they have to take for pain relief (Healthtalkonline, 2010). Similar are the implications to their ability to properly work.

These are exactly the types of situations that the developed 3-D approach could address. By taking advantage of the benefits identified within the three real-life case studies, pain sufferers could improve the quality of their lives. For instance, they could monitor the progress of their pain characteristics and accordingly adjust their medication or they could manage their pain by correlating it with painful activities they have been doing, as the results of the first case study have shown, so as it will become possible for them to attend a social event. At the same time, healthcare providers could also benefit by increasing patient satisfaction.

Hence, the work produced by this research is foreseen in the medium-term to assist in the enabling of people with some form of pain to regain their autonomy, and subsequently to aid in promoting employment growth by overcoming the burden of the inability to work, or socialize due to inadequate assessment of pain. As such, although not demonstrated by the results of this work as it was outside its purpose, the innovative concept of this research is expected to contribute both in social and economic terms.

### **9.3.2 SCIENTIFIC/TECHNOLOGICAL CONTRIBUTIONS**

People experiencing pain are the most important stakeholders of assessment practices; however, their needs are not being adequately addressed in existing approaches. To this end, the present research provides relevant scientific and/or technological communities with practical contributions in their knowledge of designing, implementing and evaluating better solutions for assessment of pain, by offering:

- **An innovative alternative to the aforementioned communities** with the development of the 3-D pain drawing in order to visualize the characteristics of pain in a more realistic manner;
- **Pressure mapping** as a proposed complementary approach to measure the subjectivity and the validity/efficiency/reliability of the diverse range of pain reporting tools;
- **Improved quality of life** for individuals with pain achieved through the developed 3-D approach

Specifically, researchers in the field are increasingly exploiting 3-D visualization technology, something that shows the huge potential that exists for it in the medical practice. As such, the 3-D pain drawing could be further exploited in the field and used for several other medical purposes by taking advantage of the potential that it offers to developers to redesign this 3-D pain drawing in ways that would meet the needs of specific medical conditions that involve pain.

Although the developed 3-D approach has been tailored in this research to visualize e.g. spinal cord injury pain, in future practical terms the 3-D pain drawing could be easily reprogrammed in order to closely match the particular pain characteristics of medical conditions, such as cancer or arthritis. For instance, it is very common in an arthritis assessment for a clinician to observe posture pain while e.g. bending over. Therefore, the 3-D pain drawing could be easily adjusted to address the above posture.

From a different perspective, pain experienced by an individual with arm impairment such as loss of limb could be similarly visualized through a realistic environment provided by the redesigned 3-D pain drawing that maps this individual's impairment. Taking this a step further, a database of pain profiles (e.g. postures, types of pain,

## CHAPTER NINE – CONCLUDING DISCUSSION AND REMARKS

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impairment(s)) mapped to specific medical conditions could be formed in the medium-term, which could then be utilised for a dynamic, on the spot redesign of the 3-D pain drawing to match any of these profiles, as compared to a more static, manual reprogramming.

As a last futuristic remark, the aforementioned 3-D pain drawing and pain profiles database could form the basis for offering more accessible and pain-relieving services to individuals with pain, such as, for instance, adjusting a restaurant seating area to the needs of persons suffering from pain of e.g. arthritis by producing equipment tailored to these people's conditions.

In retrospect, introducing the employment of 3-D technology in the visualization of pain, and further allowing for the ability to adjust it to particular painful conditions will introduce a new era in the design and development of more effective approaches to pain assessment and relief. Collectively, therefore, the 3-D pain visualization approach presented in this research is expected to contribute to the design of innovative 3-D user interfaces applied to the diverse medical conditions, advancing the existing ones. The Visible Human Project described in chapter three, for example, could benefit by adopting the 3-D approach's functionality to improve its purpose.

Accordingly, the relevant scientific/technological communities are expected to benefit from this research's contributions by:

- Taking advantage of the 3-D pain drawing, usable without the need for extreme re-programming;
- Contributing further to the relevant literature by examining the effectiveness evaluations performed in a variety of realistic cases;

- Taking advantage of the minimized need for a large number of users in the designing and implementation of solutions adapting the 3-D pain drawing, which has been already developed by taking into consideration the human factor;
- Exploiting the ability for fast and effective development of especially the user interface functionalities of the solution to be developed that have been mostly addressed by this research's work;
- Employing the metrics used to perform the evaluations of the 3-D approach within real-life environments

Conclusively, this research is also expected to provide value in the attempt to minimize the time and cost of relevant solutions, as well as to be an essential basis for the evaluation of future technological solutions in the basis of 3-D technology.

