*International Journal of Health Sciences and Research*
*Vol.12; Issue: 8; August 2022*
*Website: www.ijhsr.org*
*Original Research Article* *ISSN: 2249-9571*

# Comparing the Effects of Custom Molded Evazote Insoles with Pre-Fabricated Silicone Insoles on Balance, Functional Strength and Energy Expenditure in Patients with Diabetic Neuropathy

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**DOI: https://doi.org/10.52403/ijhsr.20220806**

## ABSTRACT

**Background:** Diabetic neuropathy disrupts the somatosensory system, causing disturbances in balance and increasing the fall risks. Predisposition to falls is also attributed to decreased neural sensitivity and muscle strength of lower limbs that increases the energy spent in walking. Prescription of patients with diabetic neuropathic feet involves the use of different types of insoles.
**Objective:** To compare the effectiveness of custom molded evazote insoles and silicone insoles in terms of design and material for balance, strength and energy expenditure of lower limbs in patients with diabetic neuropathy
**Material and Methods:** This was a prospective comparative study involving 46 patients with diabetic neuropathy, aged between 45-65 years, who were assessed using the Michigan Neuropathy Scoring Index. Through randomization, 23 patients were prescribed custom molded evazote insoles (Group 1) and remaining 23 were prescribed silicone insoles (Group 2. Pre-intervention and post-intervention scores of balance, lower limb functional strength and energy expenditure were measured at baseline and after 2 weeks.
**Results:** Independent t-tests were performed and these tests reported significant changes between the 2 groups, in balance and functional strength whereas no significant changes were found for energy expenditure of the patients.
**Conclusion:** Custom molded insoles are more effective as compared to silicone insoles in stimulating the mechanoreceptors in the feet and also increase the flow of somatosensory information, to prevent patients from falling. Custom molded evazote insoles provide better balance control and improved functional strength of lower limb muscles, when compared to silicone insoles.

***Keywords:*** [diabetic neuropathy, insoles, balance, functional strength, energy expenditure, diabetic insoles, diabetes, peripheral neuropathy, custom insoles]

## INTRODUCTION

Diabetic peripheral neuropathy (DPN) occurs in a distal to proximal direction due to deterioration of nerves in the lower limbs, leading to loss of sensation along with other complications that cause ulcers and even amputations.(1) DPN disrupts the somatosensory system consisting of different mechanoreceptors in the feet that provide information to the central nervous system (CNS). The feet, along with their receptors maintain balance and body posture. Somatosensory impairments due to DPN alter static and dynamic balance, contributing to an increased risk for falls.(2),(3) Predisposition to falls is also attributed to decreased neural sensitivity, reduced muscular strength of lower limbs and muscle reflexes that further impair balance, affecting motor activities of patients.(4) Decreased muscle strength of lower limbs in DPN reduces total concentric work of lower limbs and increases co-contractions in muscles of ankle and knee joints during the stance phase, causing the patients to adopt compensatory stabilization strategies that consequently increase their cost of walking.(5) Hatton AL et al has demonstrated that insoles trigger sensorimotor effects by increased proprioceptive sensation to feet and improve the functional balance as well as muscular function of lower limbs.(6) The material evazote is considered to be an ideal insole material for patients with diabetes, as it is a moderately stiff, closed cell polyethylene foam capable of transferring large impact forces from bones to adjacent tissues.(7) Silicone insoles, on the other hand, are commonly prescribed in diabetes due to their easy availability and affordability. There are limited studies reporting changes in balance, lower limb functional strength and energy spent in walking by patients with DPN, after using different insoles. Since stability, mobility and energy efficiency are vital parameters, the aim of this study was to evaluate, compare and improve the prescription of insoles in terms of design and material for patients with DPN.

## MATERIALS & METHODS

### Subject Selection

46 patients, both male and female, with DPN were recruited, who attended the outpatient department of a tertiary care hospital in New Delhi. Sample size was determined based on prior epidemiological data, with 5% significance, 15% precision and 10% drop out rates. Patients aged between 45-65 years were chosen in accordance with the report of International Diabetes Federation that states that DPN is most common in this particular age group in India.(8) This study was conducted after approval by the institutional ethical committee. After receiving the patients' written informed consent, they were assessed for DPN using the Michigan Neuropathy Scoring Index (MNSI) and their anthropometric measurements were also recorded.

