A Subjective Comparison of Spenco[®] and R.P.T.[™] Soft Tissue Supplements Used in Footgear

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SUMMARY

A double blind study subjectively comparing PPT_{IM} and Spenco[®] innersoles is described. Sixty patients were studied and were asked a series of questions after wearing each insole for one month. PPT_{IM} and Spenco[®] were found to work equally well in three areas: 1) Amount of time required before relief of symptoms is felt; 2) improvement of skin lesions and 3) innersole inertia, or bottoming out. PPT_{IM} was preferred by the majority of respondents. The author feels that a longer study is required to observe significantly measurable skin changes.

INTRODUCTION

Soft tissue supplements (STS) as referred to in this study are materials of any kind that are soft, resilient and protective and can be placed into a shoe as an innersole or added to any kind of orthosis or prosthesis for the purpose of protecting bony prominences and painful areas on the plantar aspect of the foot.

Several materials meet this definition: Molo_{TM}, Plastizote, felt, sponge rubber. One material Spenco[®] (closed cell neoprene) has proved to be superior to most others in regard to symptom relief, durability and malleability. One reason for doing this study is to *subjectively* determine which soft tissue supplements are most effective since they are frequently used. Checking the frequency of use of soft tissue supplements at the Denver V.A. Medical Center reveals the Prosthetic Treatment Center dispenses approximately 160 soft tissue supplements per year for foot problems alone. Recently Professional Protective Technology introduced a new STS called P.P.T._{TM}, a porometic substance claiming superiority with a slightly lower cost.

The purpose of this study is to subjectively compare Spenco[®] and P.P.T._m in regard to their effectiveness as soft tissue supplements in the management of selected foot disorders.

MATERIALS

 PPT_{TM} is a trade name for a frothed cellular urethane material which is produced by continuously casting a reactive urethane mixture to a desired thickness. The thickness and density is closely controlled because the urethane is chemically frothed. Special grades of PPT are available for orthotic, prosthetic and podiatric applications. PPT_{TM} is recommended to prevent skin problems associated with shear stress.

PPT is available in thicknesses from 1/16 inch to 1/2 inch, and is blue in color. Nylon covered PPT is used for insoles, but felt covered, uncovered, perforated and smooth skin covered PPT is available. Uses in the orthotic and prosthetic profession experienced at the Denver Veterans Administration Medical Center include liners in both above knee and below knee prosthetic sockets (1/4 inch material), backing of Plastizote insoles, as PPT does not bottom out, and shoe insoles.

PPT is easily cemented, beveled, is washable and is very durable. Human patch tests were conducted on 25 people by the United States Testing Company, Inc. and the material did not produce skin irritation nor did it appear to be sensitizing.

MATERIALS AND METHODS

Sixty participants were chosen from patients and employees of the Denver Veteran's Administration Medical Center. All participants fit the stated criteria for inclusion in the study (Table 1). Supplies of each innersole material were obtained directly from their respective warehouses. All innersoles used in this study were 1/8" in thickness and were cut to fit each individual participants shoes. The study was conducted in a double blind manner with only one person collecting data. Each participant was randomly assigned into one of two groups (i.e., P.P.T._{TM} first or Spenco[®] first). Each participant wore both innersole materials, with a minimum one month wear time for each material tested. Four questions were asked after the test period for each innersole material, and a fifth question was asked at the conclusion of the study. (Table 2).

RESULTS

Fifty-four participants completed the study, 6 were lost to followup, of those completing the study 41 (76%) were males and 13

TABLE 1 CRITERIA FOR INCLUSION IN THE STUDY

- A. Work related foot fatigue
- B. Painful or tender feet secondary to:
 - 1) Atrophied plantar fat pad
 - 2) Plantar bony prominences
 - Punctated, nucleated and/or diffuse plantar callosities
 - 4) Plantar scar
 - 5) Plantar hyperkeratosis

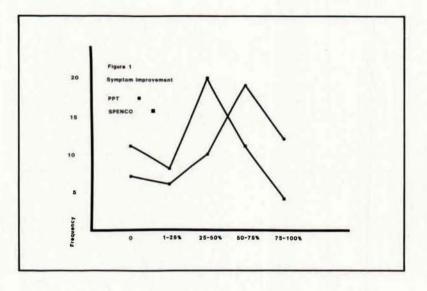
TABLE 2 QUESTIONNAIRE

- How much improvement in foot pain and/or discomfort has occurred? 0 (none) 1-25% 25-50% 50-75% 75-100%
- 2. How long did it take after wearing the material for your feet to improve? Immediately Several hours Several days Several weeks Month or more
- 3. How much improvement of the skin of your feet did you have? 0 (none) 1-25% 25-50% 50-75% 75-100%
- 4. Did the material stay in place in the shoe? No Rarely Sometimes Usually Almost always
- 5. Which material gave you the most improvement?

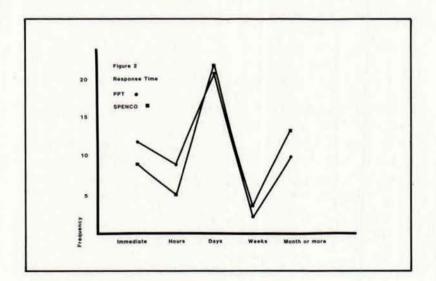
(24%) were females. Participants ages ranged from 24-83 with the average age being 49. Forty-one (76%) of the participants were caucasian, 11 (20%) black and 2 (4%) Hispanic.

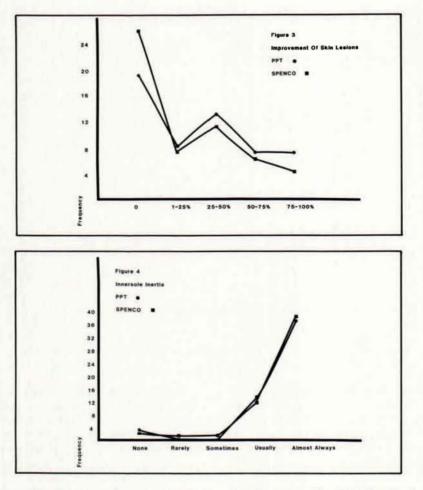
DISCUSSION

Symptom improvement (question 1) is plotted graphically in figure 1. The data sug-



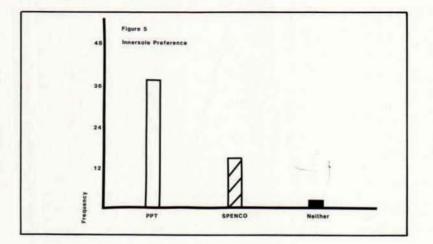
gests that a larger number of respondents felt PPT_{TM} provided 50% or greater improvement in symptoms and fewer respondents felt PPT_{TM} provided 50% or less improvement in symptoms as compared to Spenco[®]. This result is statistically significant at the 95% level of confidence (P=.05). Response time, improvement of skin lesions and innersole inertia (questions 2-4), seem to be equal for both materials, although it is this investigators opinion that significantly measurable skin changes would take longer to occur than the one month trial period this study allows.





Innersole preference (question 5) plotted by the bar graph (figure 5) clearly indicates a preference for PPT_{TM} . This is statistically

significant at the 99% level of confidence (P=.01).



CONCLUSION

 PPT_{TM} and Spenco[®] seemed to function equally well in three of the areas studied. In the area of patient preference PPT_{TM} innersoles were preferred by patients by a more than 2 to 1 ratio, and the effectiveness of PPT_{TM} as measured by symptom improvement was superior to Spenco[®] by a statistically significant margin.

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FOOTNOTE

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