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Abstract

Diabetic foot ulcers, caused by diabetes-related nerve and blood vessel damage, can lead to amputations. Silicone insoles help prevent ulcers but are often expensive. Affordable, customized insoles are available, making prevention more accessible. This research aims to create affordable, locally manufactured silicone insoles for diabetic foot ulcers, reducing costs and improving accessibility. A six-month study at the Pakistan Rehabilitation Center assessed the quality of life in diabetic foot ulcer patients using the Foot Health Status Questionnaire (FHSQ). After four weeks of using silicone insoles, participants experienced significant improvements in foot health, pain relief, and mobility. They reported easier daily tasks and enhanced social interaction. Over four weeks, silicone insoles greatly improved foot health, reduced pain, and enhanced daily functioning and social interaction. The degree of improvement varied according to the initial severity of participants' conditions.

Keywords: Hyperglycemia, Silicon Insoles, Neuropathy, Silicone Gel, Diabetic Ulcers

Authors:

Asra Maqbool: (Coprrespondant author)
MS Scholar, Rehabilitation Sciences (Orthotics & prosthetics), Superior University, Lahore, Punjab, Pakistan.
(Email: asrarajpoot6@gmail.com)

Saleh Shah: Assistant professor, Superior University Lahore, Punjab, Pakistan.

Saad Saleem: Senior Lecturer, Superior University, Lahore, Punjab Pakistan.
Manager Research and Quality, Chal Foundation, Islamabad, Pakistan.

Laraib: MS Scholar, Rehabilitation Sciences (Orthotics & prosthetics), Superior University, Lahore, Punjab, Pakistan.

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Cite Us

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Abstract

Diabetic foot ulcers, caused by diabetes-related nerve and blood vessel damage, can lead to amputations. Silicone insoles help prevent ulcers but are often expensive. Affordable, customized insoles are available, making prevention more accessible. This research aims to create affordable, locally manufactured silicone insoles for diabetic foot ulcers, reducing costs and improving accessibility. A six-month study at the Pakistan Rehabilitation Center assessed the quality of life in diabetic foot ulcer patients using the Foot Health Status Questionnaire (FHSQ). After four weeks of using silicone insoles, participants experienced significant improvements in foot health, pain relief, and mobility. They reported easier daily tasks and enhanced social interaction. Over four weeks, silicone insoles greatly improved foot health, reduced pain, and enhanced daily functioning and social interaction. The degree of improvement varied according to the initial severity of participants' conditions.

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Asra Maqbool: (Coprrespondant author)
MS Scholar, Rehabilitation Sciences (Orthotics & prosthetics), Superior University, Lahore, Punjab, Pakistan.
(Email: asrarajpoot6@gmail.com)

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Manager Research and Quality, Chal Foundation, Islamabad, Pakistan.

Laraib: MS Scholar, Rehabilitation Sciences (Orthotics & prosthetics), Superior University, Lahore, Punjab, Pakistan.

Introduction

Patients with diabetes who experience long-term consequences such as nerve damage, which significantly changes the structure and function of the foot, are more likely to develop this potentially dangerous condition. These patients become more susceptible to foot ulcers if they are not properly protected. The onset of this condition and the recurrence of a foot ulcer can

both be caused by inappropriate footwear. Over the past fifty years, research has contributed to a better understanding of the factors that should be considered when recommending or creating appropriate footwear or plantar orthoses to: control the healing process of an active ulcer; stop ulcers from returning; and stop diabetic foot ulcers primary prevention. Even so, recent research maintains that there is insufficient proof to support the clinical effectiveness of diabetic footwear, particularly when it comes to preventing the development of first ulcers. To raise awareness of the main causes of the footwear intervention's continued lack of efficacy in treating diabetes and to enhance diabetic foot care as desired, the following presents and discusses the main causes of that, including the ongoing poor adherence to treatment.

