

Dose-response effects of segmented, custom-made 3D-printed foot orthoses on plantar pressure in participants with diabetes and a central forefoot pressure pattern

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Background

Elevated plantar pressure is a modifiable pathway to diabetes-related foot complications, yet custom foot-orthosis design remains largely empirical. Pressure offloading remains variable and is often achieved through trial and error because the quantitative relationship between controllable orthosis design parameters and biomechanical response is poorly understood. This dose-response knowledge gap limits predictable optimisation and patient-specific prescription. 3D printing offers greater geometric freedom, local control of mechanical properties and the ability to introduce design features sequentially. We investigated whether cumulative modifications to segmented, custom-made 3D-printed foot orthoses (CMD) produced a dose-response in central-forefoot offloading.

Methods and Orthosis Designs

Population

- Monocentric (UZ leuven), within-participant interventional study
- Sample: n = 25

Inclusion:

- age 18-75 years;
- type 1 or 2 diabetes according to WHO; risk classification 0-3(a);
- central-forefoot pressure pattern (**barefoot (BF)** peak pressure **>400 kPa beneath metatarsal heads 2-3** (CM2-3; Fig. 1)

Procedure

F-Scan (Tekscan, Model E3000, 4 sensors/cm²) measurements during **barefoot in-shoe** (standard shoe) walking (**BFS**) and with **four custom-made foot orthosis designs** (CMD1-4; Table 1 & Fig. 3); **four valid steps averaged per condition**. Only the side with the highest CM2-3 peak pressure was analysed.



Figure 1: Central or metatarsal heads 2-3 (CM2-3) pattern

Parameters

10 anatomical segments were masked based on the anatomy of the foot (Fig. 2): T1 (Hallux); T2-5 (Toes 2-5); CM1, 2-3 & 4-5; MM (Midfoot Medial), MC (Midfoot Central), ML (Midfoot lateral); HM (Heel medial) and HL (Heel lateral). Per segment, the following parameters were measured:

- PP: Peak Pressure (kPa)
- CA: Contact Area (mm²)
- PTI: Pressure-Time Integral (kPa·s)

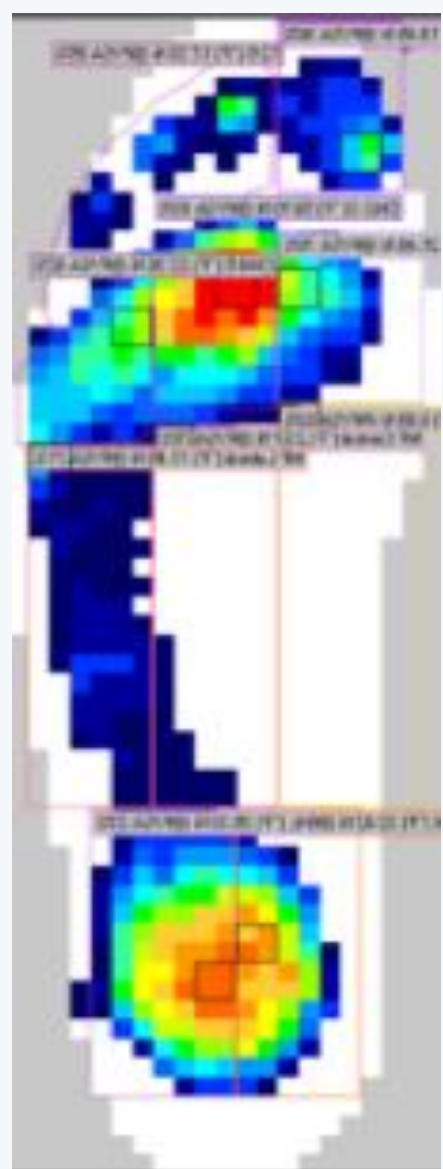


Figure 2: 10 anatomical segments

Custom-made 3D-printed foot orthosis designs (CMD)

Table 1: Cumulative segmental progression of the custom-made designs

Design	Segmental modification	Intended biomechanical effect
CMD1	Pressure-driven, total-contact orthosis without a retrocapital bar	Baseline design providing general plantar contact and load distribution
CMD2	CMD1 plus a 5-mm retrocapital bar positioned proximal to the metatarsal heads	Transfer load proximally towards the midfoot and reduce central-forefoot loading
CMD3	CMD2 plus a locally compliant segment beneath CM2-3	Provide targeted accommodation and pressure relief beneath metatarsal heads 2 and 3
CMD4	CMD3 plus compliant medial and lateral midfoot segments aligned with the first, fourth and fifth rays.	Allow the medial and lateral columns to lower relative to the central region, with the intention of further unloading CM2-3.

