

Evaluation and Optimization of Therapeutic Footwear for Neuropathic Diabetic Foot Patients Using In-Shoe Plantar Pressure Analysis

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OBJECTIVE—Therapeutic footwear for diabetic foot patients aims to reduce the risk of ulceration by relieving mechanical pressure on the foot. However, footwear efficacy is generally not assessed in clinical practice. The purpose of this study was to assess the value of in-shoe plantar pressure analysis to evaluate and optimize the pressure-reducing effects of diabetic therapeutic footwear.

RESEARCH DESIGN AND METHODS—Dynamic in-shoe plantar pressure distribution was measured in 23 neuropathic diabetic foot patients wearing fully customized footwear. Regions of interest (with peak pressure >200 kPa) were selected and targeted for pressure optimization by modifying the shoe or insole. After each of a maximum of three rounds of modifications, the effect on in-shoe plantar pressure was measured. Successful optimization was achieved with a peak pressure reduction of >25% (criterion A) or below an absolute level of 200 kPa (criterion B).

RESULTS—In 35 defined regions, mean peak pressure was significantly reduced from 303 (SD 77) to 208 (46) kPa after an average 1.6 rounds of footwear modifications ($P < 0.001$). This result constitutes a 30.2% pressure relief (range 18–50% across regions). All regions were successfully optimized: 16 according to criterion A, 7 to criterion B, and 12 to criterion A and B. Footwear optimization lasted on average 53 min.

CONCLUSIONS—These findings suggest that in-shoe plantar pressure analysis is an effective and efficient tool to evaluate and guide footwear modifications that significantly reduce pressure in the neuropathic diabetic foot. This result provides an objective approach to instantly improve footwear quality, which should reduce the risk for pressure-related plantar foot ulcers.

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As a long-term complication of the disease, foot ulceration poses a significant burden on patients with diabetes. Foot ulcers are an important precursor to infection and amputation (1,2). Approximately half of diabetic foot ulcers occur on the plantar surface of the foot (3). Peripheral neuropathy and increased levels of mechanical foot pressure are important factors in the cause of plantar foot ulceration (4,5). Therapeutic footwear is often prescribed to prevent

ulceration, particularly for patients who have suffered prior ulceration. The footwear's primary goal is to redistribute pressure on the plantar foot surface to relieve pressure at locations that are at risk for (re)ulceration.

When evaluating the efficacy of therapeutic footwear in patients with neuropathic foot problems, patient feedback is inadequate because of the presence of neuropathy. Mostly, a trial-and-error approach with subsequent inspection of the

feet is used. Eventually, feedback consists of the information on whether the patient remains free of ulceration. Objective methods to evaluate the footwear, such as in-shoe plantar pressure analysis, are not regularly used in clinical practice, despite the fact that the footwear's primary goal is to relieve pressure. Additionally, the pressure-relieving effect of footwear interventions is difficult to predict at the individual patient level because of the variability in outcomes (6–9). This result prevents establishing guidelines for effective footwear prescriptions and modification and argues for the use of in-shoe plantar pressure assessment for evaluating individual patients (6,10–13).

Within this context, in-shoe plantar pressure assessment may have the additional potential to guide modifications in the footwear to achieve a more optimal solution (in terms of pressure reduction) (10,14). If successful, such optimization will reduce the variability in outcome of footwear prescriptions and further support the use of in-shoe pressure analysis in clinical practice. Therefore, the purpose of this study was to assess the value of using in-shoe plantar pressure analysis to evaluate and optimize the pressure-reducing effects of therapeutic footwear in neuropathic diabetic foot patients.

RESEARCH DESIGN AND METHODS

Subjects

A total of 23 neuropathic diabetic foot patients participated (17 men, 6 women). Mean age was 59.1 (SD 12.6) years, and mean BMI was 33.0 (8.7) kg/m². Eight patients had type 1 diabetes, and 15 had type 2 diabetes. Mean duration of diabetes was 13.8 (10.1) years, and mean HbA_{1c} level was 7.3 (1.1) percent. A total of 18 patients had a history of plantar foot ulceration, which included nontraumatic neuropathic foot ulcers located at the hallux ($n = 3$), toes ($n = 1$), metatarsal heads ($n = 11$), or midfoot ($n = 3$). All patients had at least one foot deformity

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(claw/hammer toes, hallux valgus, mid-foot Charcot deformity, limited joint mobility, pes planus, or pes cavus). Peripheral neuropathy was confirmed by the inability to feel the pressure of a 10-g Semmes-Weinstein monofilament at one or more of six plantar foot sites.