### **9.3.3 CONTRIBUTIONS TO HEALTHCARE PROVIDERS**

The wide applicability of the developed 3-D approach across medical conditions that involve pain has led the author to assume that it can have a large contribution to stakeholders involved in the provision of health. As such, considering that individuals with pain often rely on several healthcare institutions (hospitals, health and social care institutes) for assistance, the 3-D approach could be utilized by these institutions for the purpose of assisting the sufferers, by making possible a more efficient and accurate pain assessment.

Consequently, from the perspective of reducing healthcare costs while providing improved patient care, the capabilities provided by the developed approach to assess and monitor one's pain remotely, irrespective of distance and/or time (see chapter six), could have an enormous impact to the above considerations – less hospital visits

## CHAPTER NINE – CONCLUDING DISCUSSION AND REMARKS

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could be achieved, and the waiting time to be assessed could be significantly reduced.

The above assumption is also supported by the clinicians involved in the 3-D approach's evaluation described in chapter six. According to their comments, the possibility of patients collecting their own data, especially at set times of the day might have very positive implications to the provision of care, since patients could:

- ❖ Remotely monitor the progression and type of their pain, vis-a-vis their prescribed medication/treatment;
- ❖ Become better stakeholders in managing their pain;
- ❖ Also benefit from a psychological point of view

From a clinical perspective, the developed 3-D approach could similarly offer significant insights into the assessment and management of pain. While the cornerstone to efficient pain management is the assessment of pain experience, this effort often relies on a healthcare professional's empathy, interest and understanding of a patient's condition (Fink, 2000) at the time of assessment. However, the clinician's e.g. heavy workload or tiredness often affects the aforementioned conditions. As such, although the 3-D approach does not offer a diagnosis, it could address the need for this reliance and ease the clinician with the assessment through:

- Its improved pain visualization functionality - the pain descriptors (e.g. numbness, pins and needles) employed to communicate pain sensation on particular body locations could reveal patterns that lead to such a diagnosis. For instance, repeated use of pins and needles to visualize developing pain in parts of one's leg that were previously hard to indicate could be a sign of a neuropathic condition;

## CHAPTER NINE – CONCLUDING DISCUSSION AND REMARKS

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- Its capacity to facilitate remote pain management by those clinicians, while also easing the congestion and waiting times often experienced in healthcare settings e.g. long waiting queues

Furthermore, the possibility of the 3-D approach to offer a diagnosis should not be disregarded. Several studies have been carried out in the past that employed Artificial Intelligence techniques to assess the 2-D pain drawing (see end of subsection 2.3.3.2), with very positive results. Accordingly, the pain recordings of the 3-D approach could be similarly utilised/ combined with Artificial Intelligence for more advanced diagnosis and/or treatment plans. Considering the improvements that the 3-D approach offers, it is anticipated that the results of its integration with Artificial Intelligence could be of significant importance to the pain community.

The above could not be achieved without the ability to visualize and monitor pain characteristics over time that is provided by the 3-D approach. Offering such capabilities to the clinicians', therefore, could make significant contributions both to the pain diagnosis process, as well as to *1) the assessment of potential biochemical or other changes associated with pain, 2) the measurement of the outcome of any medication provided for pain relief, and 3) the assessment of the ability of other pain assessment tools to measure pain* (see Yamamotova et al. 2010).

Moreover, it is almost the gold standard that today the health records of a patient are stored in a database that includes information from the whole medical background of an individual. Nevertheless, although this advantageous approach has improved the provision of quality healthcare, in the terms of a pain sufferer it is still in its infancy, as at the moment it is not possible to exclusively retrieve records about pain characteristics, for the simple reason that they have never been stored for this purpose. This is another contribution that the developed 3-D approach could make by

providing the ability to integrate the pain records that it stores into the health records of a patient.

