

# Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers: A NICE Medical Technology Guidance

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## Abstract:

As part of the development of NICE medical technologies guidance on Parafricta Bootees and Undergarments to reduce skin breakdown in people with, or at risk of, pressure ulcers, the manufacturer (APA Parafricta Ltd) submitted clinical and economic evidence which was critically appraised by the External Assessment Centre (EAC) and subsequently used by the Medical Technologies Advisory Committee to develop recommendations for further research. The University of Birmingham and Brunel University, acting as a consortium, was commissioned to act as EAC, independently appraising the submission. This article is an overview of the original evidence submitted, the EAC's findings and the final NICE guidance. Very little comparative evidence was submitted to demonstrate effectiveness of Parafricta bootees or undergarments. The sponsor submitted a simple cost analysis to estimate the costs of using Parafricta in addition to current practice compared to current practice alone, in hospital and community settings separately. The analysis took an NHS perspective. The basis of the analysis was a previously published comparative study which showed no statistical difference in average lengths of stay between those who wore Parafricta Undergarments and Bootees and those who did not. The economic model incorporated the costs of Parafricta but assumed shorter lengths of stay with Parafricta. The sponsor concluded that Parafricta was cost saving relative to the comparators. The EAC made amendments to the sponsor analysis to correct for errors and to reflect alternative assumptions. Parafricta remained cost saving in most analyses and savings per prevalent case ranged from £757 in the hospital model to £3,455 in the community model. All analyses were severely limited by the available data on effectiveness, in particular a lack of good quality comparative studies.

### Key points for decision makers

- The evidence base around the effectiveness of Parafricta Undergarments and Bootees was very limited.
- Analyses based on available evidence suggested that the use of Parafricta Undergarments and Bootees in people with or at risk of pressure ulcers was cost-saving to the NHS. However, these conclusions have a high degree of uncertainty due to the lack of robust data.
- More research is needed to confirm the clinical effectiveness assumptions and the scale of cost-savings presented in this paper.

### Compliance with Ethical Standards

The Birmingham and Brunel Consortium is funded by the NICE Medical Technologies Evaluation Programme to act as an External Assessment Centre for the Medical Technologies Evaluation Programme. This summary of the Medical Technology Guidance was produced following publication of the final guidance report. This summary has been reviewed by NICE, but has not been externally peer reviewed by Applied Health Economics and Health Policy. Catherine Meads, Matthew Glover, Paul Dimmock and Subhash Pokhrel have no conflicts of interest to report.

### Author contributions

The EAC report was prepared by CM, SP and MG. CM, SP and MG critically appraised the economic and clinical evidence submitted by the sponsor; and MG and SP critiqued the submitted cost model. This manuscript was prepared by CM, with contributions from SP and MG, with PD providing information and advice on the NICE process and minimal comments from Mark Campbell on the abstract.

CM is the guarantor for the overall content.

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## 1. Introduction

The Medical Technologies Evaluation Programme (MTEP) of the National Institute of Health and Care Excellence (NICE) produces evidence-based medical technologies guidance with the overall aim of evaluating, and where appropriate encouraging, the adoption of novel and innovative medical devices and diagnostic tools within the National Health Service (NHS) in England. Manufacturers or distributors of potentially eligible technologies notify their products to MTEP. Notified technologies must have a CE (Conformité Européenne) mark, or expect one within the next 12 months, and have the potential to offer significant clinical benefits to patients and the NHS at the same cost as current practice or reduce cost with the same clinical benefit. Technologies which the Medical Technologies Advisory Committee (MTAC) consider to have 'plausible promise' to deliver these benefits are selected for full evaluation. Guidance is produced after clinical and cost evidence submitted by the sponsor is independently assessed by an External Assessment Centre (EAC) and a public consultation period. Devices and diagnostic tools with more complex value propositions can be routed for evaluation through other NICE programmes such as the Diagnostics Assessment Programme or Technology Appraisals. NICE (2011)<sup>1</sup> describe the methods of MTEP in more detail. This article presents a summary of the EAC report for Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers. It is part of a series of NICE Medical Technology Guidance summaries being published in *Applied Health Economics and Health Policy*.

## 2. Background to the condition and its treatment

Pressure ulcers (also known as decubitus ulcers or pressure sores) are areas of localised skin damage caused by a number of intrinsic and extrinsic factors causing skin breakdown. Although anyone can develop a pressure ulcer, patients are at increased risk if they have significantly limited mobility (for example, people with a spinal cord injury), a previous pressure ulcer, are at risk of nutritional deficiency, are unable to reposition themselves or have a neurological condition or significant cognitive impairment. Pressure ulcers usually develop in people who have underlying health conditions or who have frail skin for whatever reason. Pressure ulcers tend to affect people with health conditions that make it difficult to move, especially those confined to lying in a bed or sitting for prolonged periods of time. They tend to occur more often in the elderly but can occur at any age. Conditions that affect the flow of blood through the body, such as type 2 diabetes, can also make a person more vulnerable to pressure ulcers. It is estimated that 412,000 people will develop a new pressure ulcer annually in the NHS<sup>2</sup>.

