Comparison of Effectiveness of Various Foot Orthoses in Treatment of Plantar Fasciitis

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Abstract
Objectives: To evaluate the effectiveness of University of California and biomechanics laboratory (UCBL) shoe insert, Silicone heel cup, Medial arch support with heel in treatment of plantar fasciitis.
Study Design: Prospective randomized study.
Setting: Department of Physical Medicine and Rehabilitation of a tertiary care hospital.
Sample Size: Hundred and five patients of age groups (18 - 60 years), with diagnosis of unilateral or bilateral plantar fasciitis.
Methodology: Subjects were randomly assigned into three equal groups. 35 to group A received UCBL shoe insert, 35 to group B received silicone heel cup, 35 to group C received medial arch support with heel pad as therapeutic method and were followed up at 1, 3 and 6 months.
Main Outcome Measurements: Assessment of scores and parameters were done using Foot Health Status Questionnaire (FHSQ) and Foot Function Index (FFI) assessed at baseline before treatment and at 1 month, 3 months, and 6 months after treatment.
Results: Statistically significant improvement of scores was noted in foot pain in all three groups during 1&3 month which were maintained till 6 months. At 1 and 3 month follow up, group A had statistically significant outcome than other two. Statistically significant improvement in foot function was noted in all 3 groups at 1 month follow up which was maintained till end of 6 month, between groups there was no statistical difference. Statistically significant improvement scores at 1 and 3 month maintained till 6 month. When compared between groups during 1 and 3 month group A were statistically significant when compared between other two.
Conclusions: Treatment of plantar fasciitis with foot orthoses like UCBL, pre fabricated silicone heel cup, medial arch support with heel pad resulted in effective pain relief and improvement in foot function and general foot health condition.
Keywords: Plantar Fasciitis, Orthoses, Foot, Shoe Inserts, Pain.

INTRODUCTION
Plantar fascia is a tough, fibrous connective tissue structure that spans the plantar surface of the foot from the inferior heel to the toes.(1) The term plantar fasciitis has been used for years in a likely attempt to recognize the actual symptoms occurring along the plantar fascia with or without concomitant presence of a bone spur. More
recently the term plantar fasciosis has been advocated to de-emphasize the presumed inflammatory component and reiterate the degenerative nature of histologic observations at the calcaneal enthesis.\(^{(2,3)}\) Plantar fasciitis is a common pathological condition affecting the hind foot and can often be a challenge for clinicians to treat successfully.\(^{(4)}\)

Various treatment modalities available at present are rest, ice, heat, nonsteroidal anti-inflammatory drugs (NSAIDs), stretching exercises, orthoses, heel cushions, heel cups, magnetic insoles, runner’s shoe, night splints, taping and short leg walking cast, steroid injections, shock wave, radiotherapy, platelet rich plasma injection and surgery.\(^{(5)}\) Orthotics, casts and insoles act by supporting the medial longitudinal arch of the foot and prevent excessive pronation of the foot thus reducing the strain on the plantar fascia.\(^{(6,7)}\)

There is paucity of evidence on effectiveness of custom made foot orthoses in long term treatment of plantar fasciitis, henceforth this research was done. The objective of this study was to evaluate the effectiveness of UCBL shoe insert, Silicone heel cup (SH), Medial arch support with heel pad (MAS) in treating plantar fasciitis with respect to functional outcomes.

**METHODOLOGY**

A prospective randomized comparative study was planned after approval from the institute ethics review committee. Subjects between the age group 18 to 60 years presenting with foot pain to outpatient department of PMR in an tertiary care centre were assessed for inclusion as per the working diagnostic criteria “Pain presenting with the insidious onset, sharp stabbing, localized to the plantar medial aspect of the heel, occurring when arising out of bed in the morning or from a chair after sitting for a long period. Physical examination revealing localized tenderness to palpation of the plantar fascia at its origin on the plantar medial tubercle of the calcaneal tuberosity”; excluded subjects with recent foot trauma, Rheumatoid arthritis, Ankylosing spondylitis, previous foot surgery and congenital defects of the lower extremity or with painful conditions of hip, knee or ankle.

After recruitment subjects had to give informed and written consent to all treatments, line of the treatment and the interventions likely to be done were explained to each subject and option of treatment did not lie with the subject. Subjects were randomly assigned by simple randomization into following - Group A received Custom made University of California Biomechanics Laboratory (UCBL) polypropylene shoe insert, Group B received pre fabricated silicone heel cup (SH) shoe insert and Group C received custom made ethaflex medial arch support with heel pad (MAS) shoe insert which were worn in shoes during all weight bearing activities. Subjects with unilateral or bilateral plantar fasciitis were considered as one subject for assessment of outcome and subjected to same treatment in both feet.