Finally, this research has also introduced the integration of pressure mapping and self-reporting as a supplementary approach to address the subjective nature of pain, and to improve its overall management. The results produced in this work demonstrated its potential as a means to identify real or imagined pain, and as such healthcare providers could benefit by this novel approach if it could be adapted in everyday medical practice.

Conclusively, the fact that the developed 3-D approach runs on both a desktop PC and on a PDA for mobility and accessibility purposes, could lead to the widespread adoption of solutions encompassing 3-D technology by a wide range of institutions. This move is expected to empower individuals with pain due to improved quality of care, and consequently, the role of healthcare institutions will be moderated and health provision costs will be reduced.

### **9.4 RESEARCH LIMITATIONS AND FUTURE ENDEAVOURS**

Notwithstanding the positive results and their encouraging contributions, this research also raised certain limitations as well as avenues for future work that accordingly need to be acknowledged. First, although one of the beneficiaries of this research's findings have been argued to be the wider range of healthcare providers, the work presented in this thesis was limited to hospitals and official organizations. As such, it has to be made clear that since this research is prototypical, it has not yet been tested in the remaining healthcare settings. In retrospect, an attractive future direction would be the investigation of the developed 3-D approach with the whole range of healthcare providers, where more findings coming from additional experienced eyes could be further produced. While the evaluation of the research findings from a clinical perspective has not been performed in this work as it was

## CHAPTER NINE – CONCLUDING DISCUSSION AND REMARKS

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outside the scope of this research, it would be of significant value and interest to include it in future efforts and examine in more detail its potential contributions to healthcare provision.

Another point of consideration is the fact that the evaluation of the artefact was not performed by including a big number of painful conditions. On the contrary, only some of the most commonly reported and with the highest prevalence were selected as fixed parameters in the real-life case study evaluations. In fact, it is argued that these painful conditions that have all overly significant impact on an individual's life may be strongly indicative of the 3-D approach's potential to improve pain assessment success. Nevertheless, future research may pay attention to other medical conditions by porting the developed solution to clinical areas involving, for instance, patients recovering from surgery or being treated for cancer.

A complication to a large-scale generalization of this research's results has been also identified due to the small group of participants taking part in each case study evaluation. Specifically, under these circumstances it was generally impractical to recruit a large number of participants, as only individuals with pain had to be considered, something that made it extremely hard in some cases for them to consent due to their painful condition. Nevertheless, the results of the present research are still obvious even to the inexperienced eye, a fact that could be argued that justifies even more the 3-D approach's potential.

As a final point, the findings of this research could be criticized that in order to be put in practice would cost the relevant healthcare sector a considerable amount of money for equipment and software. However, in defence of this assumption, it could be argued that any potential initial investment could be offset by the reduction in healthcare costs (better pacing of medication intake, as this research has highlighted; potentially fewer hospital visits) as well as by increased patient satisfaction due to

## CHAPTER NINE – CONCLUDING DISCUSSION AND REMARKS

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the opportunity to become a better stakeholder in the management of pain (again, as shown by this research, although the author is aware that it is difficult to put a price on patient satisfaction).

Conclusively, according to the findings of this research, as well as to the participants' comments, this work has demonstrated that it is possible to apply the use of 3-D visualization technology in order to assess pain resulting from certain medical conditions. As it has been overly demonstrated, the use of such technology creates the possibility for the individuals with pain to become better stakeholders in the management of their pain, by firstly allowing to communicate their pain experience in a more perceivable way to the natural environment, and, secondly, to use this visualization opportunity in order to further understand it.

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## APPENDIX A – SUPPLEMENTARY MATERIAL

### A.1 UNDERLYING PHILOSOPHICAL ASSUMPTIONS

Considering that the Design Science research cycle is not aimed at a specific research problem, one could wonder whether this approach constitutes valid and acceptable research. According to Orlikowski and Baroudi (1991), the answer could be derived from a set of philosophical assumptions whose purpose is to investigate the nature of the phenomena under study, as well as what constitutes valid research.

The IS research community, therefore, has typically adapted the three research philosophies – *positivism*, *interpretivism*, and *critical research* (Orlikowski and Baroudi, 1991) – described below.

