Clinical and cost effectiveness evaluation of low friction and shear garments

- **Objective:** To determine the effectiveness of Parafricta low-friction garments in reducing the incidence and prevalence of pressure ulceration and to evaluate the curative aspects of these products on pre-existing skin breakdown within a hospital setting.

- **Method:** Patients with a Waterlow score of ≥15 and who were unable to reposition independently were offered the low-friction undergarments and bootees. A total of 650 patient cases were initially reviewed. Of these, 204 met the criteria for use of the products in the 3 months prior to the start of the evaluation (cohort 1) and 165 patients met the criteria during the period when the garments were used (cohort 2). Data collected included pressure ulcer incidence, location, grading, and outcome of ulcer on discharge. Locally derived costs for length of stay, wound dressings, pressure-redistributing mattresses and additional cost of the low-friction garments were applied to build a cost-effectiveness model.

- **Results:** In patients at risk of skin breakdown there was a statistically significant reduction in the number of patients who developed pressure ulcers following use of the low-friction garments in cohort 2 when compared with cohort 1 (16% reduction; p = 0.0286). In addition, the number of patients who were ulcer free on admission but who developed ulcers and then improved or completely healed before discharge was also statistically significant (41% increase; p = 0.0065) when cohort 2 was compared with cohort 1. Fewer patients admitted with ulcers deteriorated when using the low-friction garments (21% reduction; p = 0.0012). The costs, which were calculated by comparing patient throughput for these patients, suggest that the savings associated with preventing skin breakdown outweighed the cost of the products used (base case model indicated a saving of over £63,000 per 100 at risk patients).

- **Conclusion:** The results support the conclusion that low-friction garment products have a role to play in the prevention of skin breakdown, and appear to be both clinically effective and cost effective.

- **Declaration of interest:** The authors have no conflicts of interest to declare. APA Parafricta provided the products, as well as financial support for training of the ward staff who participated in the evaluation and for the data collection and analysis (which was performed by Xcelerate Health Outcomes Unit, NHS Innovations London).
Method
Two medical wards and one orthopaedic ward in a UK district general hospital participated in this evaluation. Inclusion criteria were patients with a Waterlow score ≥15 (i.e. patients at high or very high risk of pressure ulceration) with or without pressure ulceration on admission who were unable to reposition independently.

Patients were divided into two consecutive cohorts, which received identical care except that patients in cohort 2 at high risk of sacrum or heel/ankle skin breakdown wore the Parafricta undergarments or bootees (the low-friction garments). The ward staff were given full details on the test garments as well as training on their use.

All patients in both cohorts were cared for on Invacare/MSS Softform Premier Glide mattress and Huntleigh Healthcare Nimbus 3 alternating surfaces, with at risk patients being repositioned two hourly. Similarly, the protocol of all other interventions (e.g. nutrition) was identical across both cohorts. A low staff turnover on these wards meant that the same group of nurses attended both cohorts, thereby providing consistency of care.

The low friction products are CE marked and were used in accordance with the manufacturer's guidelines and training.

The evaluation, including issues of consent and data sharing, was discussed with the trust’s clinical governance team prior to implementation. The product standardisation groups for the trust, which are responsible for overseeing the appropriate evaluation and use of new products in NHS settings, were also informed.

The infection control team and health and safety manager were familiarised with the products, which are machine washable at the trust’s required level for cleanliness. Standard NHS procedures were used for washing, cleansing and returning the test garments to the ward areas.

Assessment
Table 1 overviews the data collected during the evaluation. The data were kept anonymous to protect patient confidentiality and to meet the information governance requirements for sharing information with commercial organisations according to local guidance and policy.

Pressure ulcer incidence
For cohort 1, 3 months (July to September 2009) of incidence data were collected as part of the standard hospital practice for recording pressure ulcer incidence.

For cohort 2, the data were collected for 3 months (October to December 2009) from the start of use of the low-friction garments on the at-risk patients in the same manner.

Pressure ulcer prevalence
The PU prevalence of pressure ulceration was noted at the end of the 3-month assessment periods in cohort 1 and cohort 2. These data were taken from the patient documentation prepared for the tissue viability nurse (TVN) at the time of discharge from the hospital or death, which stated whether a PU had developed, and from the risk management software, which listed patients at risk of pressure ulceration.

Outcome measures
These outcomes were considered to be indicative of a positive effect for the low-friction garments:
- A reduction in the incidence of PUs in cohort 2 when compared with cohort 1
- Ulcers that occurred after admission that took longer to develop and were less severe: this was
based on the contention that if the friction and shear reduction is effective, the PU will take longer to develop and the damage (evidenced in the PU category) will be less

- The cost-effectiveness of the low-friction garments i.e. whether any reductions in treatment costs outweigh the initial item cost.