Diabetic foot ulcers affect more than 80 million people worldwide, with an increased prevalence in the elderly (above 50 years of age). The high pressure areas of the foot, primarily the toe (or metatarsal area) and the heel, are where foot ulcers most commonly develop. Walking or standing can cause active mechanical stress transmission to diabetic ulcers, which can eventually cause the ulcers to enlarge and possibly require amputation. Additionally, skin cracking and the development of new ulcers may result from passive stress accumulation in other areas of the weak diabetic foot. The mechanics of the development and progression of diabetic ulcers have been the focus of a great deal of study during the previous 10 years. The human foot has been modeled using advanced imaging techniques like magnetic resonance imaging (MRI), and the induced stresses in various foot conditions have been studied using finite element (FE) modeling techniques. Strong links were observed between the incidence of ulcers and morphological changes to the foot.

As a result of lower limb nerve deterioration, diabetic peripheral neuropathy (DPN) develops in a distal to proximal direction "Leading to complications such as ulcers, amputations, and loss of sensation, DPN affects the somatosensory system, reducing neural sensitivity, weakening lower limb muscles, and impairing muscle reflexes. These impairments exacerbate balance issues and negatively influence patients' motor activities."

Approximately 85–90% of individuals with diabetic ulcers can be effectively treated without the need for surgery. Available treatments for the remaining numbers include non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, extracorporeal shock wave therapy (ESWT), and ultrasound therapy. The goal of conservative management, which includes the use of orthotics and modifications to footwear, is to return the foot and ankle to normal function while simultaneously stopping the disease from getting worse be achieved by designing orthotics that relieve pressure points reduce shear forces, provide support and control for the foot, cushion delicate regions, and fix flexible abnormalities. Braces and other footwear modifications are particularly helpful for reducing painful motion, making up for lost motion, accommodating deformities, offering support, and enhancing walking and gait.

Evazote, a moderately stiff closed cell polyethylene foam that can transfer significant impact forces from bones to surrounding tissues, is thought to be the perfect insole material for diabetic patients. Conversely, because silicone insoles are easily obtainable and reasonably priced, they are frequently prescribed for diabetes patients. Few studies have examined how wearing various insoles affects patients with DPN's balance, lower limb functional strength, and walking energy expenditure. Given the importance of stability, mobility, and energy efficiency, this study set out to assess, compare, and enhance the material and design of insole prescriptions for DPN patients.

It is unclear how precisely custom-made foot orthoses, which are the gold standard, work. Custom orthoses performed better than prefabricated orthoses for objective outcome measures such as load redistribution across

plantar zones, dynamic balance, and pressure alleviation, according to several studies. Up until now, standard insole-based materials have been the only option for cushioning in custom molded orthoses. This may or may not help patients with their foot pain. In this study, patented human tissue simulants which are cast able in any shape or size, have adjustable cushioning properties, and have been shown to effectively reduce pressure in diabetic feet will be introduced in addition to the pain-relieving effects of standard custom orthoses. To measure the impact of these innovative materials on the alleviation of plantar foot pain, it is suggested that they be included in the specially designed orthosis at the locations of discomfort or pain in the plantar foot.

There is currently a dearth of research on the customization of foot orthoses based on objective measures, such as the plantar pressure distribution. By creating a unique personalized orthosis for the treatment of plantar pressure-induced discomfort, our work attempts to narrow this gap. It was expected that this will improve the prescription criteria for conservative plantar pain management.

Figure 1.

Silicone insole

Literature Review

(Edmonds, 2016) performed an experimental research on Seven patients with diabetes (13 feet) who had a history of diabetic ulcers or current diabetic ulcers were assessed. Three patients were female and four were male (mean age, 56.8 years; range, 37-71 years). The foot orthoses were first made of polyurethane that was custom-molded. Next, with pressure-sensitive insoles and a new foot pressure measuring device (F-Scan, Tekscan, Boston, MA), In a steady standing position, plantar pressures and their distribution were measured while wearing the patients' own footwear, both with and without pre- and post-orthotic foot orthoses. With 960 sensors, this pressure-sensitive insole was thin as paper (0.15 mm). The following is how the preorthotic measurements were completed: following the sensor. After placing sheets inside the shoes, the patients slipped on the shoes and stood up straight. Peripheral neuropathy affected each patient. without feeling of protection, and none of them had severe peripheral vascular illness. The pressures were then monitored until they stabilized. With the exception of inserting the sensor sheet in between the foot and the orthosis, the post orthotic measurements were taken as previously described. The number of pressure-sensitive elements that displayed pressure loads as well as the pre- and post-orthotic peak pressures were computed. The number of loaded elements is a representation of the contact areas between the plantar surfaces and the soles or foot orthoses. The mean + SD represents the results. The Student's paired t-

