Reduction of digital plantar pressure by debridement and silicone orthosis

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Abstract

The lesser digits are frequent sites of elevated plantar pressure and ulceration in the diabetic foot. We sought to determine whether debridement of callus and the wearing of a custom molded digital orthosis could significantly reduce digital plantar pressure. Fourteen patients with distal digital callus were studied. For each patient, the toe with the highest plantar pressure was selected. A computerized pressure mat was used to record the plantar pressure before and after debridement with and without a moldable silicone digital orthosis. Mean peak plantar digital pressures before treatment were 2.80 \pm 0.7 \text{ kg/cm}^2 for the entire group. The digital orthosis alone reduced plantar pressure to a mean of 1.95 \pm 0.65 \text{ kg/cm}^2 \ p < 0.05. Treatment by debridement similarly reduced pressure to 1.99 \pm 0.76 \text{ kg/cm}^2 \ p < 0.05. The most effective reduction of pressure for all patients, as well as the most statistically significant, occurred when both treatments were given, with mean peak plantar pressure falling to 1.28 \pm 0.61 \text{ kg/cm}^2 \ p < 0.01. Debridement and custom molded digital orthoses alleviate distal digital plantar pressure. Since elevated plantar pressure increases the risk of neuropathic ulceration, these treatments should be considered in the prophylactic care of appropriate patients.

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1. Introduction

Elevated plantar pressure associated with neuropathy, limited joint mobility, musculoskeletal deformity, soft tissue atrophy, and callus formation is a risk factor for pedal ulceration in diabetic patients [1–6].

The effectiveness of debridement and orthoses to reduce plantar pressure in the areas of the metatarsal heads and the hallux has been reported in the literature. Young et al. studied 17 diabetic patients with a combined total of 43 sites of callus with elevated plantar pressure on the metatarsal heads or hallux [7]. Debridement reduced overall peak plantar pressures by 26%. Therefore, they recommended that all patients with callus should undergo periodic debridement. Kato et al. reported that custom molded orthotics made of polyurethane reduced submetatarsal plantar pressure by a mean of 56% in seven diabetic patients [8]. Boulton et al. found a similar reduction in plantar pressure using a 5 mm thick prefabricated polymer insole [9].

As many as one-half of all diabetic patients have a hammer toe or claw toe deformity, often with callus and elevated pressure at the distal aspect of the toe [4]. Approximately, one-quarter of diabetic pedal ulcers occur on the lesser toes [10]. Thus, the lesser digits are frequent sites for ulceration, infection, and amputation.
However, only van Schie et al. describe a successful intervention to reduce digital plantar pressure [11]. In 17 symptom-free, healthy male subjects, they found that rigid rocker shoes reduced pressure in the lesser toes up to 40% when compared to a flexible, rocker-less shoe with a flat insole.

Our study was designed to investigate for the first time whether removal of callus from a toe and the wearing of a custom molded digital silicone orthosis could significantly reduce plantar pressures of the middle three toes (digits 2–4).

1.1. Patients

Fourteen patients (six males and eight females) who presented to the Diabetic Foot Clinic of Assaf Harofeh Medical Center participated in this study. The mean age was 66.7 (range 56–75) years and mean duration of diabetes was 21 (range 1–40) years. Twelve patients had type 2 diabetes, one had type 1, and one did not have diabetes. HbA1c results were available for 9/13 diabetic patients (mean 8.8 ± 1.98%, range 6.6–12%). Ten patients had significant clinical neuropathy, which was defined as the inability to perceive vibration with 128 Hz tuning fork on the dorsal aspect of the interphalangeal joint of the hallux or the inability to detect pressure from a 10 g Semmes-Weinstein monofilament in the plantar forefoot.

All selected patients had at least one toe with a digitus flexus deformity and a distal callus. From each patient we selected the callused toe with the highest digital plantar pressure. We excluded the fifth toe from the study since it usually develops a varus instead of a true claw toe deformity and is thus prone to ulceration from forces other than direct plantar pressure. Although, no patients had an active ulceration at the time of the study, nine toes, all of them neuropathic, had a history of ulceration. One patient had undergone a traumatic amputation of digits 4 and 5 of the left foot before developing diabetes; another, a partial amputation of the right hallux at the interphalangeal joint.

1.2. Evaluation of pressure

For each of the fourteen digits entered into the study, the dynamic plantar pressures were recorded four times: before debridement with and without the digital orthosis, and after debridement with and without the digital orthosis. Before any measurements were taken, subjects were allowed to practice walking in the gait analysis area so that the foot to be measured would easily land in the target area during normal ambulation. The F-mat system with software version 3.847F (Tekscan, Boston, MA) was used to take a dynamic measurement of the entire foot during the stance phase of gait. F-mat is part of the F-scan computerized gait analysis system that uses an ultra-thin sensor as a force mat. The program was set to record 50 measurements per second. Standard techniques and reproducibility of this system have been described by previously [8,12,13]. The location of peak plantar pressure in digits 2–4 was noted in replay analysis.