**Cost calculation**

Bed-stay cost was based on the average cost of stay on each ward per day. There is a clear link between ulceration, ulcer category and length of stay.\(^1,5\) For our purposes, the bed stay cost was based on the hotel cost and the average cost of nursing time per day to cover that bed (£350). The cost data were provided by the Isle of Wight PCT finance department.

Dressing audit data (most common dressing type and frequency of dressing change) from August 2009 were used. The cost for each dressing was taken from the 2009 dressing catalogues and applied across both cohorts; the daily cost for each dressing category of PU was based on an average cost of each dressing over the period used. Data were available for PU categories 1, 2 and 3. Local data for dressing types for category 4 were not available as no category 4 PUs were present during the evaluation period.

The cost of support surfaces was calculated, based on the most common high specification foam mattress in use in the wards involved (Invacare/MSS Softform Premier Glide mattress; assumed asset life 2 years), and the most commonly used alternating pressure mattress (Huntleigh Healthcare Nimbus 3 mattress; assumed asset life 3 years).

**Data analysis**

Anonymous patient data were exported from the risk management system into a Microsoft Excel spreadsheet. Data were collected for the two separate 3-month evaluation periods for cohorts 1 and 2. Patients with a Waterlow score <15 and/or ulcer(s) located in areas other than the sacrum or heel area were excluded from the analysis.

The patient and ulcer incidence flows were mapped to give a clearer picture of the various pathways for the incidences of PUs after hospital admission. There were four distinct pathways for both cohorts:

- Patients with no PUs at hospital admission who remained ulcer free
- Patients with no PUs at hospital admission who developed a PU(s) during their hospital stay
- Patients with PUs at hospital admission who did not develop any additional ulcers during their stay
- Patients with PUs at hospital admission who developed additional ulcers during their stay.

The results of the patient flows were compared to determine any statistical difference between the cohorts in terms of the four possible pathways. Also recorded were outcomes in terms of whether the ulcer improved, stayed the same or became worse. Ulcer categorising data were also collected.

We also established several other comparators in order to undertake a proper cost-effectiveness analysis, in particular whether there were any differences between the median lengths of stay between the patients in the four pathways. (Median was selected rather than mean as it is a more appropriate measure of central tendency in the dataset because of outliers.) Confidence intervals at 95% were also determined for the lower and upper limits of the median length of stay.

The assumption was that patients who developed PUs or whose PUs worsened would remain in hospital longer than those who did not. Furthermore, if the garments lower the incidence of PUs or improve healing, then the length of stay and time taken to develop ulcers would be reduced, provided that any comorbidities were also treated.

In order to compare the results between the two cohorts, it was important to establish that the cohorts were similar in terms of:

- No significant differences between their general medical conditions, as measured by Waterlow score
- Access to pressure-reducing mattresses
- The number of PU assessments made.

Statistical analysis using z test of proportion, chi square and t tests were applied to determine statistical significance and confidence intervals (CIs) for the relevant data.

- **Cost-effectiveness model** The results of the data analysis were used to build a cost-effectiveness model to determine the financial impact of using the low-friction garments if the incidence of PUs was reduced and quicker healing occurred. The objective was to determine whether it will be cost-effective to use these garments in the hospital environment and whether their extra cost is offset by the additional savings made following a reduction in ulcer incidence, improvement in ulcer outcome and reduction in length of hospital stay.

In order to build the cost-effectiveness model, three assumptions were made:

- Difference in length of stay was an acceptable measure to determine the extra burden that PU development or deterioration would have on hospital costs. The asset life of the low-friction garments was assumed to be one year as they are washable at high temperatures and can be reused a number of times. Based on the observed patient flow data in the two cohorts, for every 100 patients for whom the garments will be appropriate, 50 will be admitted with a PU and 50 without. Based on the evaluation findings that there was no statistically significant difference between the lengths of hospital stay in the various pathways between the cohorts, data for cohort 1 was used for modelling purposes.
A base model was built first. This used the median length of stay values and actual observed differences in percentage incidence between the two cohorts.

The average dressing costs were calculated from the overall distribution of PU categories across the two cohorts multiplied by the average dressing cost for each PU category. In addition, as a dressing is only applied once an ulcer has developed, the model allowed for costs to be applied only from the day that the ulcer developed. The mattress cost was similarly weighted according to the overall distribution of alternating mattress versus the soft form version.