Pressure ulcers can develop when a large amount of pressure is applied to an area of skin over a short period of time or when less pressure is applied over a longer period of time and tend to develop over bony prominences, particularly heels and the sacrum. The extra pressure disrupts the flow of blood through the skin. Without a blood supply, the affected skin becomes starved of oxygen and nutrients and begins to break down, leading to an ulcer forming. Skin damage is also believed to be

caused by friction, shear and moisture<sup>3</sup>, but the extent of the contribution of these is low – 7.5% in a sample of 28,299 hospital patients<sup>4</sup> and 13.9% in a sample of 17,966 long term care residents<sup>5</sup>.

Grading of pressure ulcers is by four grades<sup>6</sup>:

- Grade 1 – The affected area of skin appears discoloured and is red in white people, and purple or blue in people with darker coloured skin. They do not turn white when pressure is placed on them and skin remains intact but may hurt or itch. It may also feel either warm and spongy, or hard.
- Grade 2 – Some of the epidermis or the dermis is damaged, leading to skin loss. The ulcer looks like an open wound or a blister.
- Grade 3 – Skin loss occurs throughout the entire thickness of the skin and the underlying tissue is also damaged but muscle and bone are not damaged. The ulcer appears as a deep, cavity-like wound.
- Grade 4 - The skin is severely damaged and the surrounding tissue becomes necrotic. The underlying muscles or bone may also be damaged. People with grade 4 pressure ulcers have a high risk of developing a life-threatening infection.

For some people, pressure ulcers are an inconvenience that require minor nursing care. For others, they can be serious and lead to life-threatening complications such as blood poisoning or gangrene. In people with diabetes mellitus they are a cause of foot amputations. Pressure ulcers can lead to delayed hospital discharge but it is currently unclear as to how much of this is happening in the NHS. It is estimated that the cost per patient to heal an ulcer varies from £1,214 for Grade 1, £5,241 for Grade 2, £9041 for Grade 3 to £14108 for Grade 4<sup>7</sup>.

Treatment for pressure ulcers includes regularly changing a person's position, the use of dressings, creams and gels designed to speed up the healing process and relieve pressure, and using equipment to protect vulnerable parts of the body, such as specially designed mattresses and cushions. Regarding the latter, draft NICE guidance states "Pressure redistributing devices are widely accepted methods of trying to prevent the development of pressure areas for people assessed as being at risk. These devices include different types of mattresses, overlays, cushions and seating. They work by reducing pressure, friction or shearing forces. There is limited evidence on the effectiveness of these devices"<sup>8</sup>. For the most serious cases, surgery is sometimes recommended. One issue with all pressure relief equipment is the impact it has on the patient's ability to self-reposition and move around the bed. Much of the equipment currently in use in the NHS addresses the offloading issues in pressure ulcer prevention but does not address repositioning.

### 3. The Decision Problem

#### 3.1 Population

The target population was any adults or children (excluding very young children) with, or at risk of, pressure ulcers, in a hospital or community setting.

#### 3.2 Intervention

The intervention was Parafricta which can be one or two Bootees and/or Undergarment. Parafricta is made from a proprietary fabric which has a low friction coefficient and the intended mode of action is to reduce the friction component of skin breakdown. The NICE final scope did not specify whether this referred to a single garment only or the use of two or three garments together. Parafricta is used as an adjunct to pressure reducing devices used in standard NHS clinical practice.

#### 3.3 Comparators

The comparators in the NICE final scope were pressure reducing devices used in standard NHS clinical practice, and also one of the following three options:

1. No Parafricta (i.e. pressure reducing devices alone)
2. Sheepskin
3. Pressure-relieving bootees

#### 3.4 Outcomes

Relevant outcome measures included:

- incidence of grade 1 or 2 pressure ulcers progressing to grade 3 or 4
- incidence of developing pressure ulcers
- incidence of skin breakdown
- severity of pressure ulcers
- length of hospital stay
- time-to-healing for those who present with an existing pressure ulcer
- patient compliance with pressure ulcer management interventions
- patient comfort: including ability to move and self-reposition in bed
- quality of life
- morbidity
- device-related adverse events

### 4. Review of the clinical and economic evidence

The sponsor submitted clinical and economic evidence based on the scope issued by NICE. The economic evidence included a *de novo* economic model. The EAC critically appraised the submission and carried out additional analyses to evaluate the outcomes identified in the scope.

## 4.1 Clinical effectiveness evidence

### 4.1.1 Sponsor's review of clinical effectiveness evidence

There were seven included studies in the submission, of which three were single case studies<sup>9,10,11</sup>, two were small uncontrolled case series<sup>12, 13</sup>, one was a small partially controlled case series<sup>14</sup> and one was a larger case series with documented historical controls<sup>15</sup>. There was also an unpublished audit<sup>16</sup>, which has now been published<sup>17</sup>. See Table 1 and Table 2 for an overview of these studies. The submitted studies evaluated one Parafricta Bootee, one or two Bootees, or Undergarments, or a combination of Bootees and Undergarments. The evidence is generalizable to the UK setting.