test was used for statistical analysis. $P < 0.05$ was the designated P-value for the analysis. Diabetic neuropathy-related foot ulcers have been treated and prevented with great effort, but the outcomes have not been encouraging. Many materials and techniques, including total-contact casts, orthoses, custom-molded shoes, and padded socks, have been researched as means of treatment and prevention of foot ulcers because lowering the increased plantar pressures in diabetic patients with foot ulcers, or with a history of them, is essentially the only way to protect against foot ulcers. These materials disperse the pressures and increase the effective contact area, which lowers pressures at high loading sites. Nonetheless, there has long been a need for a method to quantitatively assess the effects of decompression using these materials.

(Maroti et al., 2024) used a microprocessor-controlled optical system to assess the impact of a polymer insole material. Young et al. assessed the impact of callus removal on plantar pressures using a dynamic optical pedobarograph system. It is challenging to ascertain the degree to which the measured pressures accurately represented the pressure between the plantar surface and the shoe because the pressure at the foot-floor interface was measured in these investigations. To determine the actual loads on the soles during daily life, it is obviously preferable to measure the pressure at the foot-insole interface. The pressure at the foot-insole interface was measured by Smith et al., but they adhered to local plantar areas with separate, thin, pressure-sensitive electrodes (area, 0.5 cm2; thickness, 0.25 mm). The issue with this approach is that, despite their small size and thinness, the electrodes themselves could act as foreign bodies and mask the actual loads. Moreover, high-pressure regions might just be moved to an electrode-free location, undetected, despite the fact that the pressure at the pasted electrode site is decreased. Therefore, it appears that the most effective way to assess the effects of pressure-reducing materials is to combine the high-resolution pressure distribution with the pressure measurement at the foot-insole interface. Others' issues have been resolved by the new pressure measurement system used in this study. This system features a footprint-formed sensor sheet made up of two pressure-sensitive insoles with 960 sensors apiece. The insole is sufficiently flexible to fit the curve of orthoses, and it has a thickness of 0.15 mm. As a result, pressures at the plantar pressure distribution and foot-insole interface could be measured, and the usefulness of foot orthoses composed of the widely used polyurethane material could be assessed. This new system made it possible to increase the contact area and significantly lower the pressure. The fact that this issue was readily resolved by raising the arch support or the metatarsal support, even though the post orthotic pressure distribution was occasionally unaltered, suggests that the patient's feet may not always fit the custom-molded orthoses. Furthermore, it is not possible to determine whether these instruments fit the patient's feet based solely on the subjective impression provided by the patient. It is advised that a system capable of quantitatively assessing pressures and their distribution be used to make the orthoses because diabetic patients with neuropathy frequently appear to lose protective feeling in their feet.

(Bus et al., 2020) performed a research for the prevention of diabetic foot problems is the main focus of a successful program. Wearing appropriate footwear and promoting education are two crucial components of the preventive approach. Regretfully, it happens frequently that a patient will wait to seek advice on foot care until after an issue, like a diabetic ulcer, has arisen. Many of these patients are completely unaware of diabetic neuropathy and its associated risks, and many have either never been tested for peripheral neuropathy or have not had one recently. It can be difficult to persuade someone who has never developed a foot ulcer or felt discomfort in their feet to limit their shoe selection to only those that their healthcare provider deems to be suitable. When a diabetic foot care team, with members who support one another and work together for

the patient's best interest, completes this task, it can be done most effectively.

