Evaluating the Clinical Effectiveness and Cost-effectiveness of Foot Orthoses in the Treatment of Plantar Heel Pain

A Feasibility Study

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This study evaluated the clinical effectiveness and cost-effectiveness of two different types of foot orthoses used to treat plantar heel pain. Forty-eight patients were randomly assigned to receive either a functional or an accommodative orthosis. General (EuroQol) and specific (Foot Health Status Questionnaire) health-status measures were used. Data were also collected using economic questionnaires relating to National Health Service costs for podiatry, other health-service costs, and patient costs. Data were measured at baseline and at 4- and 8-week intervals. Thirty-five patients completed the study. The results demonstrated a significant decrease in foot pain and a significant increase in foot function with the functional foot orthoses over the 8-week trial. The accommodative foot orthoses demonstrated a significant reduction in foot pain only at 4 weeks. The cost-effectiveness analysis demonstrated that functional orthoses, although initially more expensive, result in a better quality of life. Use of functional orthoses resulted in an increased cost of £17.99 ($32.74) per patient, leading to an incremental cost per quality-adjusted life year of £1,650 ($3,003) for functional orthoses. (J Am Podiatr Med Assoc 94(3): 229-238, 2004)

The health-care services in the United Kingdom, which include podiatrists, orthotists, and physiotherapists, prescribe numerous foot orthoses as part of their management of biomechanically related lower-limb pathologies, such as heel pain, midfoot arthritis, metatarsalgia, and knee pain. It is estimated that the annual National Health Service (NHS) budget for orthoses is approximately £38 million ($69.2 million), of which 30% is spent on foot orthoses and footwear.[1] Despite the frequency with which foot orthoses are

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This article is dedicated to the memory of Des Callaghan.

prescribed, limited information is available on their clinical effectiveness.

One of the most common foot disorders encountered by health-care professionals is plantar heel pain. The high prevalence of this condition is evidenced by the extensive literature, including a Cochrane Library systematic review.[2] However, as the latter illustrates, there are few well-designed and well-conducted randomized trials on treatment of this condition, making optimal strategies for its conservative management uncertain. Rest, ice, stretching, shoe modifications, heel cups, heel taping, corticosteroid injections, nonsteroidal anti-inflammatory drugs, orthoses, night splints, therapeutic ultrasound, and low-intensity laser therapy have all been described, but limited evidence of effectiveness in reducing pain exists only for topical and injected corticosteroids, night splints, therapeutic ultrasound, and low-intensity laser therapy.[2] There is no strong evidence of the clinical and economic effectiveness of orthoses, although they have been commonly advocated as the intervention of choice in the treatment of plantar heel pain. The literature on this topic is mostly descriptive, and the little evaluative literature that exists has often been dismissed as inconclusive owing to a lack of methodologic rigor.[3, 4] Criticisms are aimed at the variable nature of the patient profile, the orthotic prescription, the manufacture of the device, and the measured outcomes.

A comprehensive review of the literature indicates that no research has evaluated the cost-effectiveness of foot orthoses within the NHS. The aim of this study was to evaluate the feasibility of investigating the clinical effectiveness and cost-effectiveness of two types of orthoses commonly used in clinical practice for the treatment of plantar heel pain by means of a controlled trial and an economic evaluation over a 2-month period. This feasibility study evaluates the potential of the methods in particular areas, such as permitting power calculations based on treatment effect size, recruitment of patients, measuring and evaluating dropout rates, and identifying potential problems with orthoses.

Materials and Methods

Research Design

Our research design used a pragmatic approach involving two groups of patients. One group was prescribed accommodative orthoses, and the other group was prescribed functional orthoses. A variety of steering group meetings were held involving the research facilitator, project manager, researcher, health economist, medical statistician, and head of podiatric services.

Sample Population

A convenience sample of 48 patients was recruited from North Tyneside Healthcare Trust. The patients were initially recruited from Podiatry Services. Subsequently, patients were also recruited by means of referrals from physicians and physiotherapists. The inclusion criteria were unilateral plantar heel pain of at least 2 months' duration; a history of nighttime or early morning pain that decreased after walking and increased after exercise or prolonged periods of standing; heel pain severe enough to bring about a reduction in physical activity, a visit to a health professional, or the use of medication specifically for plantar heel pain; and good general health.[5, 6] Individuals were excluded if they met any of the following criteria: previous foot surgery, recent abrupt trauma to the foot, congenital defects of the lower extremity, diabetes mellitus, corticosteroid injection in the heel in the previous 3 months, and history of systemic disease with manifestations similar to those of plantar heel pain, including rheumatoid arthritis and seronegative arthritis. Obesity, age (from skeletal maturity), sex, and ethnic background were not part of the exclusion criteria.[7]

Outcome Measures

Valid and reliable general and specific health-status measures were used in this study. Roland and Torgerson[8] reported that a single outcome measure may be inadequate for clinicians and other health-care decision makers to evaluate the risks, costs, and benefits of a given intervention. The Foot Health Status Questionnaire (FHSQ) and the EuroQol (EQ5D) questionnaire were used in this study.