The three single case studies need no further description, and their results are in Table 2. The case series by Loehne (2013)<sup>12</sup> gave no information on the study design other than that it was a case series of the use of Parafricta Bootees in nursing home patients. Stephen-Haynes (2011)<sup>13</sup> was a case series of 25 nursing home residents evaluating Parafricta Bootees or/and Undergarment added to standard approach as outlined by NICE guidance 2005. There was no comparator. Results of these studies are also in Table 2.

Hampton (2009)<sup>14</sup> was a case series of 25 nursing home residents. A single Parafricta Bootee was used on the right heel in 10 patients, with the left heel used as comparator. Eighteen patients had Parafricta Undergarments and there was no comparison group. The duration of follow up was four weeks. The outcomes were measured in three ways

1. Bogginess and redness of skin as assessed by tissue viability nurse
2. Colour photographs and
3. High frequency ultrasound graphs.

The reason for three different ways for measuring outcomes was because of the difficulty of assessing skin oedema. Bogginess and redness was judged to be very subjectively assessed. Colour photographs did not reproduce the nature of the skin damage well as the colour reproduction depended on ambient light levels. The ultrasound graphs were an attempt to measure thickening of the skin from oedema and were felt to be the most reliable outcome measure and were presented as mean pixel number vs intensity. These have not been reproduced because of copyright issues. The results suggested that heels with Parafricta bootees became similar to normal heels within 4 weeks, and this was suggested to be because of a reduction in skin oedema.

Smith and Ingram 2010<sup>15</sup> recruited 165 patients in three months, compared with 204 historical controls recruited in the previous three months of similar conditions in same hospital wards (two medical wards and one orthopaedic ward). All patients were at high risk of pressure ulcers (Waterlow score of  $\geq 15$ ), some had pressure

ulcers on admission and some did not. All were unable to reposition independently. The intervention was the addition of Parafricta Bootee or/and Undergarment to standard pressure ulcer preventative measures. Outcomes were the incidence improvement and deterioration of pressure ulcers and cost effectiveness. This study provided the effectiveness evidence for the economic model. Smith and Ingram (2010) analysed results in pressure ulcer incidence, improvement and deterioration using differences in incidence. These are reproduced in Table 3. As incidence differences are difficult to interpret these were recalculated using relative risks (in Revman 5.2) and the results shown in Table 4. The results from the study, whichever way it is analysed suggest that the Parafricta cohort had fewer patients who developed pressure ulcers in patients without pressure ulcers on admission but no difference in the development of additional pressure ulcers in patients who already had a pressure ulcer. Also the results suggest that fewer pressure ulcers deteriorated in the Parafricta cohort. There were no statistically significant differences in length of stay between cohorts 1 and 2 but the lengths of stay were not given. The results in Waterlow scores are shown in Table 5.

The audit at St Helen's & Knowsley NHS Trust<sup>16,17</sup> was of the use of Parafricta Bootees for patients considered at risk of a heel pressure ulcer, compared to current practice of using a protective hydrogel dressing, which had not been published. This audit was started in 2013 and was planned to go on for two years, but the first year's results were available at the time of the appraisal. Gleeson D (2014) was a clinical audit of the use of Parafricta Bootees on an unknown number of patients on 6 hospital wards at St Helens and Knowsley NHS trust between January and December 2012 and was submitted as academic-in-confidence material. How it was conducted was unclear as there were no details in the manuscript. Characteristics and results are in Table 2. This study has since been published (Gleeson 2015) and the information remains consistent with that from the unpublished manuscript.

#### 4.1.2 Critique of clinical effectiveness evidence

Smith and Ingram 2010<sup>15</sup> formed the basis of the economic model so is discussed further here. It was a case series with historical controls, i.e. a single centre controlled before after study. According to the Cochrane Collaboration, a study design such as that used in Smith and Ingram (2010) in which there is only one intervention or control site, "the intervention (or comparison) is completely confounded by study site making it difficult to attribute any observed differences to the intervention rather than to other site-specific variables"<sup>18</sup> (EPOC 2014). Therefore, this study design provides relatively weak comparative evidence as the observed results may have been due to confounding. As no numerical results of length of stay by cohort, no numbers of deaths in either cohort and no demographic characteristics in either cohort or combined were given, it is impossible to tell how similar the cohorts were. The only information available was the Waterlow score from the economic submission which suggested that the cohort not given Parafricta may

have been more at risk of pressure ulcers than those given Parafricta. The difference in pressure ulcers could also be because the Parafricta cohort patients were less ill than those in the historical comparison cohort. Therefore, it cannot be inferred that any change in pressure ulcer incidence, improvement or deterioration was due to the use of Parafricta Bootees and/or Undergarments.

Additionally, as the patients in the study could not reposition themselves (an inclusion criterion for the study) they represented only a subset of the population who might potentially benefit from Parafricta. If patients couldn't reposition, then movement would be limited so it would be likely that any pressure ulcers occurring would have been caused by pressure rather than friction.