Accordingly, the research performed is considered **positivist** when attempting to test theories in order to increase the predictive understanding of the studied phenomena. The criteria adopted to classify a study as positivist include evidence of formal propositions, quantifiable measures of variables, hypothesis testing, and the drawing of inferences about a studied phenomenon from a sample representing the examined population (Orlikowski and Baroudi, 1991).

In the same lines, **interpretive** research assumes that people create their own interpretations as they interact with the world around them. Interpretive researchers, therefore, attempt to understand the studied phenomena through assessing these interpretations. Compared to positivism, interpretive research does not focus on variables, but instead, it relies on the complexity of human sense making as a situation emerges (Myers, 1997).

Lastly, **critical researchers** aim to critique the status quo through structural contradictions within social systems. Classification criteria include evidence of critical stance towards established assumptions about organizations and information

systems. Hence, the main task of critical studies is social critique in the attempt to eliminate the causes of the aforementioned assumptions (Myers, 1997).

Accordingly, as Purao (2002) correctly suggests, in order for Design Science research to claim legitimacy, it must also identify its underlying dominating beliefs and assumptions. To this end, a review of the literature indicates that Design Science research takes a philosophical perspective, which often shifts between interpretive and positivist research. It starts off by interacting with the research process, then eventually becoming a positivist observer by recording and comparing the behaviour of the artefact to the existing theories, and finally switching back to the interpretive approach (Myers, 1997).

Carlsson (2006) on the other hand, points out certain weaknesses that have been identified in positivism, and proposes the use of alternative philosophies such as constructivism (i.e. interpretivism). Nevertheless, he reveals that the majority of work on IS Design Science research is still mainly based on a positivistic philosophy. *This is the philosophical perspective that has also been chosen for this research, which, in accordance with Myers's (1997) findings, would also shift to interpretive research depending on the activities carried out.*

To reflect upon the aim of this research, therefore, which involves both quantifiable variables (utility, quality, efficacy of the artefact) and subjective variables in terms of thoughts and feelings of the participants, a philosophical perspective that shifts between interpretive and positivist research is adopted as the most appropriate approach to address the aforementioned conditions and develop our key research instruments.

## A.2 OVERVIEW OF SOFTWARE DEVELOPMENT APPROACHES

A review of the literature has revealed that the most common software development methodologies currently in use among the ones presented in Table 4-4 include the *waterfall model*, the *Spiral model*, *rapid prototyping*, and *object-oriented programming*. As such, a brief description of each is presented next (adapted from Sommerville, 2011), in the anticipation that it will enable us to understand their underlying activities, and help us in this way to consider which is the most suitable for the development of our artefact.

### The Waterfall model

This model is perhaps the oldest and best software methodology approach. Its name has derived from the ‘cascading’ that occurs from one phase to the next one, i.e. from requirements definition to operation and maintenance, shown in Figure A-1.

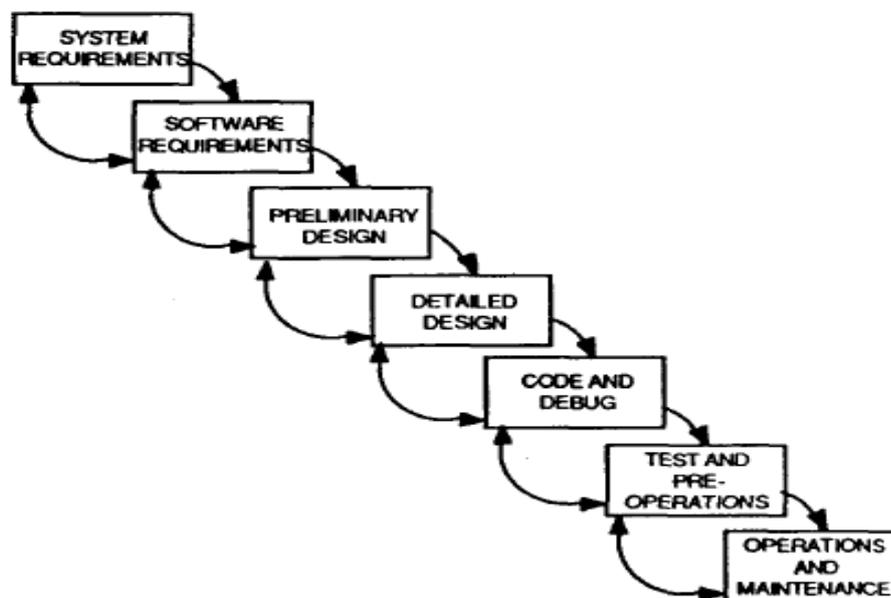


Figure A-1. The Waterfall Model (Adapted by Davis et al. 1988)

