



A Randomised Control Trial for evaluating over-the-counter golf orthoses in alleviating pain in amateur golfers

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Abstract

Background: There are few studies to evaluate the effectiveness of orthoses on foot function and pain whilst playing golf.

Objectives: The study aimed to evaluate the capacity of three different types of orthoses to alleviate levels of pain, whilst playing golf.

Method: Over a period of 3 months, 32 amateur golfers took part in a Randomised Control Trial which looked at a prefabricated over-the-counter golf orthosis against a placebo and a cushioning Poron insole using two validated tools—the Foot Health Status Questionnaire and the Foot Posture Index.

Results: Of the 27 golfers that completed the trial, the results showed that the use of orthoses whilst playing golf reduced the levels of pain experienced, with equally positive responses in the placebo group. Of statistical significance (where $p > 0.05$) was the improvement in foot posture of the right foot ($p = 0.053$), for those using the Golf Orthaheel. A visual analogue scale showed statistically significant pain reduction ($p = 0.007$) when using the Poron insole.

The results from this trial suggest that orthoses may have an effect in reducing pain and improving foot posture by controlling pronatory movements in golfers.

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1. Introduction

Golf is a growing participation sport enjoyed by all sectors of the public and by all ages which has expanded dramatically since the 1950s [1]. It is now the sixth most popular participating sport in the UK [2]. The increasing popularity of the game has led to a corresponding increase in golf-related injuries. Whilst there are numerous factors involved in predisposing someone to injury both intrinsic (specific to the individual—such as age, gender, weight) and extrinsic (specific to the sport—such as environment, equipment) [3], the main causes arise from overuse, poor conditioning or from poor swing mechanics [4–6].

As poor swing mechanics are one of the most common causes of injury, many studies have now analysed the biomechanics involved in the golf swing—a series of complex rotatory movements with a club around a vertical axis [7,8].

The distance of a golf shot (the measure by which most golfers gauge performance) is determined by the speed the club-head hits the ball at impact (club-head velocity). The golfer generates this speed by using the club as a lever and swinging it back and around the upper body, generating torque force from the coiling action and using the lower limb to drive through the shot by transferring weight between the feet [9,10]. Weight has been shown to be evenly distributed between the feet when the golfer addresses the ball, but this shifts to the back-foot during the backswing [7] with a peak shift of 20:80 body-weight ratio (front:back) [11].

One pioneering study by Williams and Cavanagh looked specifically at the biomechanics of the feet during the golf swing [12]. The research (albeit restricted to an artificial terrain and limited in sample population) analysed the pressure patterns of each foot using 3D camera techniques and a Kistler force platform. Whilst corroborating other studies in terms of weight transference, it highlighted pressure shifts and ground forces within each foot showing that the centre of pressures changed at the various stages of the swing.

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This key paper was the first to recognise the asymmetric motion in the feet through the various stages of the swing and that the interplay between the shoe and foot could help to generate greater club-head velocity (and subsequently distance). Although the study made recommendations designed to achieve optimum foot biomechanics and swing interaction, it was acknowledged these could conflict with normal gait requirements and would be both commercially unviable and unacceptable within the rules of the game concerning equipment [13].

One long accepted method of assisting optimum foot biomechanics has been the use of orthoses within the shoe. These are used to treat problems such as structural or postural deformities, insufficient shock absorption and excessive shearing. The aim is to reduce pain and inflammation on stressed structures and improve mobility [14] by controlling the amount and time that the foot pronates during midstance.

An extensive literature review by Landorf and Keenan [15] found that orthoses have a positive impact on pain and deformity, a significant impact on plantar pressures, affect foot position, and the amount and rate of pronation. More recently studies have challenged the efficacy of orthoses as, although treatment can alleviate pain and symptoms within the foot and ankle complex, research has not clearly indicated whether this is because the foot has had normal function restored [16]. A recent literature review by Payne and Chuter [17] looked at a number of studies evaluating the effect of orthoses in changing skeletal alignment and concluded that although effective in managing pathologic conditions, the mechanisms by which they do this remains unclear, thus contributing to the debate challenging the fundamentals of Root's concepts of the importance of neutral subtalar joint position and the relationship of the rearfoot to forefoot [16,18–23].