Patients from four different outpatient clinics were included. Two clinics provided four participating patients, one clinic six patients, and one clinic nine patients. All participants were consecutive referrals for footwear evaluation because of previous ulcer healing, the presence of severe deformity, or presigns of ulceration and a measured in-shoe plantar pressure >200 kPa. The study was conducted as a noninterventive study in a patient care setting. For this reason, the local ethics committee waived the requirement for ethical approval of the study.

Footwear and instrumentation

The prescribed therapeutic footwear consisted of fully customized footwear ($n = 22$) or custom molded insoles in an extra-depth shoe ($n = 1$). Nine patients wore new footwear, and 14 patients wore previously delivered footwear. The overall mean age of the tested footwear was 2.3 months. The footwear was generally manufactured on a last that was created from a negative or positive cast or foam impression of the patient's foot. Blueprints and/or glass-plate images of the feet were used to identify foot shape and specific at-risk locations to target footwear design and manufacturing. Shoes were mostly ankle high and made from leather with a stiffened rubber outsole and roller configuration. Custom molded insoles were made from multidensity-layered materials, with a moldable base and an open or closed-cell material top cover. Patients wore their own socks, which were mostly thin seamless socks. The footwear in each clinic was prescribed and manufactured by a rehabilitation specialist and an orthopedic shoe technician (qualification similar to a certified pedorthist) who had a minimum of 4 years' experience with treating the diabetic foot.

In-shoe plantar pressures were measured using the Pedar-X system (Novel, Munich, Germany). This system comprises 2-mm-thick flexible pressure-sensing insoles including 99 sensors each measuring the vertical (normal) pressure at the shoe-sock interface at a sample frequency of 50 Hz. Pedar-wide insoles were available in five different length sizes to accommodate

different foot sizes. Before the pressure measurements, each of the 99 individual sensors per insole was calibrated according to the manufacturer's guidelines.

Protocol and footwear optimization

Patients repeatedly walked at a self-selected speed along a 12-m walkway while in-shoe plantar pressures were measured. With each pressure measurement, a minimum of 15 midgait steps were collected in four walking trials. Walking speed was measured between two fixed points using a stopwatch and kept constant between trials (maximum 5% deviation).

The footwear optimization algorithm is shown in Fig. 1. In-shoe plantar pressures were first measured in the non-modified footwear (baseline assessment). From the peak pressure distribution diagrams shown on-screen in the Novel step analysis program, regions of interest (ROIs) were defined as target regions for pressure optimization. These ROIs corresponded with locations of previous ulceration, severe foot deformity (Charcot osteoarthropathy), or preulcerative signs, all in which the measured peak pressure was >200 kPa. Other regions showing peak pressures >300 kPa were also targeted. A maximum of three ROIs per foot were selected.

The shoe technician modified the footwear with the goal to reduce peak pressure at the ROI. Necessary machinery and materials were available at the testing site. The choice of modification was made by the shoe technician and/or physician and consisted of the local removal or softening of material in the insole; replacement of the insole top cover; the addition of a metatarsal pad, hallux pad, or metatarsal bar in the insole; or the adjustment of the rocker or roller in the shoe outsole or insole (i.e., earlier or more significant). More than one footwear modification was allowed at the same time. Modifications that would require significant extra time or special machinery such as the application of a new rocker outsole or the replacement of midsole materials were not applied.

Footwear modification was directly followed by an in-shoe pressure measurement. Walking speed was kept consistent with the speed measured during baseline assessment (maximum 5% deviation). Change in peak pressure at the ROI compared with baseline was calculated from the on-screen display of the peak pressure diagrams.

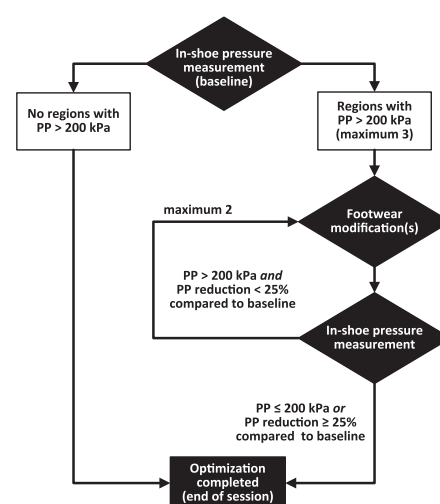


Figure 1—Schematic diagram of the footwear optimization algorithm used in the study. PP, peak pressure.