Foot Health Status Questionnaire

The FHSQ captures foot health–related quality-of-life data and has 13 key items (with Likert-scale responses) spanning four domains (subscales) of foot health: foot pain, foot function, footwear, and general foot health.[9] Because it contains several items from the 36-Item Short-Form Health Survey, the FHSQ also enables inference of a change in health status that may be attributed to the orthotic intervention. A maximum score of 100 signifies optimal foot health. The FHSQ has been reported to have good test–retest reliability, internal consistency, and construct and criterion validity.[10]

EuroQol Questionnaire

The EQ5D is a standardized instrument used to measure health status. It provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care and population health surveys.[11] The EQ5D descriptive system comprises five dimensions of health: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension comprises three levels (some problems, moderate problems, and extreme problems), generating 243 theoretically possible health states.

Foot Orthoses

Functional foot orthoses were full-length orthoses made of ethyl vinyl acetate (70 Shore A) with a 25 Shore A top cover and a 4° medial rearfoot ethyl vinyl acetate post. The standard price was £25 ($45.50). Accommodative foot orthoses were full-length orthoses made of low-density ethyl vinyl acetate (20 Shore A) with a polyurethane heel pad (Fig. 1). The standard price was £7 ($12.74). In the interest of standardization, all orthoses were manufactured by the same company (Talar Made Orthotics Ltd, Chesterfield, England). For this study, general orthotic types were taken from the Australian Podiatry Council's clinical guidelines for orthotic therapy.[12] Accommodative orthoses aim to provide cushioning and padding as well as shock absorption during gait. The aim of functional orthoses is to achieve weightbearing realignment of the foot and lower limb and redistribution of load from a focal point of increased pressure and shock absorption in gait. Each patient was given written "wearing instructions."

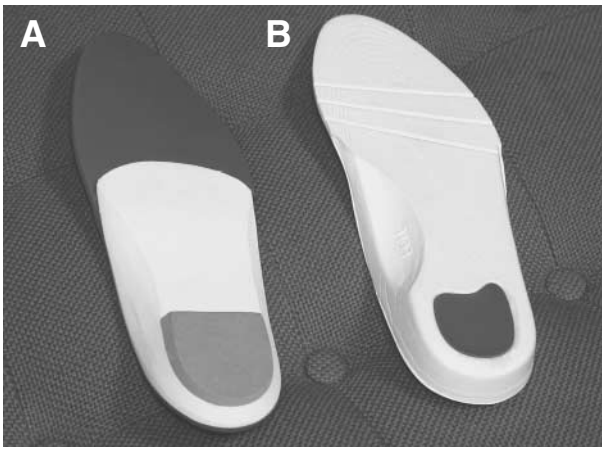

Figure 1. Functional (A) and accommodative (B) foot orthoses.

Cost-effectiveness

Costs were estimated from the perspective of the NHS and from the societal perspective (to include all other costs of the treatments outside the NHS). Effects were assessed in terms of health gain expressed as quality-adjusted life years. Data on resource use for the economic analysis were obtained from two separate sources: the patient questionnaires and the staff questionnaires (both distributed at baseline and at 4 and 8 weeks). Questions were asked regarding resource use in the Podiatry Department of the NHS, in other NHS departments, and, finally, by patients and their families, such as the purchase of creams, footwear, or nonsteroidal anti-inflammatory drugs.

Unit Costs

Unit costs were calculated as follows (conversion rate at the time of this writing: £1 = $1.82): NHS mean cost per patient = C1 + C3; total mean cost per patient = C1 + C2 + C3.