With National Health Service audits looking at every aspect of each service, there is also ongoing debate as to whether casted prescription insoles are more effective than prefabricated devices, particularly given the considerable disparity in costs. Finestone et al. carried out a substantial study [24] which looked at 874 infantry recruits who were assigned either a custom-soft, prefabricated-soft, semi-rigid biomechanical and semi-rigid prefabricated orthoses. There was no statistically significant difference in the incidence of ankle or foot problems between the recruits and they concluded there is little justification in dispensing “prophylactically” a semi-rigid biomechanical orthoses that is much more costly to manufacture than the others. Indeed one double-blind trial found no clinical benefit of a functional posted orthotic over a prefabricated placebo insole in modifying pain and disability [15].

Further research [25,26] has shown that the efficacy of orthoses over the longer term is difficult to analyse. Whilst compliance with orthotic treatment is likely to depend on a comfortable interface within the shoe, it has been shown that patients simply stop using them if uncomfortable or causing pain [23,26,27]. These studies suggest that if patients achieve

a positive outcome from prefabricated devices, then there is little justification in prescribing more expensive customised orthoses.

However, whilst comfort can be associated with performance, tiredness or injury potential, it is difficult to analyse because it is subjective. Some studies have attempted to quantify this with one study by Mündermann et al. [28] investigating whether different types of orthoses improved footwear comfort and reduced injury, recording any injuries or pain. They found that all shoe inserts improved footwear comfort compared with no insert at all, with softer devices achieving significantly higher ratings. This was confirmed in a later blinded random control trial [24] which found that softer orthoses, either prescription or prefabricated, scored highest on the comfort scale.

It has also been suggested that any orthosis which supports and facilitates the preferred nerve pathway for any given movement will lead to a decrease in muscle activity by affecting the mechanoreceptors in the foot involved in the shoe-insole/ground interface providing sensory feedback which minimises muscle work [29]. Whilst this concept proposes an optimal orthosis would reduce muscle activity, feel comfortable and thereby increase performance, it has not been supported by any evidence and awaits trials to ascertain its validity. A more recent study [30] has also suggested that different textures of shoe inserts can also alter muscle activity during walking due to altered sensory feedback.

From the limited golf studies available on orthoses, results have shown significant improvements in performance by reducing fatigue. One study by Stude and Brink [31] looked at the proprioceptive abilities of 12 subjects in single and double limb stance, before and after 9 holes of simulated golf and then repeated the study after 6 weeks of wearing orthoses daily. Before using orthoses there was a progressive decline in proprioception over the nine holes of golf reflecting possible fatigue, with a significant difference between right and left single-leg static stance showing better balance on the dominant side. However, following treatment, balance ability improved after nine holes of golf with less difference between dominant and non-dominant sides suggesting that proprioceptive ability was improved.

A similar later study by Stude and Gullickson [32] looked at the effects of orthoses on club-head velocity (CHV). They found that, after wearing the orthoses for 6 weeks, CHV increased by up to 7% (the equivalent of an extra 15 yards) because the orthoses had eliminated the effects of fatigue allowing subjects to have a more consistent golf swing. They later looked at pelvic rotation and stride length [33] with the results showing an increase in both following nine holes at the end of the treatment period, again suggesting this was associated with a reduction in fatigue. However the results showed only a minimal improvement reflecting more that a symmetrical motion had been produced, balancing out an initial asymmetrical difference in rotation possibly due to dominant-side preference, given that the sample population were all right-handed. It should also be noted that the sample

population in all three studies were low-handicappers and more likely to have good swing technique.

