Effect of customized digital orthoses on plantar pressures in people with diabetic neuropathy: preliminary results of a randomized clinical trial

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Summary

Diabetes and diabetic peripheral neuropathy (DPN) increase the risk of foot complications, such as toe deformities, ulcers, and infections. Higher peak plantar pressure is a key factor to these issues, leading to calluses and ulcers. Custom digital silicone orthoses are intended to redistribute plantar pressures and realign deformed toes, reducing the risk of ulcers formation. A clinical study involving 34 participants with toe deformities and hyperkeratosis showed that silicone orthoses used for 3 months significantly reduced forefoot and midfoot pressures, increased toe contact area, and reduced callus formation. 60% of participants using the orthoses experienced fewer calluses, compared to 27% in the control group. These findings suggest that silicone orthoses are effective in reducing calluses, which is crucial for preventing ulcers in insensate feet.

Introduction

Diabetes and diabetic peripheral neuropathy (DPN) significantly increase the risk of foot complications, including toe deformities, loss of protective sensation, pre-ulcerative lesions (calluses), ulcers, infections, and amputations[1]. One of the most important factors in the development of these complications is elevated plantar pressure during gait, which contributes to the formation of calluses and ulcers on insensate feet[1]. To prevent these complications, it is crucial to identify and redistribute elevated plantar pressure. A highly effective strategy to achieve this is the use of custom silicone orthoses, which realign deformed toes or cushion the metatarsal heads. These orthoses play an important role in alleviating pressure points, thus preventing the formation of calluses and reducing the risk of ulcerations[2]. This approach has been recently recommended by the International Working Group on the Diabetic Foot (IWGDF)[1]. We aimed at investigating the effects of using customized silicone orthoses on redistribution of plantar pressure in people with DPN.

Methods

This study involved 34 participants with diabetic neuropathy, distributed between an Intervention (IG) and a Control Group (CG), all with toes deformities (hallux valgus, claw/hammer toes, and/or overlapping toes) and/or plantar hyperkeratosis. Both groups received a standard foot care program, which included callus removal, foot and leg skin hydration, technical nail cutting and cleaning, guidance on the use of therapeutic footwear, and molded insoles. In addition to these treatments, the IG was provided with custom-made silicone orthoses to realign the toes and redistribute plantar pressure, over 3 months. The number of pre-ulcerative injuries and their severity, as well as the plantar pressure distribution during gait (with and without orthosis – emed-q plate), were assessed at baseline and after 3 months (T3). The data were analyzed using mixed ANOVA ($p<0.05$), followed by Newman-Keuls post hoc tests, while categorical results were compared using the chi-square test.

Results and Discussion

The continuous use of the orthosis for 3 months resulted in a significant reduction in forefoot ($p=0.006$) and midfoot ($p=0.037$) peak pressures, similar to previous results from another clinical trial[2], which also demonstrated a substantial reduction in these pressures. Furthermore, it increased the hallux ($p=0.047$) and toes contact area ($p=0.023$) and reduced the forefoot pressure-time integral ($p=0.043$). Specifically, 60% of participants in the IG ($n=9$) experienced a reduction in the number of calluses after 3 months compared to baseline, versus only 27% of CG ($n=4$). This difference was statistically significant ($p=0.047$). Regarding callus severity, 53% of participants in the IG ($n=8$) showed a reduction in severity after 3 months compared to baseline, while 40% of CG ($n=6$) showed similar improvement, not statistically significant ($p=0.464$). These findings suggest that increasing toes contact area, along with reducing forefoot and midfoot peak pressures, played a crucial role in reducing the number of calluses and minimizing their severity, important risk factors for ulcers in insensitive feet.

Conclusions

The use of silicone orthoses for 3 months has shown to be effective in reducing peaks pressures, preventing the formation of pre-ulcerative lesions and reducing the number of calluses compared to usual care, thus mitigating an important risk factor for the development of ulcers in people with DPN.

References

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