C1 is total costs to the Podiatry Department of the NHS. Unit cost data were obtained from a variety of sources and include the cost of the orthoses to the NHS (accommodative orthoses at £7 each and functional orthoses at £25 each). Clinician costs were based on current salary (£20,935), including overhead and capital expenses, and employer costs, such as national insurance and employer's pension contributions. All costs were calculated to cost per minute. Travel costs were based on daily mileage of £0.35 per mile. Time costs were calculated from the clinician's base of work to the patient's residence. Costs were inflated to a 2001–2002 price base using the National Service Cost Index.[13]

C2 is total costs to patient or family within the NHS and includes the cost of travel time to and from appointments; patient time, which was based on the national minimum wage of £4.10; travel expenses; and any other expenses incurred by the patient as a direct result of treatment. These figures were captured by the economics questionnaire at baseline and at 4- and 8-week follow-up. Travel costs were based on daily mileage of £0.148 for a private-car journey, £0.116 using public transportation, and £0.573 using a private taxi. No costs were incurred if the patient walked or bicycled.[14]

C3 is costs to any other NHS departments, including use of physician or physiotherapy services during the study.[13] The unit cost estimate includes cost of

training and direct-care support staff and is inflated to a 2001–2002 price base. Physician and physiotherapy costs included salary, overhead, and capital expenses.

Health States and Their Values

The EQ5D scores at baseline and at 4 and 8 weeks were converted to a "utility" score based on a "tariff" derived from interviews with 3,395 members of the United Kingdom public.[15] The two orthosis groups were compared in terms of mean changes in quality-adjusted life years during the 8-week period by plotting the EQ5D utility scores at baseline and at 8 weeks and calculating the area under the curve to estimate quality-adjusted life years gained (or lost) for each patient. Because there were two follow-up points, the area under the curve is simply the change in score divided by 2.

Incremental Cost-effectiveness Ratios

The cost-effectiveness analysis involves the calculation of incremental cost-effectiveness ratios, where mean differences in costs and effects under the treatment and control arms are presented along with 95% confidence intervals (CIs). Algebraically, the incremental cost-effectiveness ratio is represented as $(C_1 - C_0)/(E_1 - E_0)$, where C_1 is sample mean costs of accommodative orthoses; E_1, sample mean effects of accommodative orthoses; C_0, sample mean costs of functional orthoses; and E_0, sample mean effects of functional orthoses.

The total cost for each patient was calculated to determine the average cost of the interventions to a patient. The effectiveness of the interventions was estimated using two instruments that have been tested for their validity and reliability. For each intervention, a cost-effectiveness ratio was calculated to express its cost per unit of effect (effect shown in this study by the change in FHSQ and EQ5D scores). On the basis of these cost-effectiveness ratios, a decision was made regarding the cost-effectiveness of each orthosis under evaluation.

Procedure

Ethical approval for this study was obtained from the Joint Ethics Committee, Newcastle and North Tyneside Health Authority Trust. Forty-eight patients who met the inclusion criteria were invited to participate in the study. At the initial appointment, written consent was obtained and the initial questionnaires (FHSQ, EQ5D, and economic analysis) were administered. The researcher (S.C.H.) explained the aims of the study and the treatment regimen to each patient.

At baseline, 48 patients were randomly assigned to one of two groups by the use of randomized tables by an independent observer. Patients were evaluated subsequently at 4 and 8 weeks. Patients were free to leave the study at any stage. A 24-hour patient helpline was established. Patients were also prescribed stretching exercises, as previously described elsewhere.[16] Written and graphic information about the stretching program along with a personal demonstration by the researcher was given. Stretching exercises are a standard intervention for plantar heel pain.[17]

Data Analysis

Descriptive patient information was gathered at baseline, and health-status measures data were obtained at baseline and at 4 and 8 weeks. Attrition rates and noncompliance rates were also determined. All data were analyzed using the SPSS statistical package (SPSS Science, Chicago, Illinois) at the 5% level of significance. Preliminary observations of the data indicated that those from the FHSQ and EQ5D were at ordinal level and were not normally distributed. Therefore, a Wilcoxon signed ranked test was used to analyze significant differences between the orthoses at the three time intervals.

Results

Descriptive Characteristics

Forty-eight patients were entered into the study, with 22 patients receiving accommodative orthoses and 26 receiving functional orthoses. Sixty percent of the patients were women and 40% were men. Table 1 provides baseline demographic information for the two groups, separately and combined. Statistical tests demonstrated no significant differences in any baseline measurements ($P > .05$). Thirteen patients were lost to follow-up (Fig. 2). The attrition rate was 27.1%.

Clinical Effectiveness

The results demonstrate that of the 13 individuals who did not complete the study, 9 patients were given an accommodative orthosis and 4 were issued a functional orthosis. No significant difference was noted between the two dropout groups ($P > .05$).