Given the relationship between comfort and performance (and the influence the foot and shoe has on this) any intervention that assists the foot to function normally throughout gait and decrease the need for compensatory motion, would be of considerable benefit to the recreational golfer as this will lessen the stresses on local structures and reduce the potential for pain and pathology. With much of the research into golfing science carried out on artificial surfaces (thereby excluding many of the other risk factors involved with injury), this trial looked at orthoses as worn in a normal golf shoe during a game on a local course over 3 months. The aim was to determine whether there was any significant reduction in the alleviation of pain and improvement of foot function when using the prefabricated Golf Orthaheel.

2. Methodology

Following ethical approval, recruitment for the single-blinded Random Control Trial on three orthotic interventions was initiated at a Cambridgeshire golf club. The sample population for the trial was drawn from those playing in a competition during July (golfing population of 136) who had initially responded to a separate study enquiring on the type, severity and level of pain experienced by amateur golfers.

From the 43 participants who responded to the invitation to take part in a trial, some 33 met the inclusion criteria (playing members over 16, not in receipt of any treatment for existing foot pathology and with a current golfing handicap) and were subsequently recruited to the trial following formal written consent.

In allocating the three orthoses, the participants were divided by gender and age (over and under 40s) and then placed into the three orthotic groups, drawn at random by an independent person, comprising 11 in each group.

- *Group A:* The Vasyli Golf Orthaheel – a prefabricated device made of flexible EVA – marketed to “improve foot function and offer pain relief”. It is the leading over-the-counter orthotic device sold in the UK.
- *Group B:* 3 mm insole made of Poron—a light weight device offering some cushioning and shock absorbency to the wearer.
- *Group C:* The placebo—made from 1 mm EVA cover on a texon base, the insole offered no benefits but acted as a sham device for the trial.

At the commencement of the trial each participant had templates taken of their most comfortable and regularly used golf shoes; the selected device was then fitted individually to the shoes, with the participant unaware of which was the prefabricated device.

As the baseline indicators, all participants completed the Foot Health Status Questionnaire (FHSQ) [34–36] and had their Foot Posture Index (FPI) [37] assessed at the outset of the trial, with their golf handicap noted. The FHSQ, originally

developed in Australia as a tool to assess surgical outcomes, has been validated to cover assessment of general foot conditions and is said to have good test–retest reliability. It covers pain, function, footwear and general foot health and is considered to be the preferred questionnaire for health related quality of life assessment of foot orthoses.

The FPI used in this trial is a validated diagnostic clinical tool that scores a foot according to eight given criteria, giving a total ranging from -16 to $+16$ which determines whether the foot is in a supinated (-16 – -2), pronated ($>+5$) or neutral (-1 – $+4$) position. Subsequent research [38,39] has shown mixed views of its reliability with some concerned about its insensitivity to small movements. However both studies accepted its use as a broad classification tool concluding it demonstrated better reliability than other available measures.

Although participants were not required to provide previous pain levels experienced before the trial as this was not a baseline indicator, they were asked to keep a golf diary recording any pain they experienced whilst playing during the 3-month trial period. The diary used a visual analogue scale (VAS)—an unvalidated pain scale ranging from no pain, through very mild, mild, moderate or severe pain. Participants were asked to complete this after each round although some chose to complete this in an ad hoc manner—i.e. at the start, middle and end of the trial period. Thus the completed diaries do not necessarily reflect the amount of golf actually played.

On conclusion of the trial, the diaries and insoles were collected and participants were asked to undertake a final FHSQ, FPI and provide their golf handicap. The data collected was non-parametric and analysed using the Kruskal–Wallis test within the SPSS computer package.

3. Results

From the 33 recruited, only 32 actually took part, with 1 member in Group B withdrawing before the start of the trial, as this was an option that could be invoked by any member at any time. Of the 32 participants recruited to the trial, 20 were male and 12 females, all were aged over 30 years (Table 1) with the mean average age for men being 53 years, and for women 55 years. The vast majority were high handicap golfers (i.e. >15) and were right-handed.