## 4.2 Economic evidence

### 4.2.1 Sponsor's economic submission

Smith and Ingram (2010) was the single economic study identified in the sponsor submission. This cost-analysis estimated that the use of Parafricta garments may reduce the cost of pressure ulcers by £637 per at risk patient admitted to hospital, net of the cost of purchase and laundering. Costs were estimated from an NHS perspective, but the price base year was not explicitly stated. These savings were the result of the estimated reduced length of hospital stay experienced by patients using the Parafricta garments.

The sponsor acquired the raw data on incidence of pressure ulcers and associated lengths of stay from this study and used the information as the basis of a new cost model. They used this information to conduct two separate analyses; one in a hospital setting and one in a community setting to perform a cost-analysis of the use of Parafricta Bootees and Undergarments as an adjunct to other pressure reducing devices used as standard in the NHS. In the hospital model, potential cost savings were driven by reductions in length of stay and in the community model by a reduction in nurse/carer interventions reflecting lower prevalence of pressure ulcers.

The hospital model consisted of five potential pathways for patients admitted to hospital and at-risk of pressure ulcers: 1. admitted without pressure ulcer(s) and remained without; 2. admitted without a pressure ulcer(s), but developed a pressure ulcer in hospital; 3. admitted with a pressure ulcer(s) which did not deteriorate, 4. admitted with a pressure ulcer(s) which deteriorated and, 5. admitted with a pressure ulcer(s) and developed an additional pressure ulcer in hospital. The proportion of patients in each potential pathway for both the historical control group and Parafricta group is shown in figure 1, depicted as a decision tree. Median length of hospital stay for each of the pathways was weighted by incidence. In the MS Excel implementation of the model, relevant per day costs were then applied to relevant proportions of weighted stay, based on the expected time to development of an ulcer and length of stay. Costs differ for those days spent without a pressure ulcer, where only general hospital costs were incurred, and days with a pressure ulcer. Dressing costs and per-day unit costs for hospital stay<sup>19</sup> are detailed in table 6. This analysis estimated costs of £5,307 per at-risk patient without the use of Parafricta and £4,550



per-risk patient when using parafricta, a cost saving of £757. Some limited sensitivity analyses were performed which suggested the results were robust to assumptions.

The community model used data from the Smith and Ingram study (2010) and constituted a steady-state comparison of costs with and without the use of Parafricta. Using the incidence of pressure ulcers amongst those patients without an ulcer on admission, and the length of stay after development of an ulcer as a proxy for duration, the point prevalence with and without the use of Parafricta was estimated. It was assumed that without Parafricta, for every patient in the community with a pressure ulcer, there will be two other at-risk patients without a pressure ulcer. The sponsor stated that this was consistent with published audits of prevalence<sup>3,20</sup>. Costs without Parafricta were then estimated based on the cost of nurse visits/ carer interventions (1.86 per week) related to prevalent pressure ulcer cases over a year of resource use. The cost without use of Parafricta was £5,899.92 and with use of Parafricta £2,444.93, based on a relative prevalence ratio of 0.37.

#### 4.1.2 Supplementary economic analyses conducted by the EAC

The EAC verified the sponsor's search strategies and no additional economic studies were identified. The EAC validated the sponsor's economic model and reconstructed decision tree for clarity as well as validity check.

Minor errors in the unit costs used in the Hospital model were encountered and rectified, uprating to 2013/14 pounds sterling, where appropriate. A minor modelling anomaly that lead to the double counting of some dressing costs was also rectified. These changes did not have a substantial impact on results, given the relatively small cost of dressings. The EAC noted that the costs associated with the pathways reflecting change in pressure ulcer condition for those admitted with a pressure ulcer (pathways 3, 4 and 5) did not incur different costs. This differentiation had the effect of diluting data on length of stay, increasing uncertainty. Therefore, the EAC presented a slightly modified decision tree, encompassing pathways 3, 4 and 5 into one single pathway "Admitted with PU". (See figure 2)

The cost of a bed-day in the Hospital model was revisited. The EAC acknowledged the difficulty in identifying an appropriate per day cost of "hotel stay" alone, but did not feel that the sponsor estimate was sufficiently robust. National Reference Costs<sup>21</sup> for excess bed days were used as a reasonable proxy. The Smith and Ingram (2010) paper identified that the at-risk population were treated on general medical wards and trauma and orthopaedics wards. The EAC therefore used excess bed days for general medicine and trauma, and orthopaedic wards, for the gamut of skin disorders (with and without intervention and the whole range of severity) to calculate a weighted cost. The weighted costs are shown in table 7. The sponsor estimate of £325 may have been at the higher end of the bed day cost. The EAC model used £234 as the base case and ran a sensitivity analysis of £328 as an upper limit.

The Sponsor's model had used median values for length of stay in both the Hospital and Community models. Although length of stay results may be skewed, they reflected the nature of length of stay as observed in NHS practice; some patients require significantly longer time in hospital. It is hard to assume that these longer lengths of stay constitute outliers. For modelling purposes, an arithmetic mean would better represent the average length of stay experienced for each of these groups and thus the EAC subsequently used mean values in the hospital and community cost models.

