Cost comparison: orthoses – an audit.
In-house manufacture from sheet materials vs prefabricated orthoses

Sarah Brocklesby MSc BSc, Lead Podiatrist Clinical Effectiveness & Chris Wooles BSc, Clinical Lead Podiatrist: Biomechanics
South Gloucestershire PCT Podiatry Department.

ABSTRACT
Background
A specialist biomechanics podiatrist at South Gloucestershire PCT acted as a technician to manufacture his own prescribed foot orthoses. The podiatry department considered this an uneconomic use of the podiatrist’s time.

Aims
Primary: to compare the cost and therapeutic value of the use of prefabricated orthotic shells with the current method of manufacture using sheet materials in the manufacture of patients’ orthoses. Secondary: to indicate efficacy and patient satisfaction of the orthoses prescribed.

Method
Group A received orthoses (functional simple insoles) manufactured, by the current method, entirely from materials purchased in large sheets. Group B received orthoses manufactured from proprietary pre-fabricated orthoses with functional additions from sheet materials. All costs of materials and manufacture time were logged. Patients’ pain scales (0–10) were recorded at assessment and repeated at 4 weeks after issue of orthoses within a self-administered postal questionnaire. Additional questions were designed to describe the groups. Qualitative free text options were given to provide greater insight into patients’ views.

Results
A convenience sample returned 36 questionnaires in group A and 37 in group B. Median baseline pain scores in both groups were 7 (p = 0.76) with reductions in medians to 3.5 and 3 in groups A and B respectively (p = 0.77) after 4 weeks. Groups A and B were found to be similar in all respects. The average unit cost per single orthotic manufactured from group A materials was £9.35p whilst the average unit cost per single orthotic using group B materials was £5.14p.

Conclusion
A substantial cost advantage was found by the use of group B materials in terms of a reduction in time spent in manufacture. Therapeutic value was shown to be similar between the groups. Themes emerged from free text comments that suggested that further study into the possibility of additional health benefits in terms of an increase in physical fitness and quality of life may be warranted.
INTRODUCTION

Treatment outcomes using foot orthoses have been shown to be effective in NHS podiatry departments and individual prescription and manufacture of foot orthoses is established within such departments. South Gloucestershire (SG) PCT’s podiatry department utilised the postgraduate skills of a specialist podiatrist for the biomechanical assessment of individual patients, resulting in the prescription of orthoses. This podiatrist also acts as a technician in order to manufacture the orthoses for patients using a variety of materials purchased in sheet form that are cut to shape and glued together in a laboratory.

It was felt that the time spent in manufacture was an uneconomic use of this podiatrist’s time, but the department could not support the salary of a technical assistant. SG PCT’s podiatry department therefore wished to investigate whether there might be a cost advantage in using proprietary prefabricated orthoses, with the addition of shapes cut from sheet materials for pressure redistribution in order to maintain an individual prescription, without any detriment to therapeutic value or patient satisfaction.

LITERATURE REVIEW

A search was conducted in multiple databases: Cochrane Library, Allied and Complementary Medicine (AMED), The Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, and the Physiotherapy evidence database (PEDro) using the search terms: orthoses, orthotics, insoles, cost, costing, price, economic, evaluation, efficacy, effective, effectiveness, pain. The language was restricted to English. A hand search of relevant journals and articles was also undertaken.

Evidence was found to support the use of foot orthoses for specific commonly treated conditions such as metatarsalgia, pes cavus, plantar fasciitis, overuse injuries and rheumatoid arthritis. However, the orthoses used and outcome measures vary considerably in these studies, making current evidence difficult to interpret. It was felt that the time spent in manufacture was an uneconomic use of this podiatrist’s time, but the department could not support the salary of a technical assistant. SG PCT’s podiatry department therefore wished to investigate whether there might be a cost advantage in using proprietary prefabricated orthoses, with the addition of shapes cut from sheet materials for pressure redistribution in order to maintain an individual prescription, without any detriment to therapeutic value or patient satisfaction.

LITERATURE REVIEW

A search was conducted in multiple databases: Cochrane Library, Allied and Complementary Medicine (AMED), The Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, and the Physiotherapy evidence database (PEDro) using the search terms: orthoses, orthotics, insoles, cost, costing, price, economic, evaluation, efficacy, effective, effectiveness, pain. The language was restricted to English. A hand search of relevant journals and articles was also undertaken.