### Inclusion and exclusion Criteria

Patients with confirmed diagnosis of diabetes mellitus with onset duration of minimum 5 years, MNSI > 2, free from any known neuromuscular or musculoskeletal conditions and those with the ability to stand and ambulate independently without assistance or any mobility device were included. Patients with ulcers or history of ulcers on plantar surface of foot, visual, hearing impairments, previous users of any foot insole or lower limb orthosis, patients with total or partial amputation of the lower limb, history of fractures or any other ankle foot deformities in the last 6 months were excluded.

### Subject Allocation

The subjects were randomly assigned into 2 groups using simple random sampling by lottery method. Sequentially numbered, sealed, opaque envelopes were used for concealment. Patients in Group 1 were given customized insoles, fabricated as follows - polypropylene for the base to enhance balance, arch support and heel pad made from microcellular rubber for improved stability and cushioning, and evazote as the top layer for resiliency. Patients in Group 2 were given silicone insoles pre-fabricated in standard sizes with an arch support and heel cushion to prevent frictional forces and to aid in shock absorption.

### Assessment of Variables

At the baseline assessment, the Timed Up and Go Test (TUGT) was used to assess balance, the Five-Times-Sit-to-Stand Test (FTSST) to assess functional strength and Physiological Cost Index (PCI) to assess the energy expenditure. After using the insoles for a period of 2 weeks, during which follow ups were conducted over the telephone, patients were assessed again using the same scales (TUGT, FTSST, and PCI).

**Statistical Analysis**

The data was expressed as mean ± SD, and it was analyzed using IBM SPSS Statistics (version 23). Descriptive Statistics (Mean and Standard Deviation) were computed and analyzed for the variables – balance, lower limb functional strength and energy expenditure. An independent t-test was used to compare the changes in TUGT, FTSST and PCI between Group 1 and Group 2.
A significant level of $p < 0.05$ was fixed.

## RESULT

A total of 46 patients with diabetic neuropathy, divided into 2 groups, participated in the study. Out of the 46 patients, 23 patients were given custom molded evazote insoles and the remaining 23 patients were given silicone insoles. The groups were homogenous and well matched. Baseline characteristics were similar with no statistically significant differences between them. The descriptive statistics for the demographic data have been shown in Table 1, in terms of Mean and standard deviations.

**Table 1: Demographic Data**

| Patient Characteristics | Group – 1 (N=23) | Group – 2 (N=23) |
|---|---|---|
| | Mean ± SD | Mean ± SD |
| Age | 54.83 ± 5.982 | 56.83 ± 6.740 |
| Weight | 68.65 ± 10.684 | 70.13 ± 11.169 |
| Height | 168.04 ± 7.559 | 165.83 ± 6.429 |
| BMI | 24.143 ± 3.0294 | 25.348 ± 3.213 |

Age – in years, Height – in centimeters, Weight – in kilograms, BMI – Body Mass Index, Group 1 – Custom Molded Evazote Insoles, Group 2 – Silicone Insoles, SD – Standard Deviation

**Balance**

An independent t-test was conducted to compare the results of balance, tested using the Timed Up and Go Test for Group 1 and Group 2. The difference between the custom molded evazote insoles and that of silicone insoles was significant (*p* = 0.0007). The findings have been shown in Table 2

**Table 2: Results of Independent t-test of TUGT score between Group 1 and Group 2**

| POST INTERVENTION TUGT SCORE | MEAN ± SD | t value | *p* value |
|---|---|---|---|
| Group 1 | 13.65 ± 1.18 | -3.722* | 0.0007 |
| Group 2 | 15.50 ± 2.07 | | |

*** Significant at 0.05 level, TUGT – Timed Up and Go Test, SD – Standard Deviation**

**Functional Strength**

An independent t-test was conducted to compare the results of lower limb functional strength, tested using the Five Times Sit to Stand Test. The difference between the custom molded evazote insoles and that of silicone insoles was also significant (*p = 0.000*). The data has been shown in Table 3

**Table 3: Results of Independent t-test of FTSST score between Group 1 and Group 2**

| POST INTERVENTION FTSST SCORE | MEAN ± SD | t value | *p* value |
|---|---|---|---|
| Group 1 | 13.85 ± 1.33 | -4.562* | 0.0000 |
| Group 2 | 15.80 ± 1.57 | | |

*** Significant at 0.05 level, FTSST – Five Times Sit to Stand Test, SD – Standard Deviation**

**Energy Expenditure**

An independent t-test was conducted to compare the results of energy expenditure, tested using the Physiological Cost Index. The difference between the custom molded evazote insoles and that of silicone was found to be not significant (*p* = 0.807), and has been shown in Table 4.