FHSQ Results. Tables 2 and 3 provide the results of the FHSQ domains at baseline and at 4 and 8 weeks. No significant differences were found for ei-

Table 1. Baseline Descriptive Characteristics of the Sample Population

Characteristic	Foot Orthosis (mean ± SD)		Overall	
	Accommodative	Functional	Mean ± SD	Range
Age (years)	58.3 ± 12.6	61.2 ± 14.4	59.9 ± 13.5	33.1–87.9
Weight (kg)	89.6 ± 17.8	78.5 ± 10.4	83.7 ± 15.2	57.6–133.4
Duration of plantar heel pain (mo)	21.6 ± 40.5	12.4 ± 19.6	6[a]	2.0–180.0
Body mass index (kg/m^2)	31.5 ± 6.1	29.4 ± 3.9	30.4 ± 5.1	22.0–50.8
Height (m)	1.7 ± 0.1	1.6 ± 0.1	1.6 ± 0.1	1.5–1.8

[a]Median value.

ther orthosis at the time intervals for the general foot health and footwear domains. Figures 3 through 6 illustrate the FHSQ domain scores for the 8-week trial. The foot-pain domain demonstrated a significant difference at all time intervals for the functional orthosis ($P < .05$). The accommodative orthosis demonstrated a significant difference between baseline and 4 and 8 weeks ($P < .05$) but not between 4 and 8 weeks ($P = .53$). Furthermore, significant differences were noted in the foot-function domain for the functional orthosis between baseline and 4 and 8 weeks ($P < .05$). No significant differences were observed for the accommodative orthosis during the 8-week trial ($P > .05$)

EQ5D Results. No significant differences in EQ5D scores at the different time intervals were found for the accommodative orthosis ($P > .05$) (Tables 2 and 3). However, significant differences ($P < .05$) were observed for the functional orthosis between baseline and 8 weeks and between 4 and 8 weeks (Fig. 7).

Cost-effectiveness

The overall total mean cost per patient was analyzed using the Mann-Whitney U test (Table 4). There was a significant difference in mean ± SD total costs for the accommodative orthosis *versus* the functional orthosis ($16.18 ± $5.54 *versus* $34.17 ± $5.18; $P < .05$). The

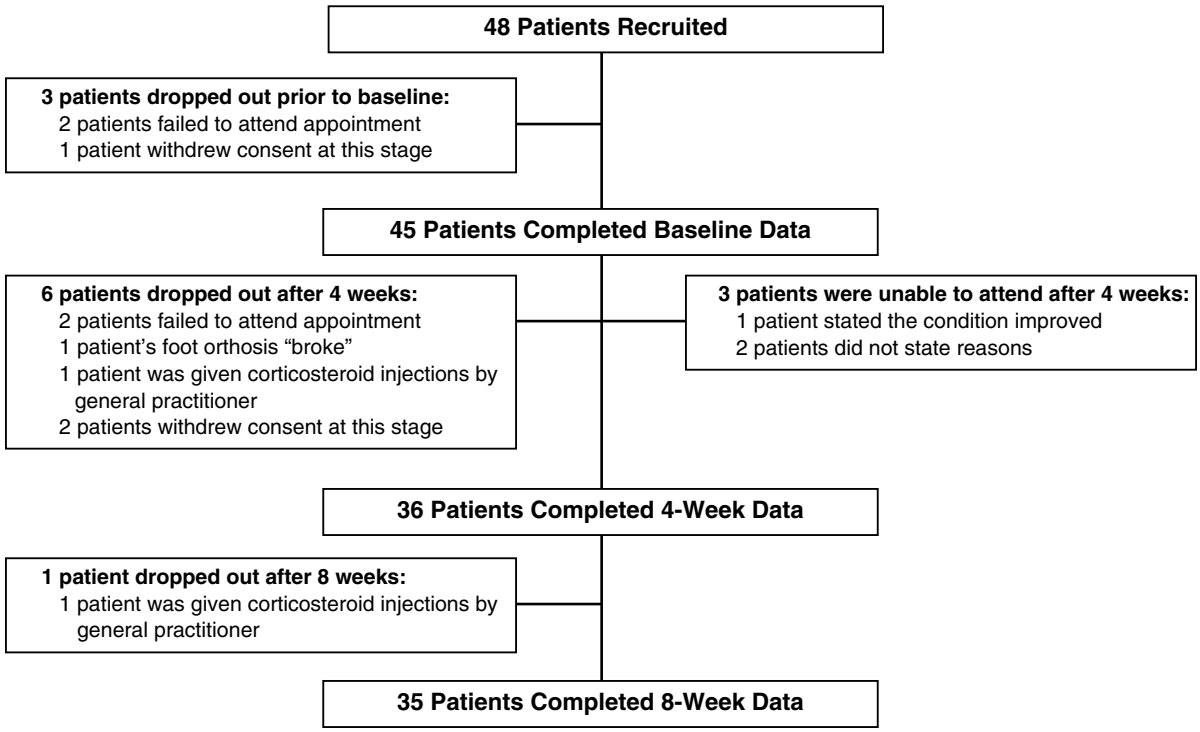

Figure 2. Flowchart of patient recruitment, including dropouts and failures.