1.3. Treatment modalities

Sharp debridement of hyperkeratosis and the fabrication of a custom made digital orthosis from moldable silicone compound were performed by the same clinician for all 14 toes. The moldable silicone compound (Accumold by Premier Medical Products, PA) consists of two putties, base, and catalyst that harden in several minutes after being mixed together. Before the compound hardened, it was molded into the webbing of the toes and between the toes so that pressure would be dispersed away from the site of the callus on the distal, plantar aspect.

2. Statistical analysis

Statistical analysis was carried out using the BMDP statistical software 1993 [14]. Analysis of variance (ANOVA) with repeated measure was used to determine the effect of the various treatments. Each patient was used as his or her control. \( p < 0.05 \) was considered significant. Multivariate analysis was used to determine correlations between pre- and post-treatments mean digital pressure and various clinical parameters.

3. Results

Mean peak plantar digital pressures before treatment were 2.80 ± 0.7 kg/cm² for the entire group. The digital orthosis alone reduced plantar pressure by 30% to a mean of 1.95 ± 0.65 kg/cm² \( p < 0.05 \). Treatment by debridement similarly reduced pressure by 29% to 1.99 ± 0.76 kg/cm² \( p < 0.05 \). The most effective reduction of pressure for all patients, as well as the most statistically significant, occurred when both treatments were given, with mean peak plantar pressure falling by 54% to 1.28 ± 0.61 kg/cm² \( p < 0.01 \) (Fig. 1). When analyzing the results by individuals, we found 12/14 (86%) had reduction of pressure with the digital orthosis alone of at least 10%
(approximately, 0.3 kg/cm²), 11/14 (79%) with debridement alone, and 14/14 (100%) with both treatments [15].

There were no statistically significant differences in measurements of pressure either before or after treatments between the neuropathic and non-neuropathic groups (data not shown).

Multivariate analysis revealed no significant correlation between pre- and post-treatment mean digital pressures with duration of diabetes, age, gender, right versus left leg, and HbA1c levels and which digit (2–4) was involved.

4. Discussion

This work shows for the first time that debridement and custom molded digital orthoses can significantly reduce plantar digital pressures of the lesser toes. The mean reduction in pressure was approximately 30% for both treatment modalities. However, when the two treatments were combined, an additional reduction of 24% was achieved. Furthermore, pressure was reduced in all 14 toes by the combined treatments as compared to a success rate of 79% and 86% with individual treatments, underscoring the importance of combined treatments. It is of interest that no correlation was found between treatment mediated pressure reduction and any of the clinical variables of our patients. This further emphasizes the independent effectiveness of these simple treatment modalities.

The only other report of reduced digital plantar pressure is by van Schie et al. who demonstrated significant reduction of digital pressure with the rigid rocker shoe [11]. However, patients with diabetes or with flexus digitus deformity were not examined. Furthermore, although the rigid rocker shoe may provide the benefit of a durable, dependable reduction of pressure, patient compliance, however, is often poor due to instability and the unaesthetic appearance of the shoes [16].

Our findings extend the conclusions of Young et al. and Murray et al. regarding the pressure alleviating effects of callus removal on plantar pressure to the smaller toes [5,7]. Debridement of callus is a simple, effective treatment for the reduction of digital pressure. In addition to the immediate steep reduction in pressure, the therapeutic benefit of debridement does not depend on the patient’s compliance with wearing recommended shoes and appliances. The custom molded silicone orthosis was equally effective in reducing digital pressure, and furthermore, it has a potential advantage over debridement because its effect to reduce pressure is durable while debridement must be repeated periodically as the callus returns. On the other hand, the device should only be dispensed if the patient is willing to follow instruction on its use since improper application may cause iatrogenic ulcerations.

The number of our non-neuropathic patients was too small to draw firm conclusions. Nevertheless, we believe the reason for the uniformity of our results between neuropathic and non-neuropathic feet is due to the characteristic that all 14 toes shared in common: a digitus flexus deformity. Indeed, Masson et al. reported that in the presence of the same musculo-skeletal deformity, plantar pressures were comparable in patients with rheumatoid arthritis and patients with diabetes [17]. Therefore, it is not surprising that we found no significant difference in plantar pressure between neuropathic and non-neuropathic toes. Whether significant reduction in digital plantar pressure actually leads to a decrease in the incidence of ulceration on long-term follow-up remains unanswered. Furthermore, a record of iatrogenic lesions caused by the misapplication of the silicone orthosis would be useful in determining whether its pressure reducing capability is worth the risk of self-inflicted harm by the patient.

In conclusion, our data shows that callus removal and custom molded digital orthoses are effective treatments for alleviating distal plantar digital pressure in neuropathic and non-neuropathic diabetic feet. Since ulcers of the middle toes can be the triggering events of subsequent high-level amputations, further research on the effectiveness of surgical and conservative treatments to alleviate digital plantar pressure is warranted.
References