The footwear was classified as successfully optimized when, compared with the baseline assessment, a minimum 25% reduction in mean peak pressure at the ROI was achieved (criterion A) or mean peak pressure was reduced below an absolute level of 200 kPa (criterion B). Both criteria were chosen to represent a significant, probably clinically relevant, reduction in plantar pressure. Criterion B was based on previous results showing an average in-shoe peak pressure of ~200 kPa using similar equipment in patients who had remained healed in their prescribed footwear after an episode of ulceration (15).

If the optimization criteria were not met after the first round of one or more modifications, additional in-shoe pressure evaluations and modifications were allowed, up to a maximum of three rounds. This number of modification rounds was maximized for feasibility reasons considering the (potential) use of this approach in clinical practice. If the optimization criteria were not met within three rounds, optimization was considered a failure. The time required to complete the session, including all pressure measurements and footwear modifications, was recorded.

Data analysis

Using Novel multimask software, masks were drawn for each ROI and, in the same foot, for each of 10 anatomical foot regions: medial and lateral heel, medial and lateral midfoot, metatarsal 1, metatarsals 2/3, metatarsals 4/5, hallux, toes 2/3, and toes 4/5. For each mask, mean peak pressure and pressure-time integral over all collected steps per foot were calculated.

Specific analyses were performed for each ROI, for each major foot location where the ROI were present (hallux, metatarsals, and midfoot), for each shoe technician, for new and already worn footwear, and for each type of modification applied. When more than one modification was made in the same round of footwear modifications, the effect of these modifications on peak pressure was considered evenly distributed. Peak pressure effects in neighboring (anatomical) regions of each ROI after modifying the footwear were calculated and considered excessive if increased >25 kPa and >25% compared with baseline. Where data were compared statistically, paired *t* tests or ANOVA were conducted in SPSS (version 16.0).

RESULTS—A total 35 ROIs were selected for footwear optimization. A total of 17 were located at the metatarsal heads (first, *n* = 6; second or third, *n* = 9; fifth, *n* = 2), 13 at the hallux, and 5 at the midfoot. In 9 of the 18 patients who had a previous foot ulcer, the ROI corresponded with the previous ulcer location.

All 35 ROIs could be optimized according to the defined criteria: 16 on the basis of a minimum 25% peak pressure relief compared with baseline, 7 on the basis of a peak pressure reduction below a level of 200 kPa, and 12 on the basis of both criteria. The mean peak pressure measured at baseline in all ROIs was 303 (SD 77) kPa. Peak pressure significantly reduced with 95 kPa (30.2%, *P* < 0.001) to a mean 208 (SD 46) kPa after all necessary rounds of footwear modification. The range in peak pressure relief across individual ROI was 17.1–51.8%. Mean relief in pressure-time integral across all ROIs after modifying the footwear was 24.3% (*P* < 0.001). The mean time required to complete the testing session was 53 min (SD 13, range 34–78).

An average 1.6 rounds of footwear modifications were needed to satisfy the optimization criteria. In the 21 ROIs requiring one round, mean peak pressure relief compared with baseline was 30.3%. In the seven ROIs requiring two rounds, mean peak pressure relief was 9.2% after the first round and 23.0% after the second round. In the seven ROIs requiring three rounds, mean peak pressure relief was 10.6% after the first, 1.7% after the second, and 18.5% after the third round. Figure 2 shows the peak pressure changes per follow-up in-shoe pressure measurement together with the applied modifications in each round of footwear

modification for all 35 individual ROIs. Peak pressure diagrams for a patient who had his footwear successfully optimized are also shown in Fig. 2.

There were no significant differences in mean peak pressure relief achieved between the ROI optimized by the four shoe technicians (range 26.7–32.8%, *P* = 0.37). There were also no significant differences in mean peak pressure relief achieved between the ROI located at different major foot locations: 33.4% (range 17.6–51.8) for the hallux (*n* = 13 ROI), 27.9% (17.2–38.2) for the metatarsal regions (*n* = 17), and 29.7% (17.1–40.0) for the midfoot (*n* = 5) (*P* = 0.23). Analysis of the 10 anatomical foot locations showed significant mean peak pressure reductions after modifying the footwear in all but three locations (lateral midfoot, toes 2/3, and toes 2/5) (*P* < 0.05). Excessive buildup of pressure in a neighboring region was present with three of the 35 ROIs.