Each intervention had a failure-to-treat. There were five in total, giving a drop-out rate of 16%. Of these three (27%) were using the Golf Orthaheel which was designed to improve function and alleviate pain. However, all failure-to-treats pulled out at different stages (some within hours) because of pain and discomfort caused when wearing the insole.

Analysis of the overall FHSQ results (Table 2) showed that comparison between groups pre- and post-trial total scores, offered some improvement in all interventions, particularly in foot pain. However, using the Kruskal–Wallis SPSS programme for this data (Table 3), no statistically significant differences (where $p \leq 0.05$) was found, thus rejecting the

Table 1
Trial participants by group

	Group A	Group B	Group C	All groups
Females				
31–40	1	1	0	
41–50	2	0	2	
51–60	0	0	1	
>61	1	3	1	
Average	51	61.5	53.8	
Overall average age				55.43
Handicaps >15				10
Handicaps <15				2
Right-handed				11
Left-handed				1
Males				
31–40	2	2	1	
41–50	3	1	4	
51–60	1	1	1	
>61	1	1	2	
Average	50.4	51.2	56.3	
Overall average age				52.63
Handicaps >15				12
Handicaps <15				8
Right-handed				18
Left-handed				2

hypothesis that there were significant benefits relating to the reduction in pain for those golfers using the commercial Golf Orthaheel. Indeed, the greatest overall difference indicated by the FHSQ results, occurred within the placebo group, illustrated graphically (Fig. 1) by the improvement shown in mean average of the scores pre- and post-trial.

Analysis of FPI data (Table 4) pre-trial showed, by mean average, a neutral classification of foot type (i.e. between scores of -1 to +4) for both feet within those randomly selected for Group 3 (the placebo group), whilst those in both other groups had a mildly pronated foot type (i.e. ≥+5). In all cases the left foot scored slightly more to the criteria than the right foot. On reassessment at the conclusion of the trial period, both Groups A and B showed a slight improvement in the scoring – reducing for the right foot to a more neutral foot type – but those in the placebo group scored slightly higher suggesting a slight deterioration towards a more pronated

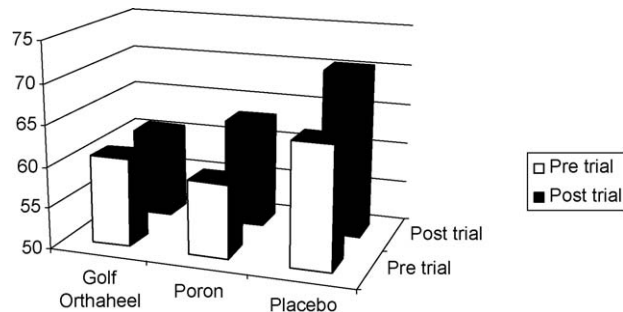


Fig. 1. The overall differences in the mean average of FHSQ scores (pre- and post-trial) by trial group.

position, albeit both feet remaining within the neutral position range.

Comparisons of the variance in FPI data, pre- and post-trial, using the Kruskal–Wallis test, indicated that there was a statistically significant difference ($p = 0.053$) noted on the right foot (Table 5) with the mean scores showing this improvement was greatest in the Golf Orthaheel (Table 6) whilst there were no significant differences for the left foot. Whilst this could suggest that the Golf Orthaheel supports the hypothesis in terms of improving foot function for the right foot only, the FHSQ findings for foot function do not corroborate this possibly due to the nature of the FPI reflecting posture in a static rather than dynamic foot.

The final baseline indicator was golfing handicaps which were monitored pre- and post-trial but was of no significance, with only one handicap changing during the duration of the trial.