Evidence was found to support the use of foot orthoses for specific commonly treated conditions such as metatarsalgia, pes cavus, plantar fasciitis, overuse injuries and rheumatoid arthritis. However, the orthoses used and outcome measures vary considerably in these studies, making current evidence difficult to interpret. It was felt that the time spent in manufacture was an uneconomic use of this podiatrist’s time, but the department could not support the salary of a technical assistant. SG PCT’s podiatry department therefore wished to investigate whether there might be a cost advantage in using proprietary prefabricated orthoses, with the addition of shapes cut from sheet materials for pressure redistribution in order to maintain an individual prescription, without any detriment to therapeutic value or patient satisfaction.
The use of a validated questionnaire was considered, but was rejected in order to minimise patients' time needed to participate and departmental resources to undertake the audit. A questionnaire was constructed with a view to describing the characteristics of the two groups for comparison. The questionnaire was constructed following consultation with podiatrist colleagues and SG PCT’s Head of Governance. It was then piloted on six patients. The questionnaire was amended at all stages following comments.

**Questionnaire content**

To compare responders in groups A and B, patients were asked:
- If they had had orthoses previously.
- How many whole weeks they had worn their new orthoses.
- Did the orthoses fit into their shoes easily.
- Level of comfort.
- Number of hours the orthoses were worn during the day.

Comments were invited to clarify the dichotomous variables regarding:
- Changes in distances walked.
- Time spent standing.
- Any unusual activities on the day of filling out the questionnaire.

Respondents could also comment on any aspect of the treatment they wished. The questionnaire was posted to patients' homes four weeks after their orthoses had been issued.

**Analysis**

**Cost comparison**

The item cost per single orthotic was calculated for patients in group A and group B. Log sheets were kept of all materials used and time spent in the manufacture of orthoses. The item costs included the cost of materials used, the salaried time of the podiatrist and the number of orthoses produced. SG PCT’s accountant was consulted to provide the ‘on cost’ of the podiatrist’s time per hour.

**Questionnaire**

Data were analysed using SPSS for windows (categorical variables and ratio data) and Excel (descriptive statistics). Free text answers were recorded individually and considered for emergent themes.

**Bias**

The lead biomechanics podiatrist only (CW) was involved in patient assessment and manufacture of orthoses for both groups to prevent bias that could occur from different methods or speeds of working of different personnel. Questionnaires and patient information sheets were sent by, and returned by post to, the researcher (SB), who was unknown to this set of patients, in order to eliminate pressure to respond favourably or fear of reprisal.

**RESULTS**

**Study sample**

A convenience sample returned 36 questionnaires in group A and 37 in group B. (Return rate: group A = 59.02%; group B = 71.15%). There were no significant differences between groups in terms of age, age range and sex distributions (Table 2).

**Conditions treated**

Conditions treated were logged in categories (Table 3).

**Group comparisons**

Both groups reported similar responses in respect of having worn previous orthoses, their new orthoses fitting easily into footwear, any change in distances walked, ability to stand or unusual activity on the day of filling out the questionnaire (Table 4).

**Free text comments – examples**

*Change in distances walked since wearing new orthoses*

Twelve of 14 group A respondents who indicated ‘YES’ they had experienced a change in distance walked also made comments. Two commented directly on distance – ‘I have walked several miles but have not tested them over 5-10 plus’; ‘I am not as reluctant to walk as I was before I had the orthotics’.

However, the majority related their change in distance walked to pain – ‘No pain during the working day. I am able to go for short walks without any discomfort, i.e. a mile, going shopping at the Mall or around town’; ‘can walk further without pain starting’; ‘prior to treatment I was unable to walk or stand without severe pain. I can now work or go shopping with only slight discomfort’.

One adverse comment was made ‘Cannot wear them too uncomfortable. Feet are sore after walking. Cannot wear for very long periods.’
pain was unbearable’ but this respondent did not appear to have benefitted from the use of the orthoses as she could not fit them into her shoes easily, found the orthoses ‘not at all comfortable’, had worn the orthoses for less than one week, and reported an increased in pain from 7 to 10 after 4 weeks, which was unlikely to have been caused by the orthoses.

All 14 group B respondents who indicated ‘YES’, they had experienced a change in distance walked, made similar comments relating to this question. Three comments related to distance only, but the majority also related the change in distance walked to pain – ‘managed much more daily walking on holiday’; ‘I felt able to walk in to work and back, a distance of a mile each way’; ‘I can walk long distances – a mile or so. Prior to the fitting – walking 100 yards was painful’; ‘I can now walk around all day and I’m not in as much pain at the end of the day as I was’. No adverse comments were made by group B respondents.

Change in the amount of time spent standing
Four out of 10 respondents in group A who indicated they had experienced a change in the amount of time spent standing made comments – ‘Had huge impact on ability’; ‘I can stand on my leg longer’. Seven of 11 group B respondents who answered ‘YES’ also made comments – ‘I can now stand for a long time each day’; ‘improvement in duration of time’; ‘I can stand up at the potato grader with less pain’; ‘all day’. No adverse comments were made by respondents in either group.

