A Novel Approach in Plantar Pressure Reduction Using Pixelated Insoles for the Offloading of Neuropathic Ulcers

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BACKGROUND

- Offloading the plantar aspect of the foot is a foundational component in the treatment of neuropathic ulcers, with the Total Contact Cast as the gold standard[1,2,3].
- TCC is contraindicated in patients with fluctuating edema, poor perfusion, lack of adequate tissue oxygenation, and morbid obesity. Restrictive devices such as the TCC can also be too burdensome for patients, inevitably resulting in treatment rejection and delayed healing[4].
- Only 6% of wound care specialists regularly utilize the TCC, leaving 94% to seek an alternative for plantar offloading[5].
- The alternative market is poorly studied and even more poorly funded, leaving many patients and clinicians at a loss for treatments other than standard footwear.

PURPOSE

Purpose: to evaluate the offloading potential of the pixelated FORS-15® Offloading Innersole system and the pixelated DARCO PegAssist™ insole system as compared to the standard insole of a DARCO surgical shoe.

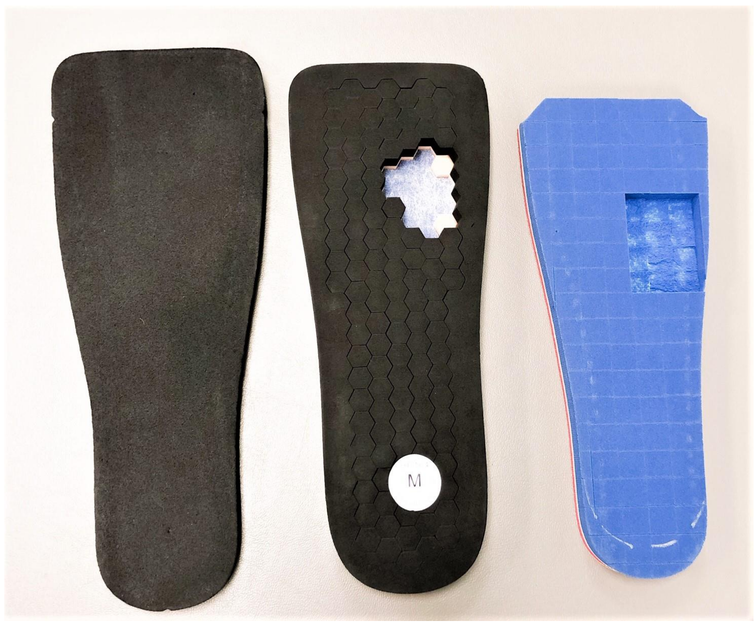

Figure 1. Standard non-pixelated DARCO surgical shoe insole (left), PegAssist™ insole (middle), and FORS-15® insole (right). The main structural difference between the two pixelated insoles is the non-removable pegs at the periphery of the PegAssist™, which lead to edge effect[6].

METHOD

Participants walked under three different conditions in a DARCO surgical shoe. In all three conditions, a designated area of high pressure was created by the addition of a ¼-inch-thick, 1.5-inch circle of skived adhesive felt on the plantar aspect of the first metatarsal head.

- **Condition 1**: Barefoot in a surgical shoe with a standard non-pixelated insole
- **Condition 2**: Barefoot in a surgical shoe with an unmodified pixelated insole.
- **Condition 3**: Barefoot in a surgical shoe with a pixelated insole modified by peg removal underneath the area of high pressure.

Subjects were instructed to walk at a comfortable cadence, and dynamic plantar pressures were collected using the F-Scan ® in-shoe dynamic pressure measuring system and software. For each condition, 5 mid-gait steps were identified, and pressure distributions were calculated for a total of 15 steps for each participant. Peak contact pressure was determined using the TekScan analysis software, and the average percentage change and average percentage deviation in pressure were calculated. A student's t-test was also performed, and the associated P-value was then used to evaluate for significant change (defined as $P < 0.05$).

RESULTS

- **Using the DARCO PegAssist™ insole system**, the percentage change of plantar pressure (kPa) under the first metatarsal between Condition 1 and Condition 2 was 10.54 ± 15.81% (P =0.022). Between Condition 2 and Condition 3 and between Condition 1 and Condition 3, the percentage changes of plantar pressure were 40.13 ± 11.11% (P<0.001) and 46.67 ± 12.95 % (P<0.001), respectively.
- **Using the FORS-15® Offloading Innersole system**, the percentage change of plantar pressure (kPa) under the first metatarsal between Condition 1 and Condition 2 was 24.25 ± 23.33 % (P= 0.0029). Between Condition 2 and Condition 3 and between Condition 1 and Condition 3, the percentage changes of plantar pressure were 23.61 ± 19.45% (P<0.001) and 43.39 ± 18.70 % (P<0.001), respectively.

