

Plantar Pressure Distribution Analysis Demonstrates Statistically Significant Off-Loading with this Novel Total Contact Cast.

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Introduction:

A total contact cast (TCC) system comprised of a clamshell cast with off-loading footplate* was developed to facilitate wound healing by reducing and by redistributing plantar pressure. The purpose of this study was to assess its off-loading and pressure redistributing ability using plantar pressure distribution analysis. The goal was to demonstrate reduction in peak plantar pressure.



Methods:

A total of 15 healthy subjects participated in the study. A standardized marker (2.5cm diameter, .5cm thick, 35 durometer) was applied to simulate a plantar ulcer at the 3rd metatarsal head. A computerized insole sensor system** was used to analyze plantar pressure per a standardized protocol. In this poster, two objectives are shown.

Objective 1: Compare TCC comprised of a clamshell cast and off-loading footplate to an athletic shoe and a competitive TCC.*** Each subject performed the following gait trials:

1. Subject's own athletic shoe (control)
2. TCC system comprised of a clamshell cast with off-loading footplate and CAM boot
3. A competitive total contact cast and CAM boot***

Objective 2: There are different methodologies for applying total contact casts. The goal was to analyze pressure reduction when different application methods were used for the TCC comprised of a clamshell cast with off-loading footplate compared to a competitive TCC.*** Each subject performed the following gait trials:

1. Subject's own athletic shoe
2. A competitive total contact cast and CAM boot
3. TCC system comprised of a clamshell cast with the off-loading footplate partially cutout and CAM boot***
4. TCC system comprised of a clamshell cast with the off-loading footplate completely cutout and Cast shoe
5. TCC system comprised of a clamshell cast with the off-loading footplate completely cutout and CAM boot

Plantar pressures from the stance phase were collected and analyzed. Peak pressures from this region were isolated; a mean peak pressure was calculated. Data from 15 subjects were analyzed. Casts were

applied according to the manufacturer's instructions for use by health care providers experienced in total contact casting. The principal investigator substituted the CAM boot from the TCC system comprised of a clamshell cast with off-loading footplate for the competitive TCC CAM boot provided with the competitive TCC system for purposes of data collection for this study. The principal investigator has assumed this substitution will not materially affect the performance of the competitive TCC system.

Results:

Compared to an athletic shoe and a competitive TCC,*** the TCC system comprised of a clamshell cast with off-loading footplate provided statistically significant lower mean peak pressures.¹ Due to the superior off-loading capabilities, it is expected that this novel TCC system comprised of a clamshell cast with off-loading footplate is an excellent option for the management of diabetic plantar ulcers. (Figures 1 and 2)

Figure 1 (Same subject used for each pressure map)

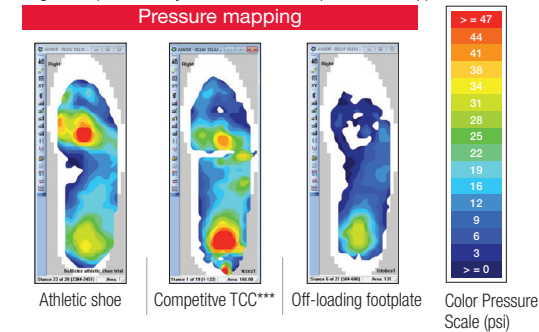
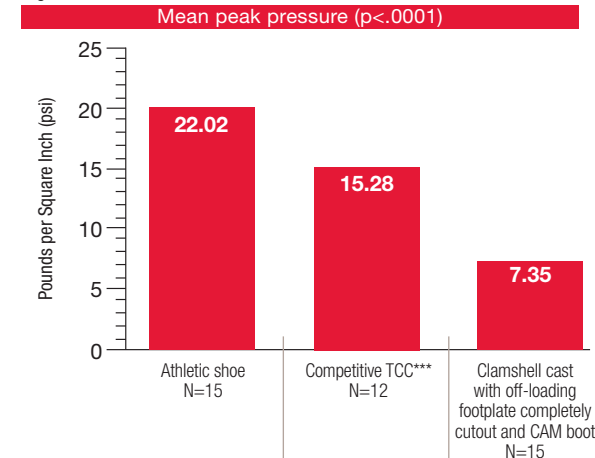