Table 2. Results of the FHSQ and the EQ5D Questionnaire

Domain	Foot Orthosis	Assessment Point Comparison	*P* Value
FHSQ foot pain	Accommodative	Baseline *versus* 4 wk	.04[a]
		Baseline *versus* 8 wk	.02[a]
		4 wk *versus* 8 wk	.53
	Functional	Baseline *versus* 4 wk	.03
		Baseline *versus* 8 wk	.01[a]
		4 wk *versus* 8 wk	.01[a]
FHSQ foot function	Accommodative	Baseline *versus* 4 wk	.18
		Baseline *versus* 8 wk	.20
		4 wk *versus* 8 wk	.84
	Functional	Baseline *versus* 4 wk	.03[a]
		Baseline *versus* 8 wk	.01[a]
		4 wk *versus* 8 wk	.49
FHSQ general foot health	Accommodative	Baseline *versus* 4 wk	.86
		Baseline *versus* 8 wk	.19
		4 wk *versus* 8 wk	.11
	Functional	Baseline *versus* 4 wk	.56
		Baseline *versus* 8 wk	.21
		4 wk *versus* 8 wk	.92
FHSQ footwear	Accommodative	Baseline *versus* 4 wk	.20
		Baseline *versus* 8 wk	.38
		4 wk *versus* 8 wk	.98
	Functional	Baseline *versus* 4 wk	.76
		Baseline *versus* 8 wk	.48
		4 wk *versus* 8 wk	.84
EQ5D health status	Accommodative	Baseline *versus* 4 wk	.09
		Baseline *versus* 8 wk	.95
		4 wk *versus* 8 wk	.14
	Functional	Baseline *versus* 4 wk	.40
		Baseline *versus* 8 wk	.02[a]
		4 wk *versus* 8 wk	.04[a]

Abbreviations: FHSQ, Foot Health Status Questionnaire; EQ5D, EuroQol.
[a]Significant at the 5% level.

Table 3. Descriptive Information from the FHSQ and the EQ5D Questionnaire

	Baseline Scores (mean ± SD)		4-Week Scores (mean ± SD)		8-Week Scores (mean ± SD)	
Domain	Accommodative	Functional	Accommodative	Functional	Accommodative	Functional
FHSQ foot pain	30 ± 23.7	39 ± 18.7	62 ± 24.1	54 ± 21.9	62 ± 26.1	74 ± 25.3
FHSQ foot function	55 ± 30.4	54 ± 24.7	71 ± 27.7	71 ± 19.3	71 ± 30.7	74 ± 25.4
FHSQ general foot health	31 ± 24.2	27 ± 23.6	37 ± 23.4	35 ± 23.8	49 ± 18.3	36 ± 22.3
FHSQ footwear	50 ± 20.4	47 ± 26.2	43 ± 25.7	50 ± 25.8	44 ± 29.7	50 ± 29.5
EQ5D health status	0.46 ± 0.30	0.62 ± 0.25	0.69 ± 0.27	0.68 ± 0.19	0.62 ± 0.35	0.79 ± 0.11

Abbreviations: FHSQ, Foot Health Status Questionnaire; EQ5D, EuroQol.

95% CIs demonstrated that the mean difference was between £21.79 and £14.17. Total mean cost to the Podiatry Department per patient was significant, with a 95% CI of £20.10 to £13.75 ($P < .05$). However, there were no significant differences in total mean cost to other NHS services per patient ($P > .05$).

Health-Status Results. The mean scores from the EQ5D health status at baseline and 8 weeks for the two orthoses were used to calculate the incremental cost-effectiveness ratio (Table 5). The mean quality-adjusted life year gain was represented as a monthly difference. Note that both groups had an increase in quality-adjusted life years during the 8-week period. These differences are small and do not approach conventional levels of statistical significance, but they indicate that the functional orthoses performed slightly better than the accommodative orthoses.