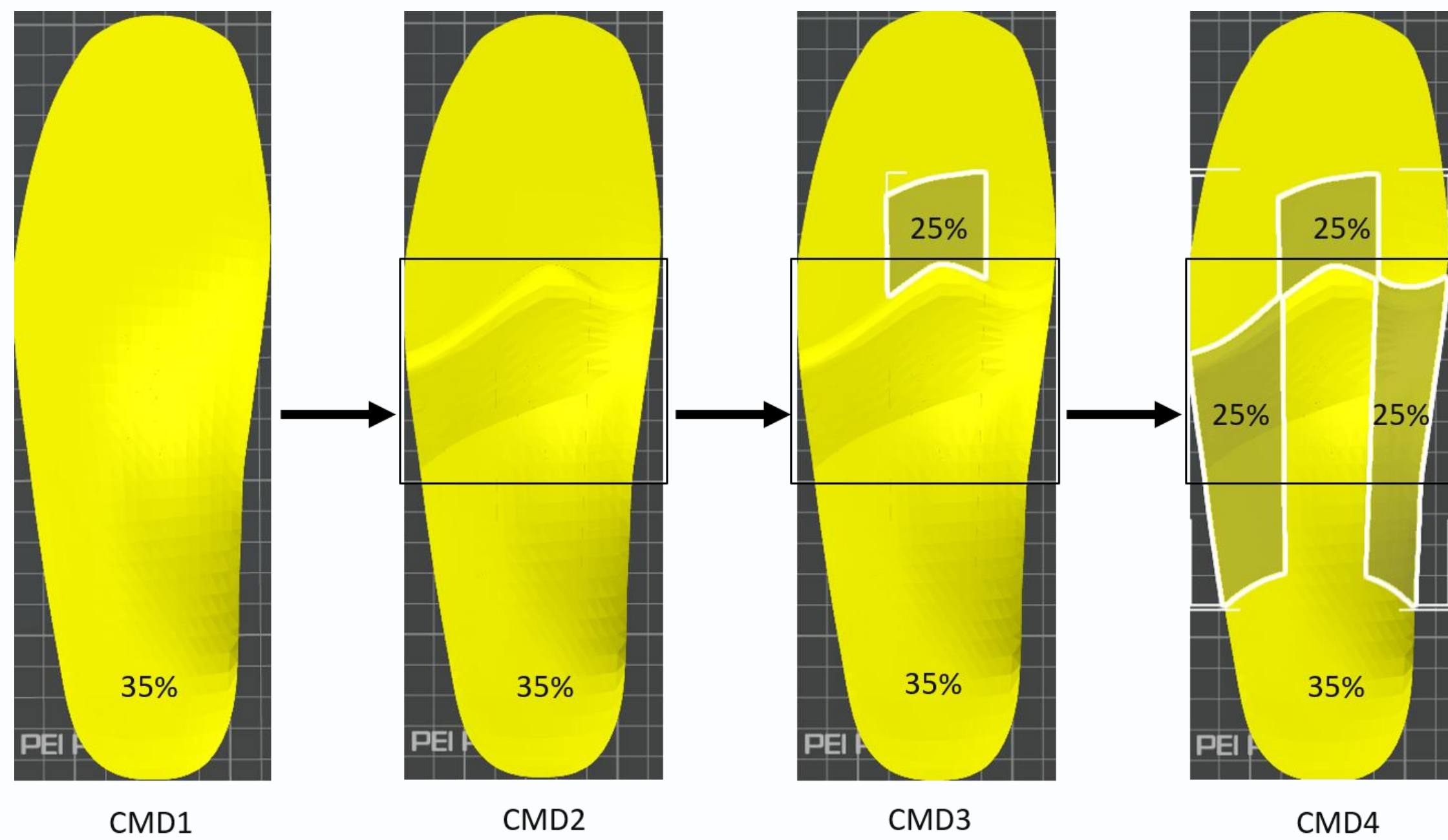


Figure 3. Visualisation of CMD1-CMD4. Each design retained the features of the preceding design. Infill densities of 35% and 25% represent relatively stiffer and more compliant segments, respectively.