Five different types of footwear modifications were used in the study. Their frequency distribution and mean effects on peak pressure are shown in Table 1. Differences in effects between the types of modification were small and nonsignificant (*P* = 0.64). Additionally, there was no clear difference in the type of modifications used and the optimization success between newly delivered and already worn shoes (mean peak pressure relief 28.5 and 31.3%, respectively).

CONCLUSIONS—The results of this study showed a substantial relief in peak pressure of ~30% at selected high-pressure ROIs after modifying the custom-made footwear of neuropathic diabetic foot patients using in-shoe plantar pressure analysis as a guidance tool to the modifications made. All selected ROIs were optimized according to the defined optimization criteria, within an average of 53 min. This result demonstrates in our view the success and feasibility of the approach. Because an increase in plantar foot pressure increases the risk for diabetic foot ulceration, such optimization results should reduce the risk of foot ulceration. However, this effect remains to be investigated in a prospective clinical trial.

The study results substantiate earlier case reports showing that significant pressure relief is achievable when using in-shoe pressure analysis as a guidance tool for footwear modification (14). Furthermore, the results support earlier suggestions that in-shoe plantar pressure analysis

should be an integral part of footwear evaluation in high-risk neuropathic diabetic patients (6,10,11,13,16). The approach offers an individual-based solution to instantly achieve more optimal footwear on the assumption that different footwear design principles or modifications may work for different patients. This result is supported by the finding that not all ROIs were optimized within one round or with one type of footwear modification, but required subsequent rounds and/or different modifications to achieve the desired outcome (Fig. 2). The result is less variability in outcome on pressure relief across individual patients. This provides the clinical team with a valuable approach to achieve better quality footwear for the individual patient.

At baseline, the patients' footwear was not yet optimal in relieving pressure, although half of the previous ulcer locations were not selected as an ROI, apparently showing already good pressure relief at these locations. The suboptimal footwear is probably due to the lack of available (evidence-based) guidelines for footwear prescription and lack of predictable effects of footwear design principles. This scenario currently makes the provision and evaluation of footwear largely a trial-and-error process, where the skills and experience of the clinical team determine the outcome. However, the lack of differences found in outcome between the four teams of physicians/shoe technicians suggest that positive results can be achieved by any experienced team. Only recently, quantitative approaches such as the use of dynamic barefoot pressure recordings and three-dimensional foot shape measurements have been introduced in the provision of footwear for diabetic patients. The application of such methods can result in footwear providing also an ~30% pressure relief compared with footwear made using conventional methods (17). Combining these methods with the current optimization approach may potentially further optimize the pressure-relieving capacity of prescribed therapeutic footwear. This scenario should be tested in future studies.

Five different types of modifications were applied, and all five were commonly used. The effect of these modifications on peak pressure was quite variable from ROI to ROI (Table 1, Fig. 2), confirming the lack of predictability of these modifications in individual cases. This result supports the use of the optimization approach, in particular, because of its flexibility to