It should be noted that the cost of dressings and mattresses has only a small financial impact on the overall costs and, therefore, variations in the weighting of the ulcer grading and mattress distribution in the model will have a minimal effect. The largest impact is the cost for bed stay, which when calculated in this trust for the purposes of generating hotel cost included nurse time. This will be most sensitive to the differences in the number of PUs avoided and bed days saved.

**Results**

**Incidence data**

A total of 650 patient cases were assessed. Cohort 1 comprised 204 incidences of pressure ulceration that met the criteria for use of the products. Cohort 2 consisted of 165 incidences.

The initial analysis showed three areas where there were statistically significant differences between the two cohorts at the 95% confidence level (Table 2):

- The incidence of patients who developed PUs after admission was 16% higher in cohort 1 than in cohort 2.
- The incidence of PUs that developed after admission that then improved was 19% lower in cohort 1 than in cohort 2.
- The incidence of PUs that developed after admission and then deteriorated was 8% lower in cohort 1 than in cohort 2.

**Table 2. Differences in pressure ulcer incidence: cohort 1 versus cohort 2**

<table>
<thead>
<tr>
<th></th>
<th>Cohort 1 (C1)</th>
<th>Cohort 2 (C2)</th>
<th>% difference</th>
<th>CI at 95% (±)</th>
<th>p value</th>
<th>CI at 95% (±)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence (%)</td>
<td>(%)</td>
<td>(%)</td>
<td>C2 – C1</td>
<td>C2 – C1</td>
<td>C2</td>
<td>C2</td>
</tr>
<tr>
<td>No pressure ulcer on admission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not develop a PU</td>
<td>67 (59)</td>
<td>58 (75)</td>
<td>16</td>
<td>2.30</td>
<td>0.02860</td>
<td>9.1 9.6</td>
</tr>
<tr>
<td>Developed a PU</td>
<td>46 (41)</td>
<td>19 (25)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure ulcer on admission</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Did not develop an additional PU</td>
<td>67 (74)</td>
<td>73 (83)</td>
<td>9</td>
<td>19.63</td>
<td>0.18380</td>
<td>9.1 7.9</td>
</tr>
<tr>
<td>Developed an additional PU</td>
<td>24 (26)</td>
<td>15 (17)</td>
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<td></td>
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</tr>
<tr>
<td>No pressure ulcer on admission but the patient developed an ulcer during their hospital stay</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The PU improved</td>
<td>16 (33)</td>
<td>14 (74)</td>
<td>41</td>
<td>8.74</td>
<td>0.00650</td>
<td>13.3 19.8</td>
</tr>
<tr>
<td>The PU stayed the same or deteriorated</td>
<td>32 (67)</td>
<td>5 (26)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Pressure ulcer on admission but the patient did not develop another ulcer during their stay</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The PU deteriorated</td>
<td>18 (27)</td>
<td>4 (6)</td>
<td>-21</td>
<td>-31.11</td>
<td>0.00120</td>
<td>10.6 5.2</td>
</tr>
<tr>
<td>The PU stayed the same or improved</td>
<td>49 (73)</td>
<td>69 (94)</td>
<td></td>
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</tr>
</tbody>
</table>

CI = confidence interval; PU = pressure ulcer; C1 = cohort 1; C2 = cohort 2.

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**Fig 1. Cohort 1 and 2 comparison of PU outcomes**

- A base model was built first. This used the median length of stay values and actual observed differences in percentage incidence between the two cohorts.
- The average dressing costs were calculated from the overall distribution of PU categories across the two cohorts multiplied by the average dressing cost for each PU category. In addition, as a dressing is only applied once an ulcer has developed, the model allowed for costs to be applied only from the day that the ulcer developed. The mattress cost was similarly weighted according to the overall distribution of alternating mattress versus the soft form version.

It should be noted that the cost of dressings and mattresses has only a small financial impact on the overall costs and, therefore, variations in the weighting of the ulcer grading and mattress distribution in the model will have a minimal effect. The largest impact is the cost for bed stay, which when calculated in this trust for the purposes of generating hotel cost included nurse time. This will be most sensitive to the differences in the number of PUs avoided and bed days saved.
cohort 2 (41% versus 25%), indicating that patients using the low-friction garments were less likely to develop a PU after admission (p=0.0286; 95% CIs: ± 9.1% and ± 9.6% for cohorts 1 and 2, respectively). The difference between cohorts 1 and 2 is 16% (CIs: 2.3%; 29.7%) (Fig 1)