Primary Results

- CM2-3 pressure decreased through CMD3, then plateaued at CMD4.**
- F(1.50,36.01)=59.98; p<0.0001; partial $\eta^2=0.714$.**

Figure 4: Mean CM2-3 peak pressure and 95% confidence interval across conditions.

CMD2-1 p=0.0002;
CMD3-2 p=0.003;
CMD4-3 p=0.12.

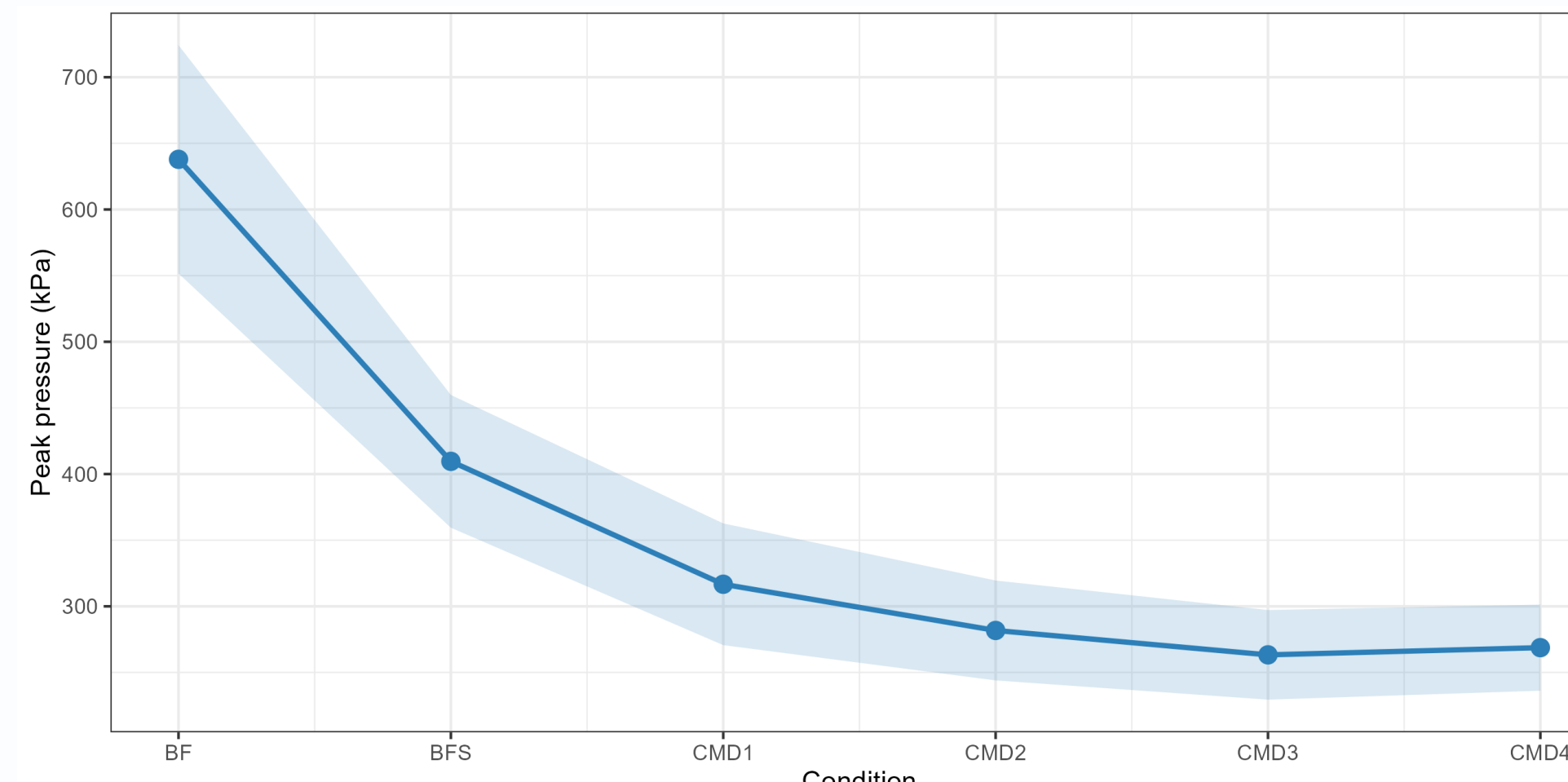


Table 2: Central Forefoot Response

Outcome	BFS	CMD1	CMD2	CMD3	CMD4
PP kPa	396.7	316.7	281.8	263.3	268.8
PP Δ	-	-20.2%	-29.0%	-33.6%	-32.3%
PTI Δ	-	-32.8%	-41.6%	-42.4%	-40.7%

Values are group means or percentage changes from BFS. Negative percentage changes indicate unloading. PP: peak pressure; PP Δ : percentage change in peak pressure from BFS; PTI Δ : percentage change in pressure-time integral from BFS.