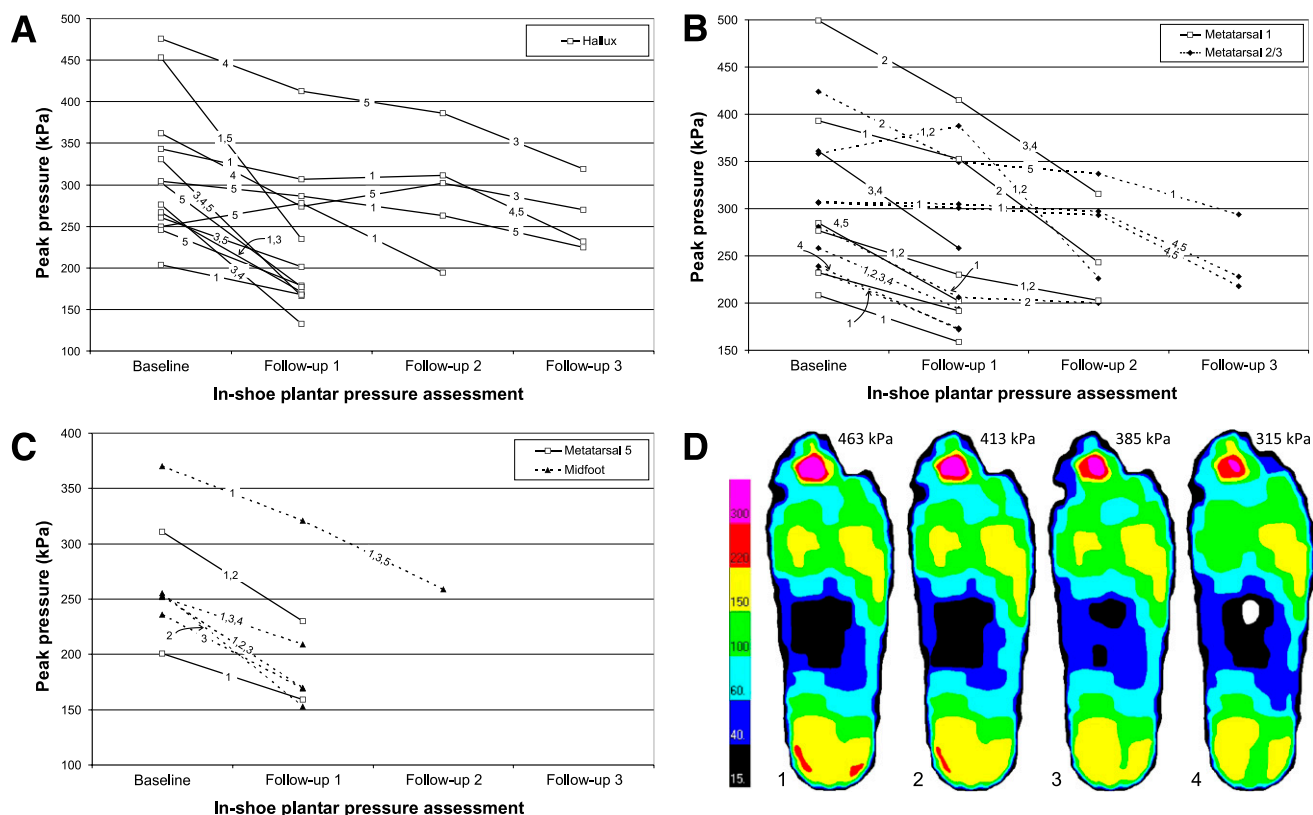


Figure 2—A–C: Line graphs showing, for each ROI per foot location, the change in peak pressure from baseline to follow-up in-shoe pressure measurement as a result of each round of footwear modification. Also shown for each ROI, as cross outs of the line graphs, are the modifications applied, where 1) denotes the local removal of material in the insole, 2) the local softening of material in the insole, 3) the replacement of the top cover of the insole, 4) the addition of a metatarsal or hallux pad or bar in the insole, and 5) an earlier or more significant rocker or roller in the shoe outsole or the insole. D: Peak pressure isobar diagrams showing the mean peak pressure measured over multiple steps in the right foot in a tested patient at baseline (1) and after three rounds of footwear modifications (2–4). This patient had limited mobility at the first metatarsal phalangeal joint and a history of ulceration at the plantar hallux. He wore fully customized therapeutic footwear. The hallux region was selected as an ROI for pressure optimization. Footwear modifications used (and their effect on mean peak pressure in kPa) were as follows: round 1: addition of a hallux bar just distal to the first metatarsal head in the insole (–50 kPa); round 2: application of an earlier roller in the shoe outsole (–28 kPa); and round 3: replacement of the top layer of the insole with 3-mm-thick $\times 2$ silicone foam (–70 kPa). Total reduction in mean peak pressure at the hallux was 148 kPa or 32%. The diagrams show a typical pattern for the study finding that footwear modification did not lead to excessive buildup of peak pressure in neighboring regions, but rather to a peak pressure decrease across foot regions.

allow multiple (rounds of) modifications to increase the chance for a significant positive result. Average effects at the ROI were quite similar between different types of modification (~10–15% pressure relief), showing that all had relevance in optimizing the footwear. Most modifications correct the foot and redistribute pressure from the ROI to neighboring regions. Excessive buildup of pressure in these neighboring regions should be prevented. In the feet of only 3 of the 35 ROIs optimized, a neighboring region showed excessive pressure buildup. Additionally, in 7 of 10 anatomical locations of the foot, peak pressure was significantly reduced after modifying the footwear. These results suggest that footwear modification did not put neighboring regions at risk and generally resulted in a more optimal solution for the whole foot.