The results of the VAS pain scales for the golf diaries analysing the differences in pain from the start to conclusion of the trial, showed a statistically significant reduction in pain in the back ($p = 0.007$) (Table 7). Further analysis shows the greatest variance occurred for the group using the Poron insole who also showed a marked reduction for foot pain ($p = 0.063$). Interestingly participants own subjective assessment of pain levels, improved at most sites in all groups by the end of the trial (Table 8).

Table 2
Mean average FHSQ scores by subsection and overall total

	Pre foot pain	Post foot pain	Pre foot function	Post foot function	Pre foot wear	Post foot wear	Pre foot health	Post foot health	Pre total FHSQ	Post total FHSQ
Group A	19.38	19.57	23.06	23.06	15.52	15.52	5.81	5.81	63.77	63.96
Group B	16.71	19.46	23.42	22.91	14.82	16.18	6.33	6.83	61.28	65.38
Group C	19.36	21.93	22.21	24.17	16.28	17.83	8	8.95	65.85	72.88

Table 3
FHSQ scores—analysis by subsection: Kruskal–Wallis test of significance levels

	Final foot pain	Final foot function	Final foot wear	Final foot health	Section one final total
Chi-square	0.211	5.077	1.724	0.364	4.746
d.f.	2	2	2	2	2
Asymp. significance	0.900	0.079	0.422	0.834	0.093

Table 4
FPI scores per criteria and group pre- and post-trial

	Talar head		Malleolar curves		Helbings		Calcaneal position		Navicular bulge		Medial arch		Lateral border		Ab/adduct. toes		Total	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
Pre-trial																		
Group A	1.00	1.00	0.50	0.38	0.25	0.13	1.25	1.13	0.25	0.25	1.00	1.13	0.75	0.75	1.13	1.00	6.13	5.25
Group B	1.00	0.89	0.56	0.44	0.11	0.22	1.11	0.78	0.22	0.33	0.89	0.67	1.11	0.78	1.22	1.22	6.00	5.11
Group C	0.80	0.74	0.38	0.37	0.06	0.10	0.91	0.54	0.16	0.27	0.69	0.43	0.76	0.64	1.06	1.01	4.60	4.01
Total per criteria	2.80	2.63	1.43	1.19	0.42	0.45	3.27	2.44	0.63	0.85	2.58	2.23	2.62	2.17	3.41	3.23	16.73	14.37
Average per criteria	0.93	0.88	0.48	0.40	0.14	0.15	1.09	0.81	0.21	0.28	0.86	0.74	0.87	0.72	1.14	1.08	5.58	4.79
Post-trial																		
Group A	1.00	0.75	0.50	0.38	0.25	0.13	1.00	0.88	0.13	0.13	0.88	0.88	0.75	0.88	1.38	1.13	5.88	4.63
Group B	1.11	1.11	0.33	0.22	0.11	0.22	1.00	0.56	0.11	0.11	0.89	0.67	1.11	1.00	1.33	1.11	6.00	5.00
Group C	1.01	1.06	0.22	0.21	0.06	0.11	0.80	0.58	0.11	0.21	0.69	0.53	0.91	0.80	1.12	0.96	4.80	4.35
Total per criteria	3.12	2.92	1.05	0.81	0.42	0.46	2.80	2.01	0.34	0.44	2.46	2.08	2.77	2.68	3.83	3.19	16.68	13.98
Average per criteria	1.04	0.97	0.35	0.27	0.14	0.15	0.93	0.67	0.11	0.15	0.82	0.69	0.92	0.89	1.28	1.06	5.56	4.66

Table 5
Analysis of the Kruskal–Wallis significance levels by foot in FPI scores pre- and post-trial

	Difference pre–post right foot	Difference pre–post left foot
Chi-square	5.886	1.457
d.f.	2	2
Asymp. significance	0.053	0.483

Table 6
The mean ranking of FPI scores (Kruskal–Wallis analysis) by foot and trial group

	Trial group	Number	Mean rank
Right foot	Golf Orthaheel	8	18.25
	Poron	9	15.06
	Placebo	10	9.65
	Total	27	
Left foot	Golf Orthaheel	8	15.94
	Poron	9	14.78
	Placebo	10	11.75
	Total	27	

4. Discussion

The purpose of the trial was to determine whether there was any significant reduction in pain and improvement of foot function when using the prefabricated Golf Orthaheel.