Fit easily into shoes
Three of the 22 respondents who indicated that their orthoses fitted easily into their shoes in group A qualified their answers with comments that suggested their choice of shoes was limited - ‘yes but only one pair of shoes’. Five group B respondents of 27 who also answered ‘YES’ made similar comments - ‘only the shoes I took to the clinic’.

Comfort / length of time worn
The majority of respondents in both groups found their orthoses to be fairly or very comfortable (Figure 1), and had worn their orthoses for the maximum number of weeks of the audit (Figure 2). However a greater number of group B patients appeared to have worn their orthoses for the maximum period of weeks and for longer periods each day (Figures 2 & 3).

Pain scores
Pain scores were found to be similar between the two groups. The median baseline pain score in both groups was 7 (range 4–10 and 4–9 in groups A and B respectively, p = 0.76, Mann-Whitney U) with reductions in medians to 3.5 and 3 in groups A and B respectively (range 0 to 10 in both groups, p = 0.78) after 4 weeks.

Cost comparison
Fifty-eight single orthoses were manufactured using group A materials whilst 66 single orthoses were manufactured for group B. Group A required 21 laboratory hours spent in manufacture in addition to clinical time whilst group B required one laboratory
hour, resulting in a significant saving in terms of salaried time. There was no difference in clinical time per patient between the two groups.

The average unit cost per single orthotic manufactured from group A materials was £9-35p (Table 5) and from group B £5-14p (Table 6). This is an average cost difference of £4-21p per single insole with the proprietary prefabricated orthoses, with additions from sheet materials being the least expensive.

**DISCUSSION**

Results showed groups A and B to be similar in all respects, making a cost comparison possible between the two methods of manufacture. The potential for large savings to be made was shown by the use of proprietary prefabricated orthoses, with the addition of materials cut from sheets, compared with the current method using entirely sheet materials. This arose from a reduced amount of time spent in manufacture as the majority of the additions were made during the usual clinical time allotted.

This agreed with findings by Springett et al\(^\text{17}\) regarding the low cost of prefabricated orthoses, but differed by combining a low-cost advantage with the retention of the facility to custom-make orthoses to individual prescription. This may have explained the similarity of therapeutic value between the two groups, measured by change in pain levels and ability regarding walking and standing.

Both groups of orthoses were shown to be clinically effective but a greater number of group B patients appeared to have worn their orthoses for the maximum period of weeks and for longer periods each day, which may suggest a greater level of comfort or acceptability (Figure s 2 & 3). This may in turn explain the higher response rate from group B patients. Responses did not appear to have been biased by any unusual activities undertaken on the day of filling out the questionnaire.

Qualitative themes emerged in both groups that suggested that the increase in distances walked and time spent standing may be linked to the reduction of respondents’ pain, thus providing the possibility of wider health benefits through increased exercise.

In addition it may be that these benefits were underestimated. Four respondents who answered ‘No change in distance’ or ‘No change in standing’ qualified their answers with positive comments whilst one who commented was excluded from the statistical analysis as he had not indicated either ‘YES’ or ‘NO’ (Table 7).

A further benefit was suggested by several free text comments with an emergent quality-of-life theme – ‘I wish that I had been introduced to orthotics years ago I had suffered foot pain for 40 years. It would have made such a difference to quality of life over this time’; ‘less pain – almost nil for most of the day, so life with three under 7s and all it entails, on my feet improved 100%’; ‘A day at Highgrove which was lovely through the osteoporosis society, which I never thought I’d do 6 months ago’; ‘main benefit – reduced pain! impacted beneficially on my life – work and social’; ‘Now able to carry out my job with much reduced pain – NHS worker, required to stand/walk for a full day. Pre-orthotics, had time off & reduced capacity to fulfil role’; ‘Able to walk dog!’

This theme arose unsolicited as investigation into this aspect was beyond the scope of this audit. However the association between pain and quality of life is well researched. In addition this agrees with studies that found that foot orthoses improved quality of life.\(^{6,22}\)

Results suggested that both groups of orthoses generally fitted well into patients’ shoes although some free text comments showed that a minority of patients were limited to wearing one pair or a limited selection of their shoes. This suggests that further consideration might be needed to determine if this is a problem that should be addressed in future.