(Wang, Yuan, Xu, & Yu, 2022) categorized foot ulcers into three categories: 0–3 for loss of protective feeling, deformity of the foot, and ulcer or ischemia history. In situations where none of the following hold true, use category 0: weakness, callus, deformity, loss of protective feeling, or a history of ischemia or ulceration. In these situations, the patients are instructed in basic foot care and are advised to wear conventional footwear. Since Category 1 only involves the loss of protective sensation, total contact orthoses, non-molded soft inlays, and in-depth shoes or sneakers are advised. Category 2, there is a loss of protective feeling along with foot deformity. If needed, external shoe modifications, custom-molded foot orthoses, and deep shoes or sneakers must be worn. All three criteria loss of protective feeling, deformity of the foot, and history of ulcer or ischemia are present in Category 3, which calls for the use of pressure-dissipating, custom-made accommodative foot orthoses. It also suggests the use of soft-leather, adjustable-lacing shoes with an inlay depth and, if necessary, external shoe modifications. As previously demonstrated, as the risk of foot ulcers rises, so do the number of requirements for orthoses or appropriately fitting footwear, as well as the complexity of prescriptions. We can consult the research conducted by Abu-Faraj in 1969 in this field. He used pressure-sensitive receptors placed in various locations on the insole to measure the plantar pressure of diabetics in a statically mode. This research shows that one foot bears 50% of the body weight when an individual stand on his own two feet. Ten percent of the weight will be placed on the heel, nine and a half percent on the first metatarsal, eight percent on the second, seven percent on the third and fourth metatarsals, and ten percent on the hallux. In 2004 he used a system with capacitive sensors to measure the plantar pressure of 107 normal feet. The plantar pressure will be distributed as follows, per this research: 60% on the heel, 8% on the midfoot, 28% on the forefoot, and 4% on the toes.

Finding the insole's stress and strain distribution following pressure application is made easy with the help of the finite element method.

(Behforootan, Chatzistergos, Naemi, & Chockalingam, 2017) measured the stress distribution in insoles, used the insole measurements to create a two-dimensional finite element model, and then connected the PPT and CLOADCREPE materials to the model. It has been suggested that the material property is hyper elastic. In 1999, Jacob and Patil used a three-dimensional finite element model (FEM) to study plantar pressure in leprosy and muscle paralysis. They compared their findings to those of a normal foot. Agati and Ladin et al. presented a linear finite element model (FEM) of an EVA insole in 1992. They determined the plantar pressure distribution by treating EVA as an elastic, isotropic, and linear material. Using Ansys software, he created a three-dimensional nonlinear static model of an insole. They looked into four different materials for a one-layer insole. Because the silicone gel had the least concentration of plantar stress, they determined that it was the best option. Petre conducted research in 2006 on a shoe manufactured by Poron, plastazote, and with a flat insole measuring 13 mm in thickness. FEM software was used to model the insoles. Using material options for the Microcell Puff volume test, sheared test, and pressure test.

(Serrato-Pedrosa et al., 2024) conducted research on the design parameter of foot orthotics to reduce pressure volume using FEM statically software. The area that is in contact with the foot can be curved more effectively to relieve pressure on the foot, according to the results. They are helpful in relieving pressure and informative. Recently, the foot and insole have been modelled together in various studies.

(Kroupa et al., 2020) simulated a healthy participant's right foot in stance phase while

wearing bare feet using a three-dimensional MRI image. Additionally, they created a nonlinear insole model using the ABAQUS program and looked into the insole's stress distribution. In 2010, Jamshidi et al. used a three-dimensional finite element model to study the relationship between an insole and an ankle-foot orthotic. They discovered that the ankle-foot orthotics' ability to function better during walking could be enhanced by the insole's ability to reduce plantar pressure. In 2010, Jamshidi and colleagues simulated a three-dimensional Poron insole model that is appropriate for Stoppage gait disorders. They determined the insole's stress distribution in both static and dynamic modes.

(Bruckner & Edelstein, 2024) conducted a comparison between a customized insole and a traditional custom insole composed of a thin shell cover and hyperplastic material. They discovered that the plantar pressure can be decreased more successfully with a custom insole whose shape matches the plantar curvature. Using experimental testing, Lavery et al. (2005) examined the shear stress parameter in a three-layer insole composed of plastazote foam (PLZ), Prone, and EVA. They discovered that by doing this, the shear stress between the insole and the foot was reduced.

Materials and Methods

gathered this data from Pakistan Rehabilitation Centre The study's sample size was limited to 4 patients, allowing for detailed experimental research focused on foundational data collection. Follow-up measurements were conducted precisely to assess improvements in diabetic foot ulcers by using custom-made silicone insoles. Patients in the hospital were selected using a random sampling method to obtain subjects for the study. The research was implemented for 6 months after the approval of the synopsis and 4 weeks of follow-up period. A tool utilized in the study was a FHSQ. Inclusion criteria was Both genders were included. They were diagnosed with diabetes and the also developed diabetic foot ulcers. They have ulcers that restricts their mobility and stop them from participate in any recreational activity.