**OUTCOME MEASURES**

Baseline values of each domain in Foot Health Status Questionnaire (FHSQ) and Foot function Index (FFI) scales was recorded. Foot Health Status Questionnaire (FHSQ) which has a high test-retest reliability (intraclass correlation coefficients ranging from 0.74 to 0.92) and high degree of internal consistency (Cronbach’s a ranging from 0.85 to 0.88) was used with consent from the developer.\(^{(8)}\) Foot function Index (FFI) which has good test-retest reliability (intraclass correlation coefficients ranging from 0.69 to 0.87) and a high degree of internal consistency (Cronbach’s a ranging from 0.73 to 0.95) scales also used. Subjects were evaluated at baseline (prior to intervention) and follow up at 1, 3 and 6 month. All adverse effects reported by the patients were recorded.\(^{(9)}\)

**STATISTICAL ANALYSIS**

Descriptive statistical analysis was done for continuous variables, frequency distribution, mean, standard deviation and their percentages for categorical variables were calculated. Independent t-test was used for knowing the significance of continuous variables. ANOVA, Kruskal -Wallis
test, chi square test, were used for comparison for dichotomous responses and to compare between multiple variables between various groups. Welch-test (assuming unequal variances) and Student - Newman - Keuls test for all pairwise comparisons were used. In our statistical analysis we have used the entire group enrolled and valid tools were used for exclusion of lost cases in follow up. The results were considered significant at 5% of significance (p < 0.05).

RESULTS
One hundred and five subjects, 35 in each group were enrolled in the study. Out of the total subjects enrolled, 97 subjects completed full six month follow up, 33 each in group 1 and 2, 31 in group 3. The randomization was effective with similar baseline parameters (demographic and parameters under study) in all the three groups. (Table 1)

Overall scores of FHSQ & FFI was evaluated, statistical significance tests were done to evaluate visit on visit improvements. Both the scales showed significant improvement of scores in all domains and overall scores at 1 and 3 month follow up which plateaued at 6 month in all three groups. When compared between groups at the end of 1 month and 3 month follow up the mean improvement of scores were better in group A (UCBL) when compared to other two groups which was statistically significant. At the end of 6 month the mean overall scores of FHSQ & FFI scale were better in group A (UCBL) & B (SH) when compared to group C (MAS) and were statistically significant (Table - 2 & 3), fig (1 & 2).

Table 1 - Baseline Characteristics (Original)

| Characteristics | Group 1 (n = 35) | Group 2 (n = 35) | Group 3 (n = 35) |
|-----------------|-----------------|-----------------|-----------------|
| Age in years    | 39.6 ± 10.31    | 40.2 ± 8.98     | 38.6 ± 9.87     |
| Male            | 23              | 13              | 19              |
| Female          | 12              | 22              | 16              |
| Right           | 15              | 6               | 6               |
| Left            | 7               | 6               | 5               |
| Bilateral       | 13              | 23              | 24              |
| Duration in months | 12.60 ± 18.46  | 12.72 ± 20.60  | 11.14 ± 17.32  |

Table 2 - Result scores Mean values with Standard deviation (Original)

| Domain          | Baseline scores | 1 month     | 3 month     | 6 month     |
|-----------------|-----------------|-------------|-------------|-------------|
|                 | Group 1 | Group 2 | Group 3 | Group 1 | Group 2 | Group 3 | Group 1 | Group 2 | Group 3 |
| FHSQ overall    | 785.71  | 795.71 | 773.57 | 1177.14 | 1102.94 | 1080.14 | 1276.47 | 1226.51 | 1184.67 |
|                 | ± 197.25 | ± 178.89 | ± 176.25 | ± 100.98 | ± 124.58 | ± 130.38 | ± 56.38 | ± 97.61 | ± 111.55 |
| FFI overall     | 61.88   | 60     | 60.54 | 9.08    | 15.91    | 17.23   | 1.44    | 5.63    | 3.29    |
|                 | ± 61.88 | ± 60   | ± 60.54 | ± 9.08  | ± 15.91  | ± 17.23 | ± 1.44  | ± 5.63  | ± 3.29  |

Table 3 - FHSQ & FFI Overall Scores with inter - group significance level (Original)

| Domain   | p Value | 0 - 1months | 1 - 3months | 3 - 6months |
|----------|---------|-------------|-------------|-------------|
| FHSQ     |         |             |             |             |
| Overall  | Group A - Group B | p<0.05 | p<0.05 | p>0.05 |
|          | Group B - Group C  | p>0.05 | p>0.05 | p>0.05 |
|          | Group A - Group C  | p<0.05 | p<0.05 | p<0.05 |
| FFI      |         |             |             |             |
| Overall  | Group A - Group B  | p<0.05 | p<0.05 | p>0.05 |
|          | Group B - Group C  | p>0.05 | p>0.05 | p>0.05 |
|          | Group A - Group C  | p<0.05 | p<0.05 | p<0.05 |
Fig - 1: FHSQ overall scores with inter - group comparison (Original)

Fig - 2: FFI overall scores with inter - group comparison (Original)
DISCUSSION

Plantar fasciitis is a common clinical problem with variety of therapeutic options. Conservative management is the first line of treatment and foot orthoses are used often including prefabricated silicone, rubber heel cups, prefabricated arch supports, felt pads, custom longitudinal arch supports like University of California Biomechanics Laboratory (UCBL) shoe insert. Our study was done to compare the effectiveness of three foot orthoses; UCBL (group 1), prefabricated silicone heel cup (group 2) and ethaflex custom made medial arch support with heel pad (group 3).