The use of in-shoe plantar pressure analysis for evaluation and optimization of diabetic footwear requires (extra) investments in machinery, measurement equipment, personnel, and training. These investments may not be possible at every treatment location, but specialized centers should consider adopting such an approach. In Germany, requirements for demonstrated efficacy of footwear prescriptions in reducing plantar pressures have recently been introduced, although it is unclear which guidelines or evidence supports these requirements. A proven cost-effective prevention of foot ulceration and other complications, using this approach will stimulate its implementation in clinical practice and help establish evidence-based guidelines. Nonetheless, the approach should be considered relative to other foot ulcer prevention strategies

(e.g., diabetes control, podiatry, vascular control, early recognition of preulcerative signs). Also, other factors may be important in determining clinical outcome such as shear, duration of pressure, and treatment adherence, although their role has not been studied to date. We are currently investigating the (cost) effectiveness of the current optimization approach and several of these additional factors in preventing secondary ulceration in a multicenter randomized controlled trial.

Several aspects of this study should be considered. First, the outcomes reflect to a certain extent the skills and experiences of the physicians and shoe technicians in modifying the footwear, which may affect the reproducibility of the results. Modifications were not determined objectively and systematically on the basis of a certain pressure distribution

method to assess and improve therapeutic footwear quality for individual patients. Such optimization should reduce the risk of plantar foot ulceration in this patient group, although this result will have to be confirmed in future prospective clinical trials.

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S.A.B. researched data, contributed to discussion, and wrote the manuscript. R.H. and T.E.B.-W. researched data, contributed to discussion, and reviewed and edited the manuscript.

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profile because guidelines on how to reduce these pressures do not exist. We followed the dominant current practice in footwear evaluation in which a trial-and-error approach is used. Nevertheless, logical choices were made in modifying the footwear using a limited set of generally effective modifications, which resulted, after one or more rounds, in optimized footwear. Differences in optimization results were not found between shoe technicians. For these reasons, reproducibility of the results may still be quite high. Second, the optimization criteria were chosen somewhat arbitrarily. They were based on what we considered a clinically relevant pressure reduction, partly on the basis of previous recommendations (15), which could be achieved in a reasonable time. Nevertheless, future research will have to show whether these chosen criteria are clinically meaningful. Third, the number of tested patients could be considered quite small given the variability in pressure distribution profiles and footwear modifications applied. However, all 35 selected ROI were optimized, and percentage peak pressure reductions in the ROIs were significantly skewed toward the positive side (17–52%). On the basis of these consistent results, we believe that relevant conclusions can be drawn from this small study sample. Finally, the majority of footwear tested (14 of 23) was previously worn for some period. This concerned mostly footwear in which patients had developed an ulcer and which was modified after the healing of the ulcer in another device. Wear and tear of this footwear may have increased the chance for successful optimization, although the results show no clear differences in types of modifications used and pressure relief achieved between the new and already-worn footwear. The results show that evaluation and optimization is worthwhile in footwear of any age, but the most appropriate moment is probably close to delivery. Future studies will have to demonstrate the optimization success in a larger sample of newly prescribed footwear and the optimal frequency for in-shoe pressure evaluation.

In conclusion, the results of this study show that custom-made therapeutic footwear of at-risk neuropathic diabetic foot patients can be effectively and efficiently optimized for its pressure-relieving capacity when using in-shoe plantar pressure analysis as a tool to guide modifications to the footwear. This provides the clinical team with a valuable, objective, and efficient

Table 1—Type and number of footwear modifications and their mean effect on in-shoe peak pressure for all ROIs and for the ROIs per foot location

Type of footwear modification	n	All locations (n = 35 ROIs)	n	Hallux (n = 13 ROIs)	n	Metatarsals (n = 17 ROIs)	n	Midfoot (n = 5 ROIs)
Local removal of material in insole	26	11.2% (−4.2 to 30.2)	7	13.0% (−1.3 to 30.2)	15	10.1% (−4.2 to 26.7)	4	9.8% (5.7–13.2)
Local softening of material in insole	12	14.1% (−4.2 to 40.0)	0	—	10	11.8% (−4.2 to 31.2)	2	25.5% (10.9–40.0)
Addition of metatarsal or hallux pad or bar in insole	12	16.0% (6.2–28.0)	5	18.6% (12.7–25.9)	7	14.2% (6.2–28.0)	0	—
Replacement of top cover of insole	14	14.4% (6.2–25.9)	6	16.7% (10.6–25.9)	4	11.7% (6.2–14.6)	4	13.6% (6.4–10.9)
Earlier or more significant rocker or roller in shoe	16	12.3% (−11.2 to 41.6)	11	11.5% (−11.2 to 41.6)	4	12.9% (3.4–23.6)	1	6.4%

Data are n or mean effect (range), with the effect on peak pressure expressed as percentage reduction compared with the previous in-shoe pressure measurement in the session (negative values denote an increase in peak pressure).

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