In principle, several variations of the above diagram seem to have been evolved and currently exist in the literature, specifically with respect to the terminology used to describe the respective activity carried out during each phase. Nevertheless, the result

of a phase is typically in the form of one or more documents that act as the prerequisite for the next one to start. However, in practice these phases seem to overlap as feedback is normally fed from one to another during the process.

Although this iterative aspect adds to the value of this approach, nevertheless, the lack of flexibility in adapting to changing user requirements seems to be the biggest drawback of the Waterfall model, which makes it rather impractical to use. In fact, this model should only be used when the requirements are well-defined and highly unlikely to change after been gathered in the first phase, as its nature makes it impractical to involve iterations that would allow such changes.

### The Spiral Model

Boehm was the first one to propose this model in 1988 that took its name from the way the software process is carried out. Hence, unlike Waterfall model's cascading approach, here the software process is represented as a 'spiral' with each of its loops demonstrating a phase of the software development process (Figure A-2).

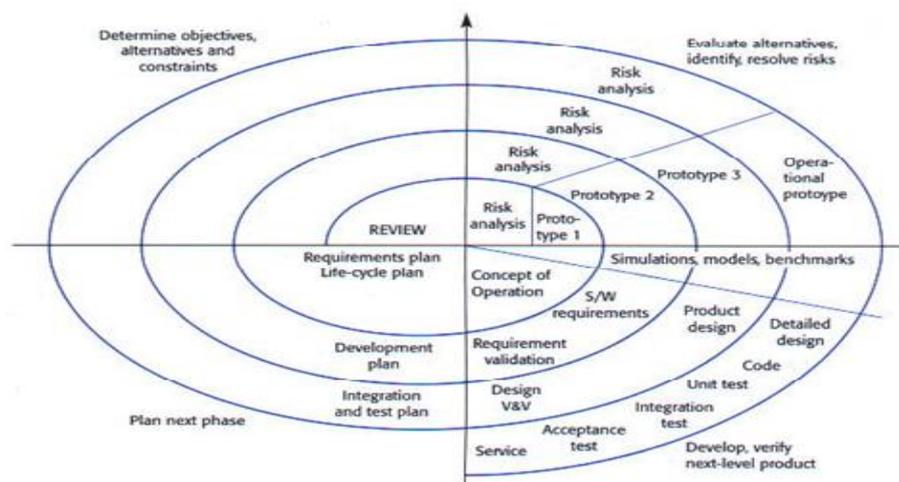


Figure A-2. The Spiral Model (Adapted by Boehm, 1988)

In response to the drawbacks of the Waterfall model, this approach has included the *iteration* aspect in its software development process. In fact, the Spiral model adds

the flexibility that the Waterfall model was lacking by allowing backtracking from one activity to another. That means that its greatest advantage lays in the fact that its iterative nature allows software development to be carried out irrespective of the user requirements status – i.e. whether they change or are not all known. In addition, risk management is also another contributing factor to its wide usage. In fact, each activity in the spiral cycle is first assessed against potential sources of project risk prior to proceeding to further planning and development.

### **Rapid Prototyping**

In coping with change and the demand for faster, but cheaper software development, prototyping was introduced as an improvement over the traditional methodologies, which have been exhaustively used and proven unable to perform against these requirements. Compared to the Waterfall and Spiral models, prototyping involves the quick development of a version of the system or part of it for the purpose of evaluating it early in the software process against the user requirements and the feasibility of the design decisions, and so allow their refinement, if needed (see Figure 4-2).