FHSQ overall scores - Statistically significant improvement in overall scores of FHSQ scale were noted in all three groups during 1 and 3 month follow up period, which were maintained at 6 month follow up period in all three groups. At the end of 6 month the mean overall scores of FHSQ scale were better in group UCBL and SH when compared to group MAS and were statistically significant which are comparable to studies by Landorf and associates (10), Pfeffer and associates (11).

FFI overall scores - Statistically significant improvement in overall scores of FFI scale were seen during 1 and 3 month follow up period which were maintained at 6 month follow up period in all three groups. When compared between groups at the end of 1 and 3 month follow up the mean improvement of scores were better in group 1 when compared to other two groups which was statistically significant. At the end of 6 month the mean overall scores of FFI scale were better in group UCBL and SH when compared to group MAS and were statistically significant; which are comparable to studies by Landorf and associates (10), Pfeffer and associates (11).

None of the subjects in the study required rescue analgesics during the entire follow up period. We noted no adverse events during the study period. Our study compares favorably with most of the other studies using foot orthoses in the treatment of plantar fasciitis. Since foot orthoses are cost effective, helps to effectively relieve pain, improve function and also address the biomechanical aspect of plantar fasciitis and are an effective way of treating plantar fasciitis.

At the end of the study the outcome suggest that UCBL foot orthosis was more effective in treatment of pain and functional improvement than others during one and three month, followed by silicone heel cup and then by medial arch foot orthoses in treatment of plantar fasciitis. While six month both UCBL foot orthosis and silicone heel cup had similar outcomes on effectively treating plantar fasciitis. While, all three foot orthoses resulted in significant improvement.

On the other hand the outcome measures in successfully treating plantar fasciitis in terms of general foot health are effective and similar in all three groups.

CONCLUSION

Foot orthoses like UCBL, silicone heel cup, medial arch support with heel pad are an effective method to relieve pain, improve foot function and general foot health condition in plantar fasciitis. UCBL which is generally used in the treatment of flexible hyper pronated foot can be effectively used in treatment of plantar fasciitis. UCBL is more effective during early period and helps in faster recovery than other two orthoses. As there is paucity of literature on effectiveness of foot orthoses in long term efficacy of plantar fasciitis, further research should be done. As this study was a time bound study, further studies may be initiated with bigger sample size and longer duration of follow up.

REFERENCES

1. Saraffin SK. Anatomy of the Foot and Ankle. 2nd ed. Philadelphia, Pa: J B Lipincott; 1993.
2. Lemont H, Ammirati KM, Usen N. Plantar fasciitis: a degenerative process (fasciosis) without inflammation. J Am Podiatr Med Assoc. 2003;93:234-237.
3. Hammer WI. The effect of mechanical load on degenerated soft tissue. J Body Mov Ther 12:246 - 256, 2008.
4. Sammarco GJ, Helfrey RB. Surgical treatment of recalcitrant plantar fasciitis. Foot Ankle Int. 1996;17:520-526.
5. Thomas JL, Christensen J, Steven R K, Robert W M, John M S, Lowell S W et al. The Diagnosis and Treatment of Heel Pain: a clinical practice guideline revision 2010. The Journal of Foot & Ankle Surgery. 2010;49:S1-S19.
6. Young CC, Rutherford DS, Niedfeldt MW. Treatment of plantar fasciitis. American Family Physician. 2001;63:467-74,477-8.
7. Martin JE, Hosch JC, Goforth WP, Murff RT, Lynch DM, Odom RD. Mechanical treatment of plantar fasciitis. A prospective study. Journal of the American Podiatric Medical Association. 2001;91:55-62.
8. Budiman ME, Conrad KJ, Roach KE. The Foot Function Index: A measure of foot pain and disability. J Clin Epidemiol. 1991;44(6):561-70.
9. Bennett PJ, Patterson C, Wearing S, Banglioni T. Development and validation of a questionnaire designed to measure foot health status. J Am Podiatr Med Assoc. 1998;88:419-428.
10. Landorf KB, Keenan AM, Herbert RD. Effectiveness of different types of foot orthoses for the treatment of plantar fasciitis. J Am Podiatr Med Assoc. 2004;94(6):542-549.
11. Pfeffer G, Bacchetti P, Deland J, Lewis A, Anderson R, Davis W et al. Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis. Foot & Ankle Int. 1999;20:214-21.