They did not experience excessive shortness of breath while walking short distances. They had no lower-limb injuries at the time of testing that could have affected their ability to walk. Did not have tumor. Did not have renal or kidney dysfunction. Did not have high blood pressure issues. Did not have metabolic disorders, acute myocardial infarction, unregulated irregular heartbeat, Ongoing heart valve infection, Noticeable severe narrowing of the aortic valve, or acute pulmonary disorder.

Exclusion criteria was presence of other musculoskeletal conditions affecting the foot, inflammatory conditions such as rheumatoid arthritis or grout and neurological condition effecting foot or leg.

Participants

Table 1.

Participant	Gender	Age	Initial condition	Treatment
1	Female	55	Diabetic foot ulcers with limited range of motion, pain, and limitation in physical activities.	Custom-made silicone insole
2	Male	57	Diabetic foot ulcers with limited range of motion, pain, and limitation in physical activities.	Custom-made silicone insole

3	Male	51	Diabetic foot ulcers with limited range of motion, pain, and limitation in physical activities.	Custom-made silicone insole
4	Male	45	Diabetic foot ulcers with limited range of motion, pain, and limitation in physical activities.	Custom-made silicone insole

Results

The study included 4 participants, comprising1 female and 3 male patients. The demographic and clinical characteristics of the participants are summarized in table no. 1.

1st participant

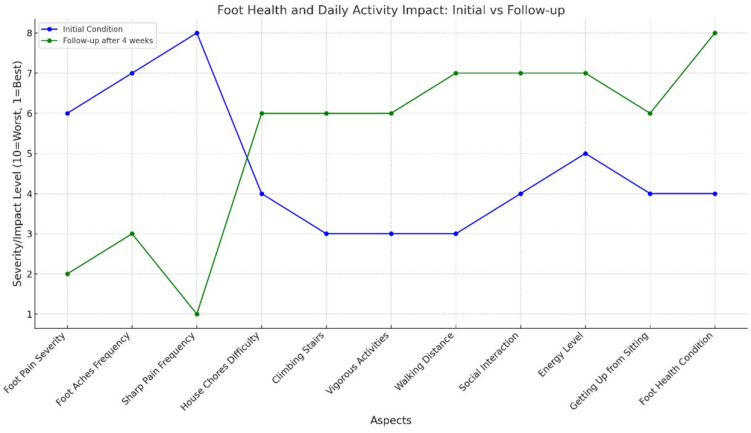
Initial condition: level of foot pain is moderate, she feels foot aches many times, feel sharp pain in feet after wearing shoes due to high diabetic level. To what extent do her feet hinder the things she could perform in a normal day? Difficulty in performing any house chores, difficulty in climbing stairs due to forefoot ulcer. Forefoot ulcers make her uncomfortable while performing any work. Does her health currently prevent her from engaging in these kinds of activities, such as strenuous ones? (running, lifting heavy objects), moderate activities (cleaning house, lifting a chair)? She feels difficulty in performing vigorous activities like running, lifting heavy objects, not able to walk more than a kilometer. How often over the last four weeks have your physical health issues and mental issues gotten in the way of your social activities (such going to see friends, family, etc.)? Moderate amount of times she feels very tired and drainage of energy limited social interaction. She also feels difficulty from getting up from sitting position. Foot health was FAIR before using insoles.

Follow-up after 4 weeks: level of pain is very mild. Occasionally, she feels foot aches, never feel sharp pain in feet after wearing silicone insoles. It became easier for her to do her house chores, able to climb the stairs easily, lift objects. She comfortably walks after wearing insole. This insole reduce pressure from ulcers and provide extra cushioning effect. After wearing insole, she will be able to walk more than a kilometer. Improve social interaction and restore her self-esteem. Her foot health become very good after using insole

.