In retrospect, system prototypes allow users to see how well the developed software meets their requirements. Accordingly, the prototyping method offers the following main advantages:

1. It can identify areas of strength and weakness in the software by giving the opportunity to users to evaluate it and provide feedback that would help in improving the software's functionality;
2. A system prototype can be used during the design process to carry out experiments to measure the feasibility of a proposed design;

3. Prototyping constitutes an essential part of the user interface design process, as by involving end-users in the process who would evaluate and refine makes it the only effective way to develop them

Nevertheless, the main drawback of rapid prototyping appears to be in the usability of the product, as the tester may not be typical of system users, and therefore proper testing with respect to non-functional requirements (e.g. performance, security, reliability) may not be done. However, this is typically improved through the several refinements that occur during the development process.

### **Object-oriented Model**

Software that has been developed using the object-oriented model is made up of objects that interact with each other to satisfy the identified user requirements. The main characteristic of this model is its attempt to represent real-world phenomena (e.g. student, university) by using objects and the interactions that occur between them. In object-oriented programming terms, these objects are defined by ‘classes’ and the interactions between them are represented by ‘methods’.

The major advantage of object-oriented models is that they allow the software to change in a significantly easier way than other approaches do. This is because of the nature of the developed objects that stood in the process as standalone entities; therefore, changing the implementation of an object should not affect other objects that co-exist.

Like in the previous software methodologies described, with the exception of the Waterfall model, the activities of this model are not carried out in a sequential process, but rather, an iterative approach is similarly involved that includes roughly the same activities as the others. It has to be mentioned at this point, however, that Sommerville deliberately does not include a diagram of the model in this case, in the attempt to avoid confusion with a sequential software development process.

As a final point, it is imperative that we take a moment to examine all three figures of the software development methodologies presented. In doing so, we would identify that all of the above methodologies, irrespective of their form or nature, typically evolve around four activities that are essential to software development (Sommerville, 2011):

- 1. Software Specification** This activity defines the general functionality of the software;
- 2. Software Design and Implementation** The development of the software according to the defined specifications is involved;
- 3. Software Validation** The software is validated to ensure it meets the requirements;
- 4. Software Evolution** The software should adapt to changing user requirements, and evolve

As such, the aforementioned activities constitute the fundamental basis for all software development approaches that are in use.

## APPENDIX B – INTERVIEWS AGENDA

Name:

Organization/hospital:

Position/specialty (for Clinicians):

Date:

### **Part 1: Interview Questions for Clinicians and Patients (Identifying User Requirements)**

1. How often do you use a PC/Mobile device in your everyday life? Do you use or you consider using such equipment in the future?
2. How comfortable do you feel using computers, mobile devices and internet, in general?
3. Are you satisfied about the responsiveness of out-person assistance provided/requested? If not, what didn't meet your need or expectation?
4. What do you think could improve the way medical staff/patient responds to your requests/replies for medical information?
5. How comfortable would you be submitting medical information online via your computer/Mobile device, and what kind of information would you like that to be?
6. Do you think a computer application would be useful for the intended purpose?

## APPENDIX B – INTERVIEWS AGENDA

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7. Are there any special requirements regarding the "look and feel" of such an application?
8. Do you believe a 3-D pain drawing would be useful for the purpose intended, as compared to the 2-D pain drawing currently used?
9. What are your concerns about such an application and how comfortable would you be using it?
10. What do you like and what you do not like about the current pain management process?

### **Part 2: Interview Questions for Clinicians (Evaluating the Acceptability of the 3-D Pain Drawing in Clinical Practice)**

1. What are your prior experiences using computer technology at work?
2. Overall, do you think the 3-D pain drawing is easy or difficult to use? Please describe from your experience problems that could be confronted when used in practice.
3. How informative are the descriptors (e.g. in menus, on buttons) and can they help you understand how this application functions?
4. What did you find getting through each step to record pain information, easy or difficult? What problems or concerns did you have when getting through each step?
5. What do you think about the visual appearance of the 3-D pain drawing? Is it detailed enough to describe the location of pain? What are your suggestions to improve it?

## APPENDIX B – INTERVIEWS AGENDA

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6. How useful and practical do you think this tool is as compared to your experience of using other methods for the intended purpose?
7. Do you think patients will find it easy or difficult to use? Do you see any influence made by the 3-D pain drawing on the management of pain?
8. What are your concerns and suggestions to this application? Can you recommend parts of this tool that should be or can be improved?

APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D PAIN  
DRAWING

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**APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D  
PAIN DRAWING**

PLEASE COULD YOU FILL IN THE FOLLOWING INFORMATION:

**Part I : Patient Profile**

First Name:	
Last Name:	
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female
Date of Birth:	_/_/___
Symptoms:	

**What is your level of injury?**

- Paraplegia
- Tetraplegia

**My injury is:**

- Complete
- Incomplete

## APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D PAIN DRAWING

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**Can you walk?**

Yes

No

**Do you have any other disabilities?**

Mental Illness

Hearing

Visual

Speech

Other Impairments, not listed here:.....

**Do you have any significant medical conditions (e.g. Diabetes)?**

### **Pain Factors/Treatment**

**Please list all those factors that worsen your pain/discomfort to date, in relation to physical activities:**

Lifting and/or transferring

Prolonged Sitting

Prolonged Standing

Prolonged lying and/or sleeping

Walking

Other (please list below)

## APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D PAIN DRAWING

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**Please list all those factors that worsen your pain/discomfort to date, in relation to personal care:**

- Dressing
- Turning
- Washing
- Bowel care
- Bladder management
- Other (please list below)

**Please list all those factors that relieve your pain/discomfort, to date:**

- Applying Ice or Heat
- Rest
- Change of Position
- Change of Location (e.g. other chair)
- Other (please list below)

**Please list the kind of medication/treatment received to date.**

- Painkillers  
Please also list the usage frequency (e.g. daily)
- Acupuncture  
Please also list the usage frequency (e.g. daily)
- Physiotherapy  
Please also list the usage frequency (e.g. daily)

## APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D PAIN DRAWING

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TENS

Please also list the usage frequency (e.g. daily)

Nothing

Other (please list below with the corresponding usage frequency):

### **Part II : Pain Questionnaire**

When you are in pain, you may find it difficult to do some of the things you normally do.

The questions on the next page contain some body parts that clinicians normally use to monitor pain from, and which have also been used by patients in the past to describe their pain. In addition, information is requested for the kind of medication/treatment taken in the last 2 hours.

Finally, you are requested to fill in a pain drawing with information regarding the type of pain you are suffering from, and the most exact pain location possible corresponding to this pain.

As you read the questions, please think of your condition **up to date**, and remember to read the instructions before filling the answer in.

## APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D PAIN DRAWING

### **Discomfort Level**

People normally experience pain in several body areas. Below is a list of the most common body areas affected, as related to your pain.

For each body area, please list the pain intensity on a 0-9 Scale by **CIRCLING** the number on the right which fits best to your discomfort as you experience it **TODAY**.

Zero (0) means you do **NOT** experience any pain/discomfort and Nine (9) that you experience the worst pain/discomfort you can imagine – but remember you may choose any number from zero (0) to nine (9).



Body Parts	No Pain										Worst Pain									
<b>Back</b>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
<b>Neck</b>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
<b>Buttocks</b>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
<b>Legs</b>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
<b>Arms/Shoulders</b>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
<b>Feet</b>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
<b>Hands</b>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
<b>Overall Pain/discomfort level</b>	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
<b>Please list other areas and/or the discomfort level below:</b>																				

**Please select the kind of treatment taken in the last 2 hours, if any:**

- Painkillers
- Acupuncture
- Physiotherapy
- TENS
- Nothing

## APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D PAIN DRAWING

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### **Pain Drawing**

In the next page, you will find the pain drawing, on which you are kindly requested to select your **current** pain type from the four (4) predefined listed on the top of the drawing, as well as to indicate the location of your **current** pain on the drawing provided.

Please make sure that the information you will provide reflect the pain you are experiencing **TODAY**, at the point of the pain drawing completion.

# APPENDIX C – PAIN QUESTIONNAIRE WITH THE 2-D PAIN DRAWING

Study number: 200A

MARK THE AREAS on your body where you feel these sensations.

Use the symbols.		Mark all the affected areas.	
Numbness	Tins and needles	Ache	Pain
= = =	U U U U	X X X X	/ / / /
= = =	O O O O	X X X X	/ / / /
= = =	O O O O	X X X X	/ / / /