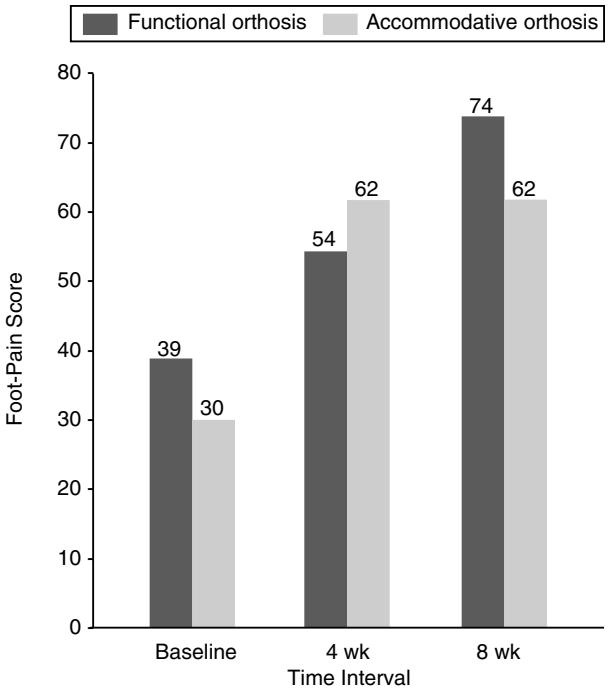

Figure 3. Foot Health Status Questionnaire foot-pain domain mean scores.

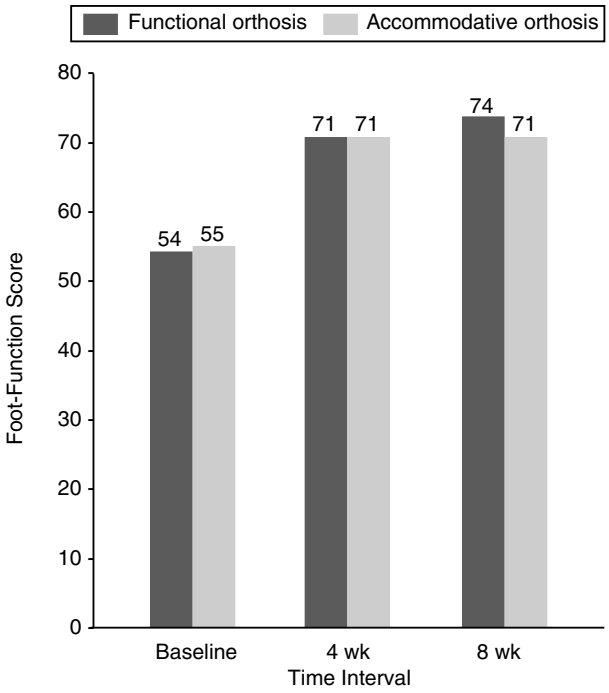

Figure 4. Foot Health Status Questionnaire foot-function domain mean scores.

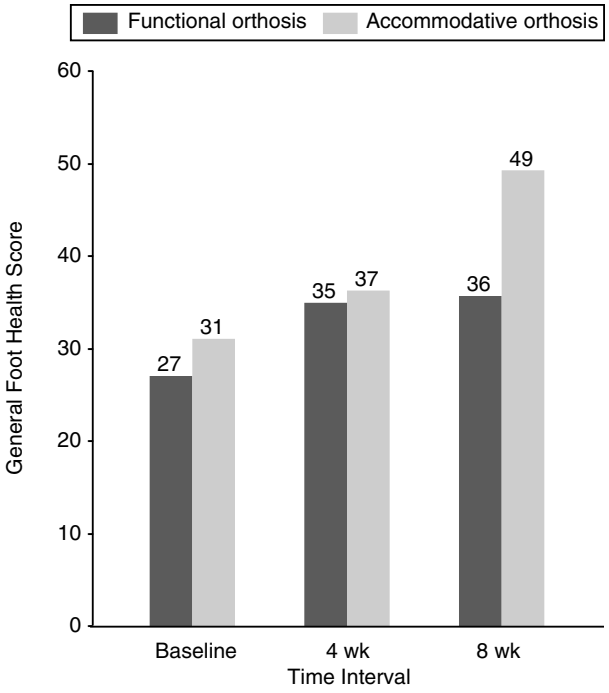

Figure 5. Foot Health Status Questionnaire general foot health domain mean scores.