- For patients who developed a PU after admission, the incidence of PUs that improved in cohort 2 was 41% higher than in cohort 1 (74% versus 33%), indicating that patients using garments had a better outcome (p=0.0065; 95% CIs: ± 19.8% and ± 13.3% for cohorts 2 and 1, respectively). The difference between cohorts 1 and 2 is 41% (CIs: 19.2%; 62.8%) (Fig 1)

- Although there was no significant difference between the cohorts in terms of the incidence of additional PUs for patients who already had a PU on admission, there was a statistically significant difference in terms of the outcome of the ulcer in patients who did not develop additional ulcers. In cohort 1, 21% more of the ulcers deteriorated compared with cohort 2 (27% versus 6%), indicating a better outcome for patients using low-friction garments (p=0.0012; 95% CIs: ± 10.6% and ± 5.2% for cohorts 1 and 2, respectively). The difference between cohorts 1 and 2 is 21% (CIs: 10.7%; 31.3%) (Fig 1).

Within each cohort, there were significant differences in median length of stay between patients who did and who did not develop PUs (t-test for two-sample assuming unequal variances was selected, Table 3). For example, in cohort 1 the median value for patients who developed a PU after admission in cohort 1 was 21 days compared with 10 days when no PU developed. Data showed a greater median length of stay for patients whose PU status worsened: 14 days for those patients who had a PU on admission but did not develop an additional PU during their hospital stay, compared with 27 days for patients in whom the PU deteriorated and 21 days for those who developed additional heel or sacral PUs. However, as stated above, there were no statistically significant differences between the lengths of stay in the corresponding pathways between cohorts 1 and 2.

When examining all the other comparators, including Waterlow scores, ulcer category and longest period between assessments, there were no significant differences between the two cohorts, indicating that the cohorts had similar profiles. The only parameter to show any difference was number of assessments, which showed that cohort 1 patients were assessed more frequently than cohort 2.

**Prevalence data**

Prevalence data were compared for the three wards for August 2009 and December 2009. In August 2009, 39 of the 70 patients audited met the criteria for use of the test products; in December 2009, 37 of the 58 patients audited met the criteria. Only sacral, buttok, hip, heel, ankle and foot ulcers were included in the data. The calculation was made as a single figure. Prevalence data are given in Table 4.
In August 2009, 43.6% (17/39) of the patients who were eligible for low-friction products were admitted with PUs. This compared with 48.6% (18/37) of patients in December 2009.

Of the 15 patients with PUs whose outcomes were recorded in August 2009, 10 (66.6%) remained the same and five (33.3%) were deteriorating when audited; two outcomes were unrecorded. No patients showed signs of improvement. Of the 12 patients with PUs whose outcomes were recorded in December 2009, five patients (41.7%) remained the same, three (25%) were deteriorating, and four (33.3%) were improving; six outcomes were unrecorded.

Fifty per cent (11/22) of patients who were admitted in August 2009 without a PU went on to develop an ulcer, compared with 36.8% (7/19) of patients who were audited in December 2009.

Cost-effectiveness data
The base case model (Tables 5a–c) suggests that using these products can save over £63,000 per 100 at-risk patients within the hospital environment. The saving for the community is potentially higher as more patients (nine) will be discharged with improving or healed ulcers, reducing the financial burden.

Minimum and maximum scenarios were also run based on the premise that, with 95% probability, the true value will lie within the minimum and maximum range (Table 6). Using the lower CIs for length of stay and percentage differences for the pathways, the model was re-run. If the cost minimum scenario occurred, the cost saving would be £3,800, with three more incidences of improved ulcers discharged into the community. The cost maximum scenario, using higher CIs, indicates a cost saving of over £220,000 based on the garments being reused three times and 17 more patients being discharged with improved ulcers in cohort 2. The distribution of data is, however, skewed due to a number of outliers, so the probability of reaching the maximum cost scenario is lower. The predicted cost saving is therefore more likely to be between the cost minimum and base rather than between the base and maximum.

Discussion
The use of the low-friction products, in addition to the other normal interventions required to manage patients at risk of skin breakdown, appears to be associated with better patient outcomes. Of the patients who were ulcer free on admission but went on to develop PUs, significantly more of those who used the low-friction garments went on to improve or completely heal prior to discharge, compared with those who did not use the garments. These results reflect the findings of Hampton et al.

The number of patients admitted with PUs who then developed additional ulcers was similar in both cohorts. However, significantly more of those admitted with ulcers and who wore the low-friction garments did not deteriorate; again, this supports the findings of Hampton et al.

Patients who were ulcer free at admission and who wore the garments were significantly less likely to develop PUs than those who did not wear these products. While patients admitted with ulcers and who wore the garments were more likely to improve, this result was not statistically significant.