**Table 4: Results of Independent t-test of PCI score between Group 1 and Group 2**

| POST INTERVENTION PCI SCORE | MEAN ± SD | t value | *p* value |
|---|---|---|---|
| Group 1 | 0.109 ± 0.135 | $0.245^{NS}$ | 0.8078 |
| Group 2 | 0.10 ± 0.122 | | |

**NS – Not Significant, PCI – Physiological Cost Index, SD – Standard Deviation**

## DISCUSSION

Results of comparative data analysis between the scores of Group 1 and Group 2 indicate that significant changes in balance and lower limb functional strength were evident. However, for energy expenditure, comparative data analysis revealed changes that were not significant between the 2 groups.

Prior studies on the effects of different insole designs and materials on balance in DPN have reported contradicting results. Paton et al (2016) concluded that soft, flat insoles could be the preferable design option for patients with DN to improve balance as compared to customized insoles with arch supports. In a different study by Bus et al (2004), it was reported that customized insoles were preferred over flat insoles for DPN patients as customized insoles provided better pressure distribution and reduced peak plantar pressures for preventing the formation of ulcers. On the other hand, few researches have attempted to study the effects of insoles on lower limb functional strength and energy expenditure, but these have never attempted to compare the effects of customized insoles and flat insoles.(9),(10).

Significant improvement in balance and functional strength for Group 1, as compared to Group 2 can be attributed to the use of evazote as the top layer, stimulation of cutaneous mechanoreceptors due to the microcellular rubber arch support as well as the sturdy polypropylene base that led to better postural control and stability. The various elements in the customized evazote insoles also provided biofeedback when placed under the mid-foot and forefoot, by enhancing afferent feedback from cutaneous receptors on the plantar surface of the feet as demonstrated by Van Geffen et al and Gross et al in their previous researches.(11),(12) The custom molded insoles also aid in realignment of the lower limb to assist the muscles in their functioning and decrease the overall energy spent in walking .The augmentation of the arches and cutaneous mechanoreceptors alters the muscular work to maintain foot posture, and also dissipate and absorb this impact, in turn affecting levels of fatigue, intensity of muscular work, performance and comfort. This concept was also reported and reviewed by Hatton et al. (13).

According to Fauli et al, customized insoles adapt to the feet of every individual and reduce pressures exerted at different points on the foot, especially those at risk for ulceration. Depending on their function in the insole, materials are classified as: adaptation or accommodation, cushioning, and filling materials. These accommodation materials avoid high pressure points and are perspiration resistant. The cushioning material absorbs the impact energy during gait. The filling material provides stability to the assembly.(14) Therefore, custom molded evazote insoles with a polypropylene base and a foamed rubber arch support and heel pad yielded better results when compared to the pre-fabricated silicone insoles.

The reported results from this study can help clinicians in formulating orthotic prescription of insoles for diabetic patients with neuropathic feet and reduce fall risks through stimulation of mechanoreceptors. Similar insole materials and designs can be prescribed to the patients for a stable and energy efficient gait pattern. Moreover, future studies can be conducted on a larger sample of patients with DPN along with longer intervention periods for an even better generalization of outcomes and results.

## CONCLUSION

Reported results highlight the significance of using the appropriate material and designs of insoles when prescribing these orthoses for patients with diabetic peripheral neuropathies. Insoles will function to improve important patient parameters for secure and steady locomotion, while simultaneously aiding in the performance of day-to-day activities.

**Acknowledgement:** None

**Conflict of Interest:** The authors declare no conflicts of interests and no competing interests

**Ethical Approval:** This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Ethics Committee at the Indian Spinal Injuries Center, Vasant Kunj in New Delhi.

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How to cite this article: Khalid S, Saharawat, Sakshi Saharawat. Comparing the effects of custom molded evazote insoles with pre-fabricated silicone insoles on balance, functional strength and energy expenditure in patients with diabetic neuropathy. *Int J Health Sci Res.* 2022; 12(8):45-49. DOI: *https://doi.org/10.52403/ijhsr.20220806*

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