After rectifying minor errors, re-estimating bed day costs and modification to the structure of the hospital model, supplementary analyses conducted by the EAC focused on attempting to account for the two main weaknesses identified in the economic modelling included in the submission:

- Adjusting estimates of patient length of hospital stay for potential confounders.
- Reflecting uncertainty in input parameters in a more comprehensive manner.

The EAC was provided with the raw data from Smith and Ingram (2010) by the sponsor. The information was reanalysed by the EAC to consider a limited number of confounders: patient's gender, Waterlow score and the ward of admission. A log-linear model of length of stay was fitted on Parafriacta (1/0), gender (male/female), Waterlow score (medium/high risk) and location (medical1/medical2/orthopaedic ward). Model diagnostic tests confirmed a good fit. As expected, the model was only able to explain about 4% of the variation in length of stay, as the potential predictors of length of stay were limited. Nevertheless, it was thought to provide better estimates than unadjusted estimates. Lengths of stay and their standard errors for all potential pathways were then predicted from the model.

The EAC version of the hospital model estimated the base-case cost savings to be £595, as opposed to the sponsor's estimate of £757. For the one way sensitivity analysis with a bed day costing £328 the costs saving increased to £863. The probabilistic sensitivity analysis suggested that in nearly 8 out of 10 occasions the use of Parafriacta resulted in cost-savings.

The use of adjusted mean length of stay data fed into the community model, to estimate a prevalence ratio. Probabilistic analysis incorporating distributions around the time to develop a pressure ulcer and the length of stay was not possible because a negative value of the duration of ulcer could be encountered during distribution draws. An illustrative deterministic sensitivity analysis using upper and lower 95% limits of length of stay was performed to re-estimate cost savings. The EAC version estimated the cost savings in the community as £2,510 per annual prevalent case, as opposed to £3,455 per annual prevalent case. The deterministic sensitivity analysis suggested that the cost-savings could be between £2,295 and £2,799.

## 5. NICE guidance

### 5.1 Preliminary guidance

The evidence submitted by the sponsor and the EAC's critique of this evidence was presented to MTAC who provided draft recommendations relating to Parafricta Bootees and Undergarments following their meeting in May 2014. These were:

“1.1 Parafricta Bootees and Undergarments show potential to reduce the development and progression of skin damage caused by friction and shear in people with, or at risk of, pressure ulcers. However, more evidence for their effectiveness in clinical practice is needed to support the case for routine adoption of Parafricta Bootees and Undergarments in the NHS.

1.2 Research is recommended to address uncertainties about the claimed patient and system benefits of using Parafricta Bootees and Undergarments. This should take the form of comparative research against standard care, preferably carried out in secondary care for ease and speed of generating findings. The research should include development of criteria to recognise people who would most benefit from the technology in community and secondary care. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will review this guidance when substantive new evidence becomes available.”

### 5.2 Consultation response

During the consultation period NICE received 19 consultation comments from 4 consultees (3 NHS professionals and 1 manufacturer). The comments concerned further academic in confidence data and requests to focus the recommendations on the effect of Parafricta Bootees on skin breakdown of the heel in adults only. The Committee considered the further academic in confidence data and the suggested focus on the effect of the Bootees only. The Committee judged significant uncertainties in the evidence base remained and could not recommend routine adoption of Parafricta in the NHS. There were therefore few changes made before publication of the final NICE guidance.

## 6. Key challenges and learning points

Key Challenges:

- The lack of good quality comparative studies reduced the scope for a robust economic analysis
- Ambiguity in the presentation of sponsor's submission posed challenges in understanding some of the basic ideas and facts used to describe the cost model and its inputs

Learning points:

- Future studies should collect and record detailed data on potential confounding variables

- Future submissions should, where possible, provide the raw data on which the economic model is based, as having raw data in this appraisal was very helpful to test the underlying assumptions and validity of the model

Tables and figures:

Table 1. Comparative studies

Primary study (acronym)	Population	Intervention	Comparator	Outcomes measured and their results	Comment
Hampton S (2009)- (JCN2009)	Case series of 25 nursing home residents with grade 2-3 pressure ulcers on one or more heels (10 patients) or the sacral area (18 patients). All patients had appropriate pressure ulcer equipment for at least 2 weeks prior to the study start. No information on ages, medical conditions or durations of pressure ulcers.	Single Parafricta Bootee on right heel, or undergarment according to damage location Duration 4 weeks but unclear whether this was for all patients.	For heel: comparator was patient's untreated left heel. For sacral ulcers – historical comparison only	Skin oedema and damage as assessed by: 1. Bogginess and redness of skin as assessed by tissue viability nurse 'in 100% of the heel cases the 'bogginess' of the skin was reduced' 2. Colour photographs 3. High frequency ultrasound graphs These show an apparent improvement in the Parafricta Bootee'd heels compared to a control heel	Bogginess – subjective outcome. Colour photograph results not presented as they were not always representative of nurse assessment of the skin. Ultrasound – no independent validation presented, would need to link improvement curve shown in graphs presented to clinical improvement in the patient. Therefore graphs difficult to interpret clinically.
Smith and Ingram (2010) - (JWC2010)	Case series of 165 patients recruited in 3 months, compared with 204 historical controls (previous 3 months) of similar condition in same hospital wards (2 medical and 1 orthopaedic wards, UK hospital). All patients were at high risk of pressure ulcers (Waterlow score of $\geq 15$ ), some had pressure ulcers on admission and some did not. All were unable to reposition independently.	Cohort 2. Addition of Parafricta Bootee or/and Undergarment to standard pressure ulcer preventative measures.	Historical comparison Cohort 1: standard pressure ulcer preventative measures (without the addition of Parafricta Bootees and Undergarments)	For incidence of pressure ulcers and deterioration see separate table. No statistically significant differences in length of stay between cohorts 1 and 2	If patients couldn't reposition then movement would be limited so likely that pressure ulcers caused by pressure rather than friction. No numerical results of length of stay by cohort. No numbers of deaths in either cohort. No demographic characteristics in either cohort or combined. Cannot tell how similar the cohorts were.

**Table 2. Case studies or series with no comparative groups fully described**

<b>Primary study (acronym)</b>	<b>Population</b>	<b>Intervention</b>	<b>Comparator</b>	<b>Outcomes measured and their results</b>	<b>Comment</b>
Bree-Aslan (2008). (NRC3)	Case study of one nursing home diabetic patient aged 85 with arterial and venous insufficiency and a Grade 4 heel pressure ulcer measuring 3.5x3.3cm, being nursed on a dynamic air mattress and using a soft fibre bootee.	Cavilon spray, Hydrogel dressing then Versiver dressing on top. Plus Parafricta Bootee over it for one week.	Historical comparison from the same person only	'marked improvement in the wound bed and no further damage to the surrounding tissues'.	Impossible to determine whether the improvement was temporary or permanent or was due to the hydrogel dressing, the Parafricta Bootee or unrelated to either and would have happened anyway.

Primary study (acronym)	Population	Intervention	Comparator	Outcomes measured and their results	Comment
<p>Gleeson (2014)</p> <p>(unpublished manuscript)</p> <p><i>(information from Gleeson 2015 in italics)</i></p>	<p>Clinical audit of 6 hospital wards with patients at high risk of pressure ulcers.</p>	<p>232 Parafricta Bootees used with unspecified number of patients. <i>(for the first 6 months, rising to 1024 bootees in total)</i></p> <p>Also pressure reducing/relieving products including 4-sectional electric profiling beds, pressure-reducing foam, alternating air mattresses, heel troughs and cushions. <i>(Some patients also given a transparent film dressing to protect the heel)</i></p> <p>Also education and training on pressure ulcers</p>	<p>Summary historical comparison only, not described</p>	<p>32% reduction in reportable hospital-acquired grade 2 pressure ulcers compared to the previous year, presumably on these wards. Overall there was a Trust-wide drop in pressure ulcers of 76%. There was a 9% increase in Trust-wide activity in 2012, presumably compared to 2011</p>	<p>The decrease in pressure ulcers was probably not due to a decrease in hospital activity but may be related to education and training initiatives and investment in a range of pressure reducing products. It is unclear how much of this 76% reduction in pressure ulcers in the Trust overall was due to Parafricta Bootees and how much was due to the other initiatives taking place at the Trust.</p>

<b>Primary study (acronym)</b>	<b>Population</b>	<b>Intervention</b>	<b>Comparator</b>	<b>Outcomes measured and their results</b>	<b>Comment</b>
Hampton S (2007) (NRC1)	Case study of one nursing home patient aged 82 with multiple sclerosis and with sore and broken skin over the buttocks for several months, being nursed on an air mattress.	Parafricta Undergarment for one week	Historical comparison from the same person only	'in less than one week the soreness had disappeared and the skin was clear'	Impossible to tell whether the improvement was temporary or permanent or whether it was due to the Parafricta Undergarment or would have happened anyway.
Kerr A (2008). (NRC2)	Case study of one nursing home patient aged 70 years with poor mobility and with at least 3 month's history of macerated and excoriated buttocks with deep split wounds and inflammation. Sudocreme had been applied.	Parafricta Undergarment	Historical comparison with Sudocreme on the same person only	'reduced inflammation with the open areas showing signs of closure'	Impossible to tell whether the improvement was temporary or permanent or whether it was due to the Parafricta Undergarment or previous allergy to Sudocreme or would have happened anyway.
Loehne, H.B. (2013). (SAWC1)	Case series of an unknown number of US nursing home patients. No information on sex, age, current condition, duration, grade or site of pressure ulcers.  Excluded were patients with, or at risk of, pressure ulcers on the heel or foot due to pressure only.	Parafricta Bootee.  Unclear if both feet or only one.  Dressings (not specified) in some patients.  Follow up at 30 days.	Unclear.	None of the unknown number of patients had developed pressure ulcers or had re-opening of closed wounds.	This does not present any evidence of effectiveness as there is minimal information on patients.