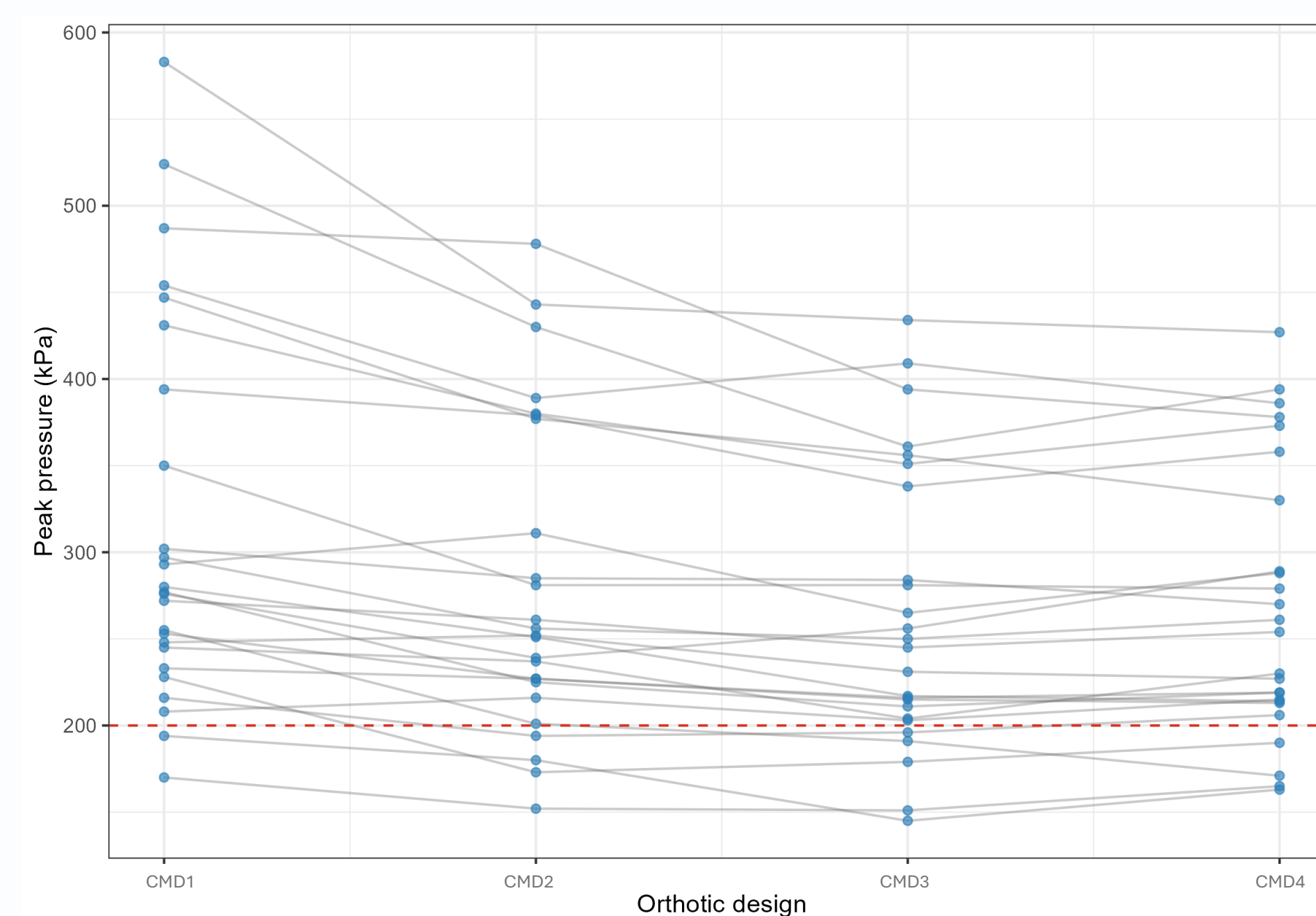


Figure 5: Individual CM2-3 peak pressure across the different custom-made foot orthoses.