Figure 2

Foot health and daily activity impact: initial vs follow-up



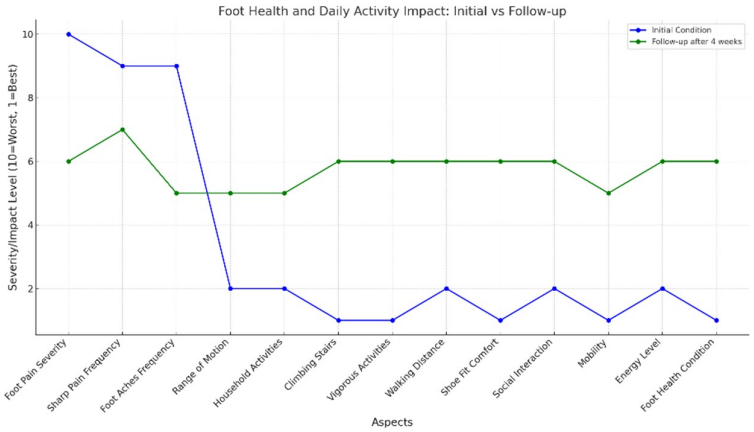
2nd Participant

Initial condition: Level of foot pain is very Severe, Very Oftenly he feel sharp pain and foot aches. He has ulcer on the bottom of toe. To what extent do his feet make it difficult for him to go about his daily business? Limited range of motion, feel extreme difficulty in performing any task. Does his health currently prevent him from engaging in these activities, such as mild activities like cleaning the home or raising a chair, or intense ones like sprinting and carrying large objects? Feel extreme difficulty in climbing stairs, extreme difficulty in performing vigorous activities like running, lifting heavy objects, not able to walk more than a kilometer. How often over the last four weeks have your physical health issues and mental issues gotten in the way of your social activities (such going to see friends, family, etc.)? He has limited social interaction. He has difficulty in findingshoes that fit his feet properly and do not hurt him? He could not be able to wear any shoes properly because it put a lot of pressure on ulcer and cause discomfort and pain. Extremely limited mobility. He feels very tired after a small walk and every time he feels out of energy. Foot health was POOR before using insoles.

Follow-up after 4 weeks: Level of pain is moderate. Occasionally, he feels foot aches and very Oftenly feels sharp pain. It became easier for him to do his work either it will be in home or outside, able to climb the stairs easily, lift heavy objects, carry shopping bags from market. After using insole, he will be able to wear shoe properly that help him to reduce pressure from ulcer and provide comfort. He will be able to walk more than a kilometer. Improve social interaction and restore his self-esteem. His foot health improves after using insole. Now sometime he feels out of energy. His foot health becomes fair after the use of silicone insole.

Figure 3

Foot health and daily activity impact: initial vs follow-up



3rd participant

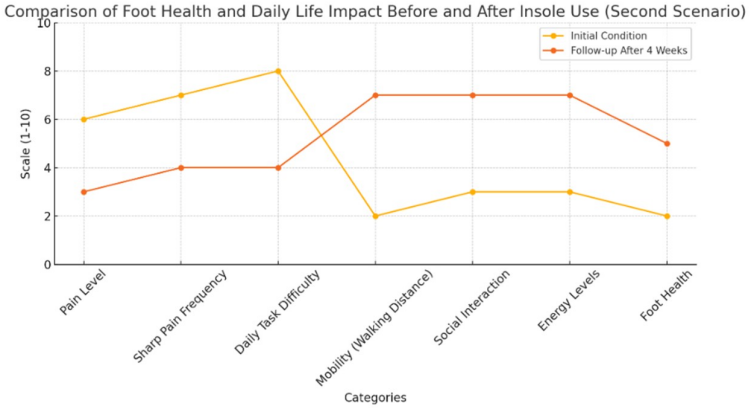
Initial Condition: The level of foot pain is moderate. He feels foot aches very often and occasionally feel sharp pain. He developed ulcers at the plantar aspects foot under metatarsal area due to poor glycemic control. How much his feet hinder him from doing things he could accomplish in a normal day? He Feel very difficult in performing any house chores. Does his current state of health prevent him from engaging in these activities, such as strenuous ones like jogging and carrying large things, or moderate ones like cleaning the home and moving a chair? Feel extreme difficulty in climbing stairs, difficulty in performing vigorous activities like running, lifting heavy objects, not able to walk more than

a kilometer. How much has your physical health and mental issues interfered with your social life (such as going to see friends, family, etc.) over the last four weeks? he has very limited social interaction. Is it hard for him to get shoes that fit his feet well and don't hurt? He feels he has limited shoes option to wear due to his condition. Most of the times feel tired and loss of energy. Foot health was POOR before using insoles.