<b>Primary study (acronym)</b>	<b>Population</b>	<b>Intervention</b>	<b>Comparator</b>	<b>Outcomes measured and their results</b>	<b>Comment</b>
Stephen-Haynes (2011) (WUK2011)	<p>Case series of 25 nursing home patients at-risk of pressure ulcers (n=5) or with a pressure ulcer (n=20, 10 with category 1 ulcer, 10 with category 2 ulcer).</p> <p>Characteristics included steroid use (n=1), CVA (n=6), dementia (n=3), multiple sclerosis (n=3).</p>	Parafricta Bootee or/and Undergarment added to standard approach.	None	<p>Skin improvement: 76% improvement, 24% same. Ease of use: very easy in 64% patients, easy in 16%, fairly easy in 16% and difficult in 4%). Garment retention: 48% clinicians found it very easy to keep garments in place, 16% easy, 20% fairly easy, 16% not easy. Patient comfort: 76% very comfortable, 24% comfortable.</p>	Impossible to tell whether any improvement in pressure ulceration was temporary or permanent or whether it was due to the Parafricta Undergarment or would have happened anyway.

**Table 3. Reported results from Smith and Ingram (2010)**

	Subgroups	Historical controls incidence (%)	Parafricta cohort incidence (%)	% difference (Parafricta – control )	P value
No pressure ulcer on admission	A, Did not develop a pressure ulcer	67 (59)	58 (75)	16	0.03
	B. Developed a pressure ulcer	46 (41)	19 (25)		
Pressure ulcer on admission	C. Did not develop an additional pressure ulcer	67 (74)	73 (83)	9	0.18
	D. Developed an additional pressure ulcer	24 (26)	15 (17)		
Subgroup B.	The pressure ulcer improved	16 (33)	14 (74)	41	0.01
	The pressure ulcer stayed the same or deteriorated	32 (67)	5 (26)		
Subgroup D.	The pressure ulcer deteriorated	18 (27)	4 (6)	-21	0.001
	The pressure ulcer stayed the same or improved	49 (73)	69 (94)		

**Table 4. Calculated relative risks for Smith and Ingram 2010**

		Cohort 1 (no Parafricta)	Cohort 2 (Parafricta)	Relative risk (95%CI)*
Pressure ulcer on admission	That pressure ulcer deteriorated	18/67	4/73	4.90 (1.75-13.75)
Pressure ulcer on admission	Developed an additional pressure ulcer	24/91	15/88	1.55 (0.87-2.75)
No pressure ulcer on admission	Developed pressure ulcer	46/113	19/77	1.65 (1.05-2.59)
No pressure ulcer on admission but one developed during hospital stay	Pressure ulcer same or deteriorated	32/48	5/19	2.53 (1.16-5.52)
*Calculated in Revman 5.2				

**Table 5. Waterlow scores from Smith and Ingram (2010)**

<b>All incidences</b>			
	Waterlow score	Number	Percentage
Cohort 1	15-19	103	50.00%
Pre Parafricta products	20-24	82	39.81%
	25+	21	10.19%
<b>Total</b>		<b>206</b>	
Cohort 2	15-19	94	56.97%
Post Parafricta products	20-24	52	31.52%
	25+	19	11.52%
<b>Total</b>		<b>165</b>	
Chi Square Test result P value			
		0.2553898	
		p-value from Chi-square test (implies non-difference if > 0.05)	

Table 6 Hospital model unit costs

<b>Unit cost</b>	<b>Per day cost</b>	<b>Source</b>
Bed day	£325.00	Sponsor assumption
General dressing	£0.74	Smith and Ingram (2010)
Average Mattress cost	£0.59 <sup>†</sup>	Smith and Ingram (2010)
<b>General hospital costs</b>	<b>£326.33</b>	(£325 +£0.74 +0.59)
<b>Average PU dressing</b>	<b>£0.74<sup>‡</sup></b>	Smith and Ingram (2010)
<sup>†</sup> (86% mattress @ £0.30, 14% Nimbus @ £2.37), <sup>‡</sup> (70% cat 1 dressing @ £0.48, 25% cat 2 dressing @ 1.11, 5% cat 3 dressing @ £2.59)		

Table 7 EAC bed-day costs

<b>Ward</b>	<b>Type of admission</b>		
	Elective	Non-elective	Weighted
General Medicine	254.2	225.9	226.3
Skin disorders only	510.2 <sup>†</sup>	222.8	225.7
Trauma and Orthopaedics	310.1	265.2	274.7
Skin disorders only	241.2	274.5	271.3
Combined GM and T&O	302.5	236.1	241.1
Skin disorders only	327.5	231.4	<b>233.9</b>
†based on a small numbers of cases (281)			