The analysis demonstrates that use of the products favourably alters patient outcomes. Ultimately, this should have a positive impact in terms of reducing overall length of stay. This translates into real cost savings, estimated to be over £63,000 in the base case. Even in the worst case scenarios, there were cost savings within the hospital setting and more incidences of improved outcomes when patients were discharged. In addition, there would be an improvement in quality of life.

While the method by which the garments were evaluated does not have the rigour of a randomised controlled trial, the evaluation does offer evidence to suggest that the products contributed significantly to reducing skin breakdown. While our methodology did not case match the patient groups individually, the evaluation does give an insight into the use of the garments in a real-life clinical setting.

As stated above, the results indicate that the low-friction garments reduced the risk of skin breakdown and therefore, in turn, the length of stay. While the literature differs on the importance of the relationship between length of stay and pressure ulceration, many authors have concluded that a longer length of stay increases the risk of pressure ulceration and that PUs are predictive of a longer length of stay. Gallagher et al. reported a correlation between length of stay and PU development, but would not commit to skin breakdown being a predictor of a longer inpatient stay.
Anthony et al. reported that patients who developed PUs had a significantly longer stay, independent of their Waterlow score or age. Graves et al. agreed that developing PUs as an inpatient is a predictor of a longer length of stay, but warned that other published literature on the subject often overestimates the difference in length of stay and that any evaluations that use length of stay as a cost component should be conservative, although they should not be discounted. Rademakers et al. held that, in inpatients with orthopaedic problems, the pre-operative length of stay increases the

<p>| Table 5c. Overall cost savings per 100 admissions (based on 50% of admissions without a PU and 50% with a PU) |</p>
<table>
<thead>
<tr>
<th>£</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs of additional PUs</td>
</tr>
<tr>
<td>Additional costs of low-friction garments</td>
</tr>
<tr>
<td>Total cost saving</td>
</tr>
<tr>
<td>Total cost saving if low-friction garments are reused three times</td>
</tr>
</tbody>
</table>
risk of pressure ulceration, but that once ulceration has developed the stay will be longer. 11

The limitations of this evaluation, which include not controlling the groups before and during the treatment period, could have introduced bias into the results. However, comparison of the groups suggests that they reflect the patient group likely to benefit from these garments. This indicates that the results are likely to hold true for other clinicians expecting to replicate these results when using these low-friction products.

This is the first time that the low-friction garments have been made available to patients in an NHS inpatient environment. Evaluation of the findings indicated that the garments were of clinical benefit to the patients and cost-effective for the hospital.

### References


### Table 6. Summary of cost savings

<table>
<thead>
<tr>
<th>Description</th>
<th>Worst case (minimum savings)</th>
<th>Base case</th>
<th>Best case (maximum savings)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Value per 100 Incidences (£)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of additional PUs</td>
<td>5,136</td>
<td>64,714</td>
<td>224,119</td>
</tr>
<tr>
<td>Additional costs of low-friction garments</td>
<td>3,995</td>
<td>3,995</td>
<td>3,995</td>
</tr>
<tr>
<td>Total cost saving</td>
<td>1,141</td>
<td>60,719</td>
<td>220,124</td>
</tr>
<tr>
<td>Total cost saving if low-friction garments are reused three times</td>
<td>3,805</td>
<td>63,715</td>
<td>223,121</td>
</tr>
<tr>
<td><strong>Value per 100 patients admitted with no PU (£)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of additional ulcers</td>
<td>0</td>
<td>61,833</td>
<td>240,328</td>
</tr>
<tr>
<td>Additional costs of low-friction garments</td>
<td>3,995</td>
<td>3,995</td>
<td>3,995</td>
</tr>
<tr>
<td>Total cost saving</td>
<td>-3,995</td>
<td>57,838</td>
<td>236,333</td>
</tr>
<tr>
<td>Total cost saving if low-friction garments products are reused three times</td>
<td>-1,332</td>
<td>60,502</td>
<td>238,996</td>
</tr>
<tr>
<td><strong>Value per 100 patients admitted with PU (£)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of additional ulcers</td>
<td>10,273</td>
<td>67,595</td>
<td>207,911</td>
</tr>
<tr>
<td>Additional costs of low-friction garments</td>
<td>3,995</td>
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<td>3,995</td>
</tr>
<tr>
<td>Total cost saving</td>
<td>6,278</td>
<td>63,600</td>
<td>203,916</td>
</tr>
<tr>
<td>Total cost saving if low-friction garments products are reused three times</td>
<td>8,941</td>
<td>66,263</td>
<td>206,579</td>
</tr>
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</table>

PU = pressure ulcer