Figure 2



The following data is provided for informational purposes only. When the off-loading footplate was left intact, the TCC system of a clamshell cast with off-loading footplate provided comparable pressure to the competitive TCC*** but provides significantly less pressure reduction than when the TCC system of a clamshell cast with off-loading footplate was used as instructed by the manufacturer. The TCC system of a clamshell cast with off-loading footplate should be used only as specified in the IFU. In addition, significant difference in pressure reduction was observed between the athletic shoe and TCC system of a clamshell cast with off-loading footplate intact and CAM boot. (Figure 3)

Figure 3

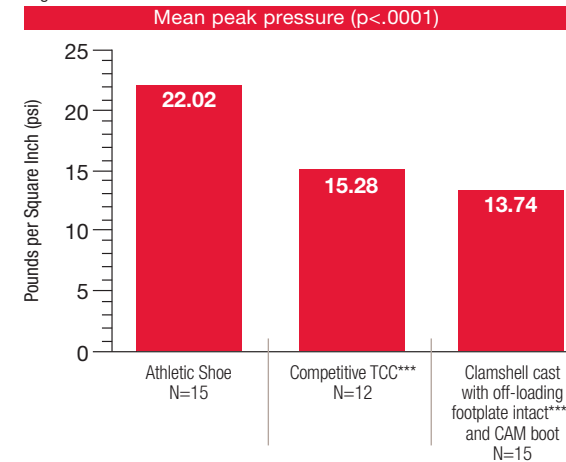
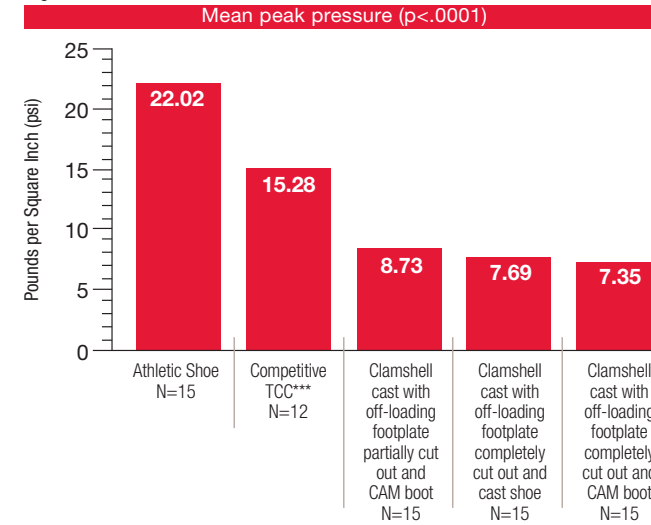


Figure 4



The TCC system comprised of a clamshell cast with off-loading footplate having the footplate partially or completely cut out provides statistically significant greater pressure reduction than the competitive TCC.*** Significant difference in pressure reduction was observed between the athletic shoe (control) and the three application techniques used with the TCC system comprised of a clamshell cast with off-loading footplate shown in Figure 4. In addition, using a cast shoe showed comparable pressure reduction compared to a CAM boot. (Figure 4)

Conclusion:

Compared to an athletic shoe and a competitive TCC,*** the TCC system comprised of a clamshell cast with off-loading footplate provided statistically significant lower mean peak pressures. Different application techniques of the off-loading footplate also showed a statistical difference in pressure reduction compared to the athletic shoe and the competitive TCC.*** Due to these superior off-loading capabilities, it is expected that this novel TCC system comprised of a clamshell cast with off-loading footplate is a superior option for the management of diabetic plantar ulcers.

REFERENCES

1. Data on file.
- * FastCast OLS, Distributed by Hollister Incorporated.
 ** F-Scan; Tekscan, Inc
 *** In this study, the CAM Boot provided with the TCC system comprised of a clamshell cast with off-loading footplate was used with the competitive TCC.
 ****The TCC system of a clamshell cast with off-loading footplate should be used only as specified in the IFU.