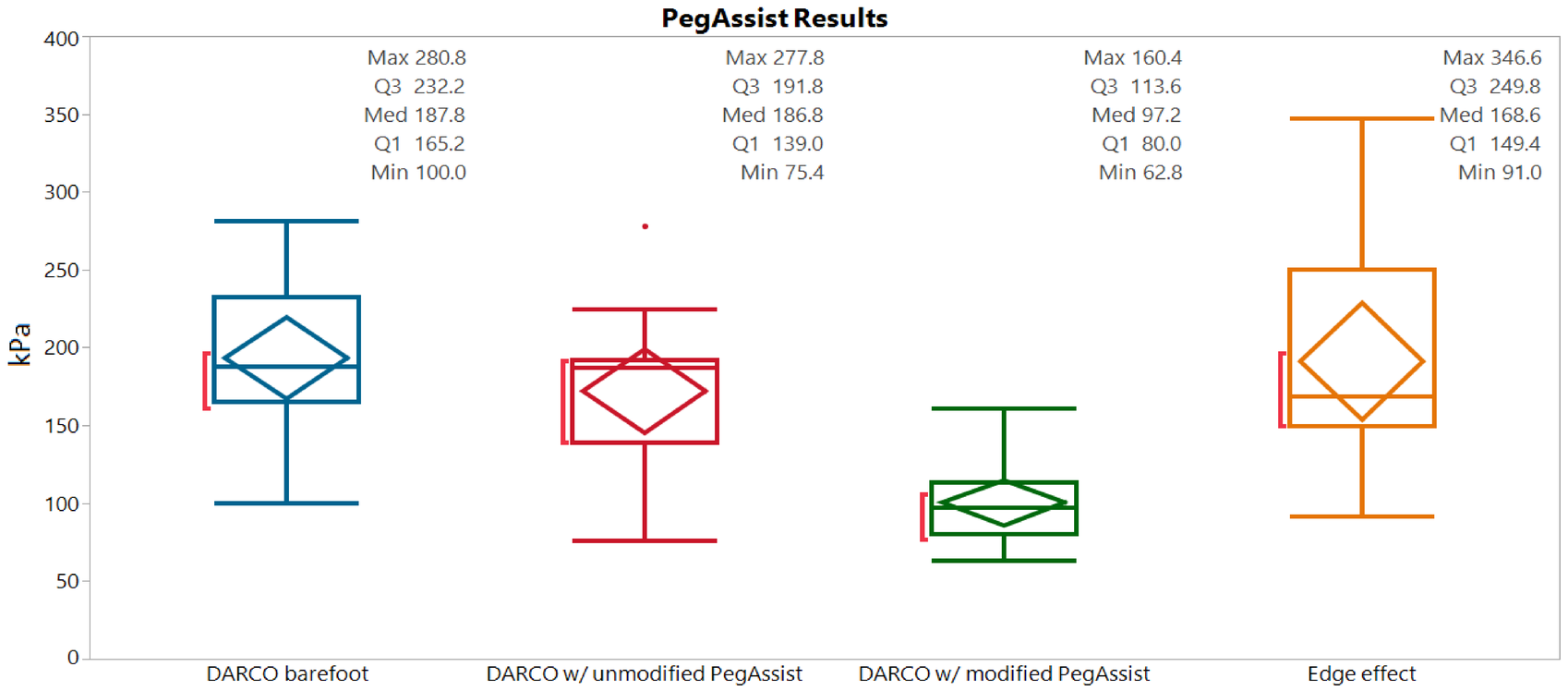

Figure 2: Plantar pressure (kPa) under the first metatarsal of all three conditions using the **DARCO PegAssist™ insole system**. Plantar pressure under the first metatarsal decreased immediately after switching from the standard non-pixelated insole to the PegAssist™ insole, even without peg removal. The modified PegAssist™ recorded the lowest plantar pressure measurements. Edge effect[6] at the periphery of the modified PegAssist™ exhibited the highest plantar pressure average and the highest single pressure measurement.