Follow-up after 4 weeks: Level of foot pain is mild. Occasionally, he feels foot aches and sharp pain. He feels slight difficulty in doing different activities and daily routine work able to climb the stairs easily, lift objects. After wearing insole, he will be able to walk more than a kilometer. Improve social interaction and restore his self-esteem. His foot health improves after using insole. He feels less tired and full of life. His foot ulcer condition become fair.

Figure 4

Comparison of foot health and daily life impact before and after insole use (Second Scenario)



4th participant

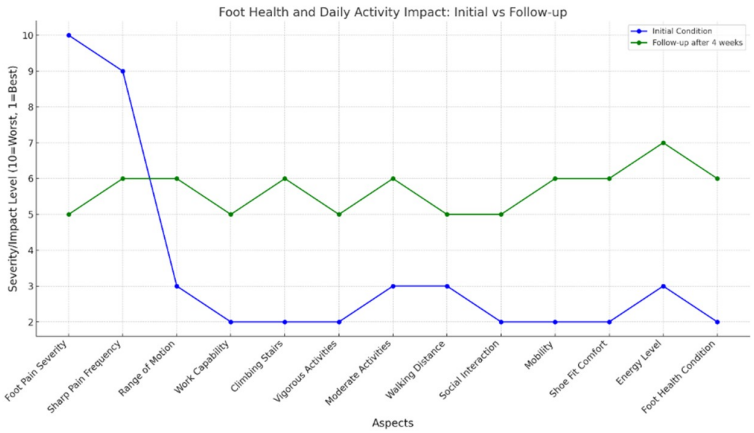
Initial condition: Level of foot pain is Severe foot pain, feel foot aches very often. He feels sharp pain in foot very Oftenly. Limited range of motion due to heel ulcer that do not allow him for more walk. What degree of disruption do his feet provide to his daily activities? He has tremendous problems working. Does his current state of health prevent him from engaging in these activities, such as strenuous ones like jogging and carrying large things, or moderate ones like cleaning the home and moving a chair? He feels extreme difficulty in climbing stairs, difficulty in performing vigorous activities like running, lifting heavy objects. He has limited activities like showering and dressing himself. How much of the last four weeks' worth of social activities—such as getting together with friends and family—have been hampered by your mental issues and physical health? Could not able to walk more than a kilometer. Poor range of motion. Limited social interaction and mobility. Does he have trouble finding shoes that fit his feet well and don't bother him? He feels extreme discomfort while moving. It's hard for him to find proper fit shoes that do not hurt his foot. All the time he feels very tired and loss of energy. Foot health was POOR before using insoles,

Follow-up after 4 weeks: level of foot pain is moderate. Fairly many time he feels sharp pain and foot aches. He feels slight improvement in his foot condition like he do not feel that every time discomfort. It became slight easier for him to do his work either it will be in home or outside, able to climb the stairs easily, lift objects. After wearing insole, he will be able to walk not more than a kilometer. His foot health improves after using insole. Increased range of motion and social interaction. Most of the times he feels tired and very little time he feels out of energy. Now he can

properly wear shoes with insole that help him in walking. His foot health condition become fair.

Figure 5

Foot health and daily activity impact: initial vs follow-up



Comparison with Existing Literature

The findings are matched with previous research highlighting the importance of dynamic, patient-targeted orthotic foot care insoles. Existing prefabricated silicone insoles provide effectiveness but the major drawback of these prefabricated insoles is that they are not affordable to everyone and available in standard size. It is not easily accessible to everybody. On the other hand, custom-made silicone insoles provide comfort, according to patient ulcer conditions, are durable, and easily available for everyone in affordable ranges.

Our findings support this principle by proving that a cheap custom-made silicone insole can achieve the same results comparable to more expensive market options, thereby improving treatment adaptability and patient outcomes.