The only statistically significant reduction in pain levels ($p = 0.007$) was recorded by the visual analogue scales for

those using the Poron insole. The FHSQ showed no statistically significant results, but found that the placebo was equal in terms of pain reduction.

One of the major benefits of orthoses during sport activities is that of shock absorbency. Indeed, many studies have looked at the type and thickness of material used both in the shoes and in orthoses concluding that softer insoles were more comfortable [24,28] and better at shock absorption [40]. These findings would suggest that the softer the insole, the better the response and whilst no statistically significant results were found, the anecdotal evidence found the Poron group showed a statistically significant improvement in reducing back pain. However, in evaluating the positive responses of the placebo group, consideration should be given to the general design and construction of the golf shoe. Both the design and the condition of a shoe (in terms of its quality, age and wear) will have an impact on its capacity for shock attenuation and ability to reduce risk of injury [3]. The advanced technology now employed by sports shoe manufacturers in the battle to win market share, includes reasonable shock attenuation in the outsole—suggesting golfing footwear has sufficient absorption to negate the effect of a non-shock absorbing insole. Although this trial used participants own choice of shoe (assessed as the shoe most comfortable and regularly used), these varied considerably in terms of design, wear and age. A further study could be undertaken to investigate what happens when introducing a standardised shoe.

It should also be noted that the majority of the sample population had high handicap (>15) and may therefore be more prone to injury due to poor swing technique [4–6]. Although

Table 7
Analysis of the Kruskal–Wallis significance levels of difference in the pain experienced by site, pre- and post-trial

	Final foot pain	Final ankle score	Final calf score	Final anterior score	Final knee score	Final quads score	Final hams score	Final back score
Chi-square	5.516	1.700	2.592	1.700	2.375	1.700	1.700	9.989
d.f.	2	2	2	2	2	2	2	2
Asymp. significance	0.063	0.427	0.274	0.427	0.305	0.427	0.427	0.007

in the trial were right-handed golfers—therefore transferring maximum weight on their right foot.

All three orthoses reduced fatigue (Table 8) which confirm previous studies [31–33] relating to orthotic intervention in golf which suggest that wearing orthoses reduced fatigue through improved pelvic rotation and increased stride length but that they could also increase distances (club-head velocity).

However, the different methods of data collection (FHSQ, FPI and VAS) produced variable findings and, in hindsight, were not specific enough for the purposes of this trial. The FHSQ, relevant in ascertaining the benefits of orthoses in terms of daily general foot health and pain, is not easily converted for a more focussed activity such as golf. Future research into orthoses and sports use may require a different validated tool that focuses directly on the activity involved. In turn, the FPI has been considered open to misinterpretation by inexperienced clinicians [39] because of ambiguous definitions which may raise questions of assessor reliability.

Other considerations relating to methodology design include the potential for bias from the sample population, the need for testing the statistical accuracy of the population and the non-exclusion of variables that may have had significance on the findings, such as individual footwear, pre-existing golfing injury, golf handicap, limb dominance and body weight.

5. Conclusions

The results of this trial showed that the prefabricated Golf Orthaheel was more beneficial than the Poron or placebo orthoses in terms of foot function ($p = 0.053$) with significant improvements for the right foot for those using the Golf Orthaheel. However, the trial showed that all three orthoses had a positive effect in reducing pain and fatigue whilst playing golf. Significant reductions in back pain ($p = 0.007$) found anecdotally when using the Poron insole may indicate orthotic intervention is a useful treatment for an amateur golfer experiencing pain whilst playing golf and is worthy of further investigation.

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