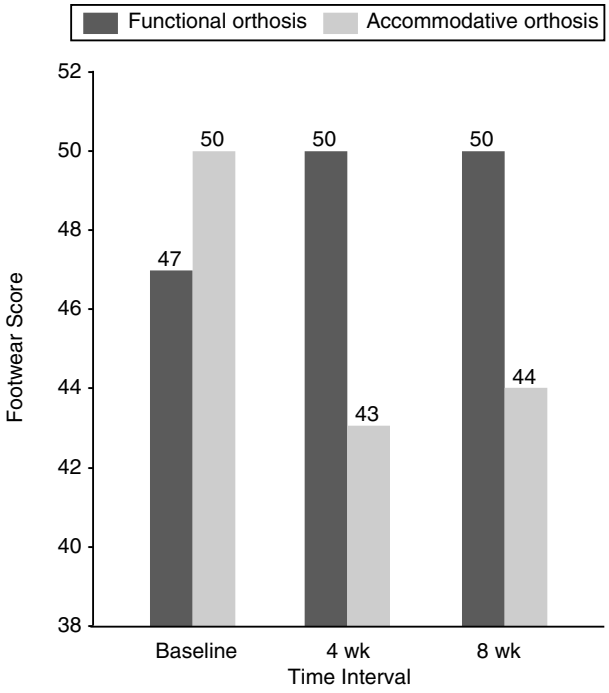

Figure 6. Foot Health Status Questionnaire footwear-domain mean scores.

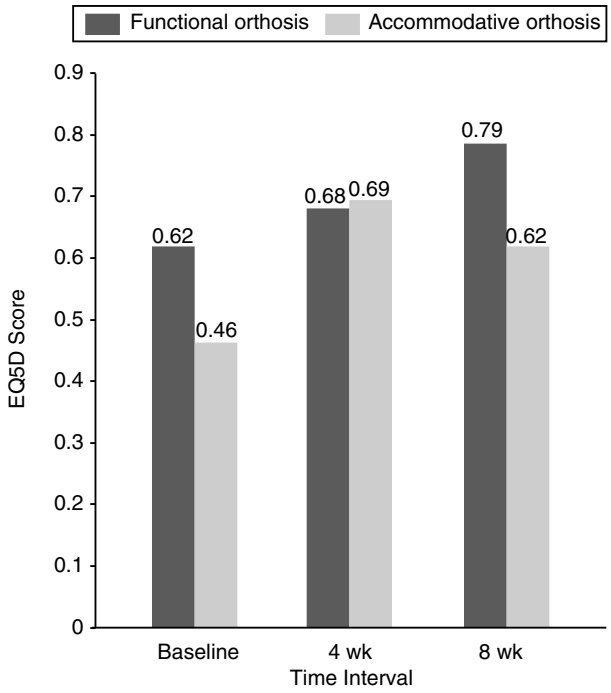

Figure 7. EuroQol (EQ5D) questionnaire mean scores.

Incremental Cost-effectiveness Ratio. The functional orthosis is associated with a better quality-adjusted life year profile but at a higher cost to the NHS. Specifically, the functional orthosis results in a quality-adjusted life year gain of 0.0109 compared with the accommodative orthosis and an increased cost of £17.99. Using the incremental cost-effectiveness ratio calculation, this results in an incremental cost per quality-adjusted life year of £1,650 for the functional orthosis group.

Discussion

The results of this feasibility study indicate that there was an improvement over time in the FHSQ foot-pain and foot-function domain scores and the EQ5D scores following the intervention of orthoses over a 2-month period but no significant differences in the footwear and general foot health domain scores. Landorf et al[10] measured the effectiveness of orthoses for plantar heel pain using the FHSQ and demonstrated significant differences in all FHSQ domain scores. Nancarrow[18] showed only the foot-pain domain to be statistically significant in a sample of patients prescribed insoles.

The overall attrition rate in the present study was 27%. These results are consistent with those of previously published plantar heel pain studies, with attrition rates ranging from 19% to 55%.[6, 12, 18] Although previous studies used different populations, the occurrence of high rates of attrition is consistent. In the present study, 69% of the patients who withdrew consent wore accommodative orthoses. Although not statistically analyzed, individual comments made by the patients included that the orthosis had become "uncomfortable to wear after 4 weeks," that the orthosis was "losing its function as a cushioning device after 4 weeks," and "the insoles had gone hard and flattened out." These comments, together with the data from the FHSQ and the EQ5D, suggest that the accommodative orthosis may have been compromised. This is commonly seen in clinical practice.

Outcome Measures

The foot-pain domain evaluates the type, severity, and duration of foot pain.[19] The functional orthosis demonstrated a significant decrease in foot pain from baseline to 4 and 8 weeks, but the accommodative orthosis demonstrated no significant decrease in foot pain from 4 to 8 weeks. This suggests that the accommodative orthosis reached its maximum potential to reduce foot pain at 4 weeks. This trend could be related to the design and construction of the orthosis. Crawford[17] reported that orthoses can be made

Table 5. Mean Change in Quality-Adjusted Life Years (QALYs) During the 8-Week Period

	Foot Orthosis	
	Accommodative	Functional
Mean QALY gain per year	0.07	0.09
Mean QALY gain per month	0.0379	0.0488