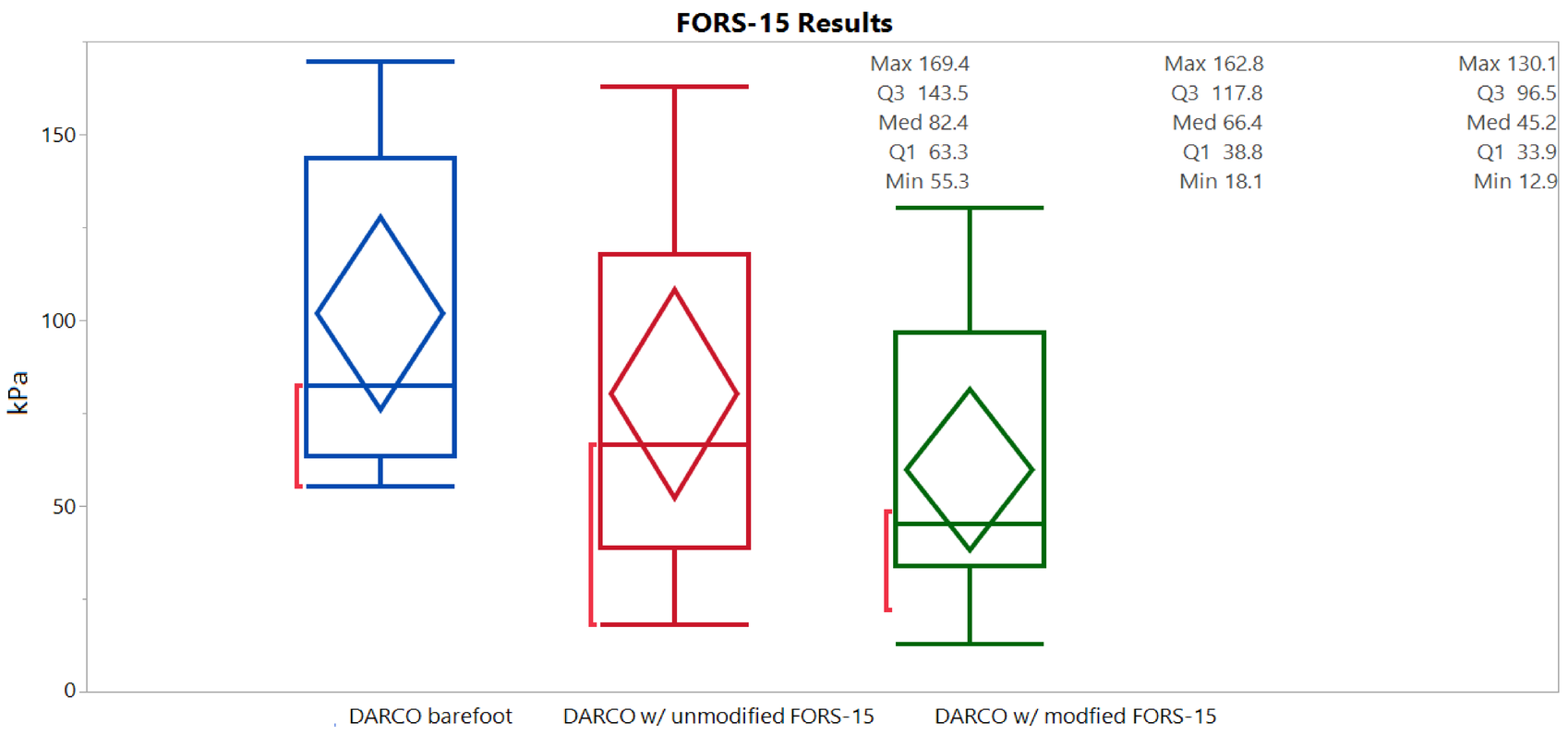

Figure 3: Plantar pressure (kPa) under the first metatarsal of all three conditions using the **FORS-15® Offloading Innersole**. The standard surgical shoe insole exhibited the highest plantar pressure recordings. Transitioning to the FORS-15® Offloading Innersole improved offloading immediately with further pressure reduction after peg removal. No edge effect was noted with these insoles.

CONCLUSION

- Both the PegAssist™ and FORS-15® devices offer significant initial pressure reduction underneath the first metatarsal head compared to the offloading achieved by the standard insole of a DARCO surgical shoe.
- Edge effect in the PegAssist™ is a concerning finding unique to this insole.
- Materials utilized in these insoles are also very different with regard to the possible compaction over time. The FORS-15® device has a thick Poron ™ base with a thin Alcantara™ topcover that should not bottom out, whereas the PegAssist™ is an EVA™ - Plastazote ™ base with a thin Poron ™ cover that may compress over time.
- Wear studies on these devices should be performed to ensure that they will hold up for the 12 weeks average treatment time for wounds.
- Future studies will also focus on developing a classification system for using shoe-based offloading.
- We are optimistic that these shoe-based devices can be effective in offloading uncomplicated, small, and shallow DFUs (UT classification A-1,2), allowing clinicians to have confidence in choosing these devices over a TCC.

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