Figure 1

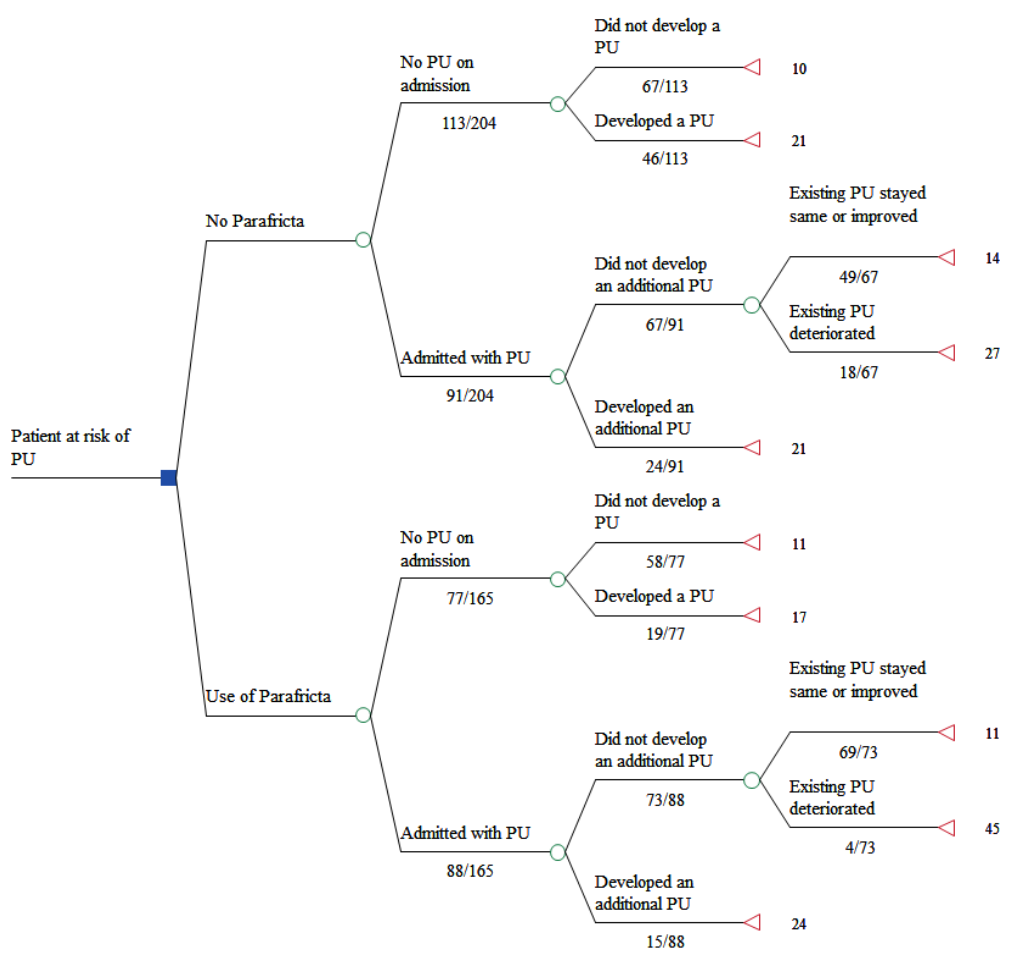
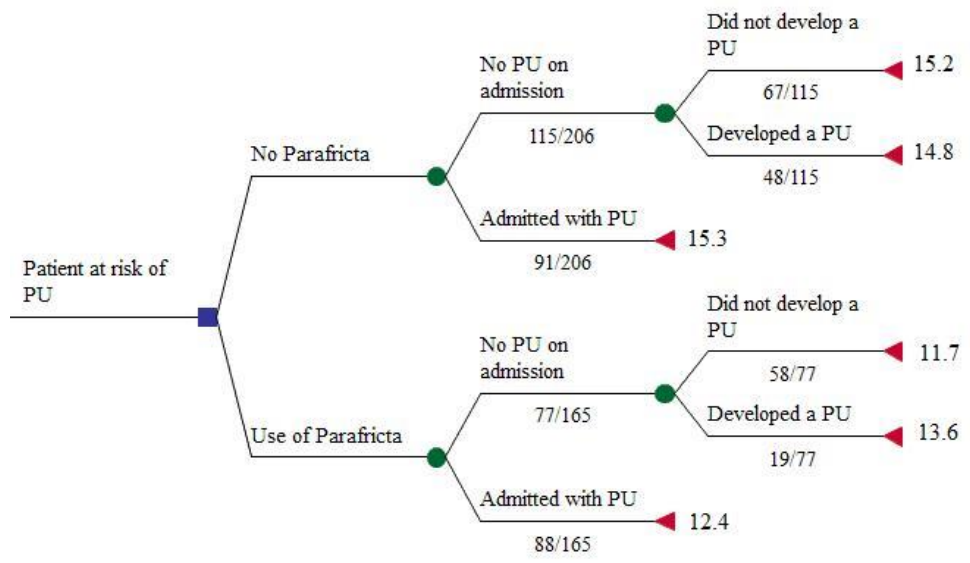


Figure 2



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