Clinical Implications

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Discussion

The study involved four participants, each suffering from varying degrees of foot pain and associated complications due to diabetic ulcers. The main objective was to assess, during a four-week follow-up period, the effect of silicone insoles on the participants' general well-being and foot health. The results demonstrate a general trend of improvement in foot health, mobility, and quality of life across all participants, though the degree of improvement varied depending on the severity of their initial conditions.

Effectiveness of Insoles

1. Pain Reduction: For each individual, using silicone insoles resulted in a considerable reduction in foot discomfort. Pain dropped from "severe" to "moderate" in one participant and from "moderate" to "mild" in three others. This indicates that the foot pain brought on by diabetic ulcers may be considerably reduced with silicone insoles.
2. Improvement in Functional Abilities: The ability of the participants to carry out daily tasks and housework improved. Initial challenges with stair climbing and object lifting significantly improved. This improvement in performance implies that the insoles offer sufficient cushioning and support, which can improve mobility and lessen pain when performing strenuous activities.
3. Social and Emotional Well-being: Both emotional health and social interaction showed a noticeable improvement. The subjects reported feeling more energized and having higher self-esteem. This is important because it emphasizes how foot health affects quality of life in a broader way. Improved social interaction and reestablished self-worth highlight the psychological advantages of better foot health.
4. Mobility and Shoe Comfort: When insoles were used, participants reported having more comfortable and fitting shoes. It appears that insoles assist in distributing pressure and offering essential cushioning when shoes are worn without aggravating foot pain or ulcers. There was also an improvement in mobility, including walking distances.

Participant-Specific Insights

1st Participant: exhibited the greatest improvement, going from fair to very good foot health. The experience of this participant shows how insoles can effectively address functional limitations as well as pain.

2nd Participant: experienced severe pain at first, which limited their mobility; however, after the intervention, their pain improved to a moderate level and their functional abilities increased. Even though this participant's improvement was not as great as the first participant's, it still shows how effective the insoles are at reducing excruciating discomfort and improving daily living.

3rd Participant: Initially showed signs of moderate pain, which subsided to mild pain after wearing insoles. The advantage of insoles in treating moderate diabetic foot pain is further supported by the improvement in walking ability and social interaction.

4th Participant: demonstrated improved functionality and a slight improvement in pain from severe to moderate. Although the improvement was not as significant as in other cases, it indicates that insoles can still offer some relief from extreme discomfort and improve quality of life in general

Limitations and Future Directions

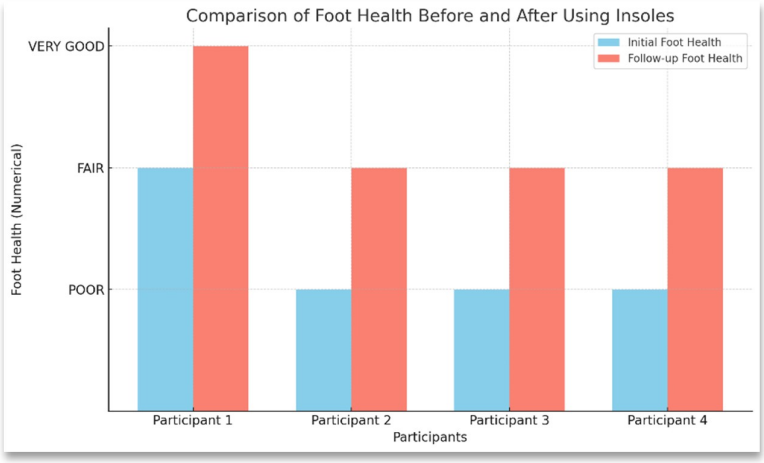
Although the results show promise, the study's small sample size restricts how broadly the conclusions can be applied. More studies with a bigger cohort and a control group would give us a more complete picture of the insoles' efficacy. Long-term research is also required to evaluate the benefits of the insoles' durability and long-term effects on foot health.

Conclusion

The application of silicone insoles seems to be a helpful intervention for people with diabetic ulcers and foot pain. Better functional abilities, reduced pain, increased emotional well-being, and improved shoe comfort are all facilitated by the insoles. These results highlight how crucial it is to take into account insoles as a practical option for treating diabetic foot conditions and enhancing general quality of life.

Figure 6

Comparison ..of foot health before and after using insoles



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