Table 4. Foot Orthoses Total Mean Costs

	Accommodative	Functional
Total mean ± SD cost to the Podiatry Department per patient (£)	16.19 ± 5.54	33.11 ± 3.30
Total mean ± SD cost to other National Health Service departments per patient (£)	1.59 ± 5.17	0.73 ± 3.73
Total mean ± SD costs (£)	**16.18 ± 5.54**	**34.17 ± 5.18**

from several different materials, which can make the results difficult to interpret. The range of materials available for the manufacture of orthoses is continually increasing with advancement in technology. Despite the frequency with which orthoses are prescribed and their costs incurred, limited information is available about their mechanical and clinical effectiveness. The choice of material tends to be based on personal experience, cost, and availability. Rome[20] suggested that any given type of material is marketed on the basis of the price of materials and a description of its properties and processibility. The present study used two prefabricated orthoses to avoid any variability in producing custom-made orthoses. Prefabrication applies the principles of neutral casting, a technique often used in clinical practice. The justification for the two orthoses was based on anecdotal evidence. Currently, there are no guidelines to define orthoses, as illustrated in the literature.[6, 10, 12, 18, 21, 22] Petchell et al[12] postulated that the lack of universal terminology for orthotic prescription creates difficulties for discourse on almost any aspect of orthotic therapy.

The FHSQ foot-function domain is designed to evaluate an individual's functional abilities specifically on the basis of the health of the patient's feet.[19] In the present study, functional orthosis mean scores improved in a statistically significant manner between baseline and 4 weeks, suggesting that the patient could perform physical activities such as working, walking, and climbing stairs. However, there was very little change between 4 and 8 weeks for the accommodative orthosis, suggesting that foot function had stabilized.

The FHSQ general foot health domain may be seen as the composite personal expression of well-being in terms of foot-related function, foot pain, and footwear-related health status.[19] However, this domain has been reported not to be very discriminating between patients owing to the limited number of questions.[10] The present study demonstrated no significant differences between the orthoses during the 8-week period, possibly indicating an inability in this domain to discriminate between participants who have similar, but not identical, general foot health.

The present study found no significant differences between the two orthoses over time in FHSQ footwear-domain scores. Landorf et al[10] found a significant difference in FHSQ footwear-domain scores assessing the intervention of a functional orthosis for plantar heel pain. The authors stated that the low numbers and the lack of a control group may have compromised the results. The mean age of the participants was 44.6 years in the study by Landorf et al, compared with 59.9 years in the present study, suggesting that the perception of footwear may vary across different age and gender populations.

The findings from the EQ5D are similar to those from the FHSQ foot-pain and foot-function domains. Both orthoses demonstrated an increasing trend in the mobility subscale, suggesting that both questionnaires are sensitive enough to use when evaluating the effect of orthoses on patients with plantar heel pain.

Cost-effectiveness

To our knowledge, the present work is the first study to evaluate the cost-effectiveness of orthoses within the NHS. From an NHS perspective, the results demonstrate a significant difference in costs between accommodative and functional orthoses. The mean total costs for the functional orthoses were higher than those for the accommodative orthoses by £17.99. However, the incremental cost per quality-adjusted life year of £1,650 suggests that over an 8-week period the functional orthosis is more cost-effective than the accommodative orthosis. This analysis indicates that scarce NHS resources would be best allocated to functional orthoses in the treatment of plantar heel pain.

Conclusion

The present study demonstrates a significant difference after using the functional orthosis for 8 weeks in foot pain and foot function (FHSQ) and overall health status (EQ5D). The quality-adjusted life year results demonstrate that the extra cost to the NHS for issuing functional orthoses was £1,650 to improve quality of life during the patient's life span. A future study might evaluate the clinical effectiveness and cost-effectiveness of orthoses during a 12-month period using a randomized clinical trial. A 12-month study would reduce the incremental cost per quality-adjusted life year during the year and might improve quality of life. Future studies may also include not only a cost-effectiveness analysis but also a cost-benefit analysis—the willingness of patients to pay.

A randomized clinical trial would build on the emerging evidence underpinning the clinical use of orthoses and, in particular, would better establish the clinical effectiveness and cost-effectiveness of orthoses. This will enable future practice to be based on evidence of which type of orthosis provides the greatest clinical benefits. Moreover, in an environment where cost-effectiveness in resource use is ascending on the UK government's agenda, a randomized clinical

trial will enhance clinically effective and cost-effective use of orthoses. Information could be disseminated through the National Health Service Centre for Reviews and Dissemination. Thus clinical trials will ultimately result in clinical evidence through primary research and scientific review, the production and dissemination of clinical guidelines based on the evidence available, and implementation of evidence-based, cost-effective practice.

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