Dashed line indicates the proposed clinical offloading target of <200 kPa

Redistribution

PTI decreased at CM2-3 while contact and cumulative load shifted principally towards the medial and central midfoot. CM2-3 contact area did not change progressively across CMD1-D4, suggesting that the dose-response in peak pressure was not explained solely by increasing contact beneath the target region.

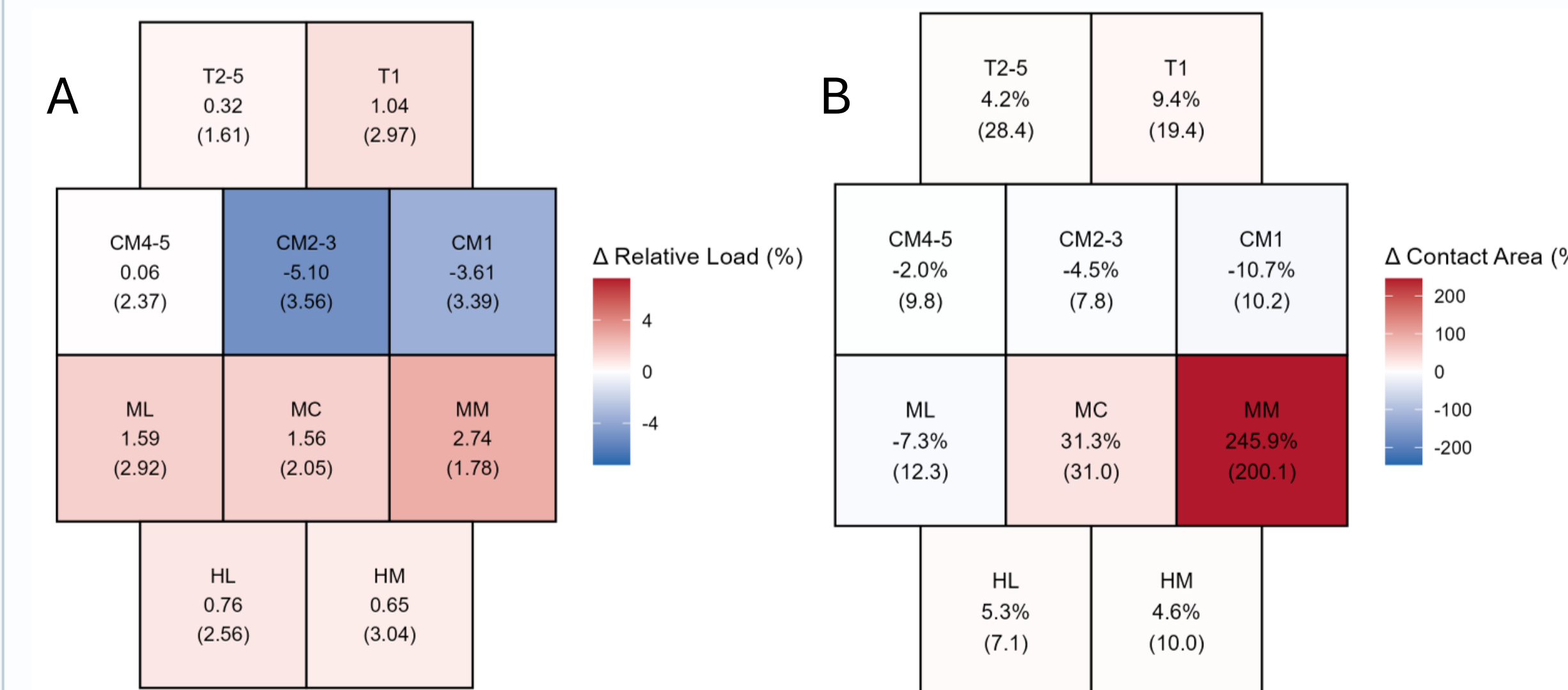


Figure 6. A Relative change in the pressure-time integral (%); B Relative changes in contact area (%) in comparison with BFS. Blue equals reduction; red equals increase.

Conclusion

Peak pressure fell by 20.2%, 29.0% and 33.6% with CMD1-3; CMD4 added complexity without further group-level benefit. CMD3 was the population optimum. This configuration successfully achieved the targeted 25% pressure reduction for diabetic foot management, but individual optima varied.

“3D printing enables orthotic design changes to be controlled, quantified and tailored to the individual patient.”

References

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