---

**Table 5. Costs associated with Group A.**

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algeos Poron grey: 6mm</td>
<td>£14.45</td>
</tr>
<tr>
<td>Algeos Poron green: permfresh 3mm</td>
<td>£14.45</td>
</tr>
<tr>
<td>Algeos EVA wedge strips: 3&quot;</td>
<td>£15.00</td>
</tr>
<tr>
<td>Algeos EVA wedge strips: 5&quot;</td>
<td>£3.35</td>
</tr>
<tr>
<td>Algeos Vinyl: black yampi</td>
<td>£10.34</td>
</tr>
<tr>
<td>Algeos Ultrapol xt cloth covered: 3mm</td>
<td>£19.26</td>
</tr>
<tr>
<td>Algeos Ultrapol xt cloth covered: 1.6mm</td>
<td>£1.48</td>
</tr>
<tr>
<td>Algeos EVA 3mm Black</td>
<td>£0.66</td>
</tr>
<tr>
<td>Algeos Glue: Renia thixotropic adhesive</td>
<td>£19.08</td>
</tr>
<tr>
<td><strong>Total Materials Cost</strong></td>
<td><strong>£143.47</strong></td>
</tr>
<tr>
<td><strong>Podiatrist’s Time in Manufacture</strong></td>
<td></td>
</tr>
<tr>
<td>(South Gloucestershire PCT ‘On Cost’)</td>
<td><strong>£399.00</strong></td>
</tr>
</tbody>
</table>

---

**Table 6. Costs associated with Group B.**

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobiles X-Line insole</td>
<td>£83.23</td>
</tr>
<tr>
<td>Algeos Slimflex insole</td>
<td>£17.25</td>
</tr>
<tr>
<td>Slimflex Plus insoles</td>
<td>£2.53</td>
</tr>
<tr>
<td>Algeos Duomed full length insole</td>
<td>£129.57</td>
</tr>
<tr>
<td>Double-sided tape</td>
<td>£3.00</td>
</tr>
<tr>
<td><strong>Additions in laboratory from group A materials:</strong></td>
<td></td>
</tr>
<tr>
<td>Algeos Poron grey: 6mm</td>
<td>£27.20</td>
</tr>
<tr>
<td>Algeos Poron green: permfresh 3mm</td>
<td>£45.22</td>
</tr>
<tr>
<td>Algeos EVA wedge strips: 3&quot;</td>
<td>£9.00</td>
</tr>
<tr>
<td>Algeos EVA wedge strips: 5&quot;</td>
<td>£3.35</td>
</tr>
<tr>
<td><strong>Total Materials Cost</strong></td>
<td><strong>£320.35</strong></td>
</tr>
<tr>
<td><strong>Podiatrist’s Time in Manufacture</strong></td>
<td></td>
</tr>
<tr>
<td>(South Gloucestershire PCT ‘On Cost’)</td>
<td>£19.00</td>
</tr>
</tbody>
</table>
STUDY LIMITATIONS
Therapeutic value was assessed in terms of pain with no validated measure of change of disability. The manufacture of orthoses for study participants could not be separated from non-participants, necessitating sheet materials to be cut and costed as smaller A4 units.

CONCLUSION
A substantial cost advantage was shown with the use of prefabricated insoles with additional materials added during clinical time. This method enabled the biomechanics specialist podiatrist to continue to prescribe and supply custom-made orthoses.

This method did not result in any loss of therapeutic value and was well accepted by patients. Efficacy of both sets of orthoses was shown to be positive in terms of reduced pain scores and increased ability in walking and standing.

Further investigation is required in order to determine whether any additional benefits of increased physical fitness and quality of life can be attributed to treatment with foot orthoses by SG PCT’s podiatry department.

REFERENCES

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Distance</strong></td>
<td><strong>Standing</strong></td>
</tr>
<tr>
<td>‘This is only due to the fact that my left knee is very bad but the insoles have greatly improved my foot, less painful’</td>
<td>‘Do not get pain while standing’</td>
</tr>
<tr>
<td>Excluded: ‘As I have arthritis in my knees I do not walk any long distances but the pain to my foot is very much improved’</td>
<td>‘I am normally standing most of the day’</td>
</tr>
</tbody>
</table>

Table 7. Respondents who answered no change in either distance or standing (or excluded).


15. Landorf K, Keenan AM, Herbert R. Effectiveness of different types of foot orthoses for the treatment of plantar fasciitis.

AUDIT RESPONSIBILITIES
Sarah Brocklesby: study design, questionnaire, data collection, analysis.

Chris Wooles: data collection, cost calculation.

ACKNOWLEDGEMENTS
Thank you for advice and support: Dr Rosemary Greenwood, Medical Statistician, Research and Development Support Unit, University Hospitals Bristol NHS Foundation Trust; John Down, Head of Podiatry Services, South Gloucestershire PCT.