

Innovation and Commercialization



Dual Layer Active Insole for Diabetic Foot Ulcer Prevention

Tech ID: UTA 16-35

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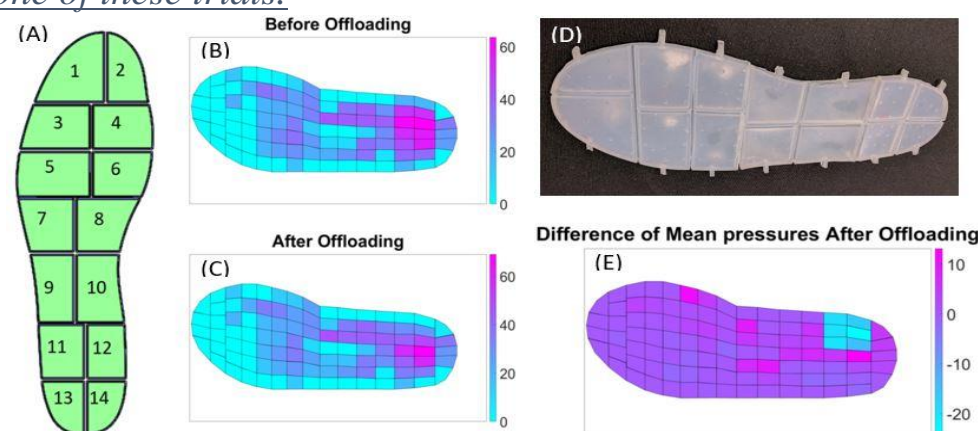
TECHNOLOGY NEED

Up to 10% of patients with diabetes develop a foot ulcers. More than half of all foot ulcers become infected, requiring hospitalization and 25% of infections result in amputation. Nearly 100,000 amputations are performed annually, burdening the quality of lives of diabetic patients. Repetitive mechanical stresses in diabetic neuropathic patients are postulates to be the cause of most diabetic ulcers. Based on studies, a means of redistributing mechanical stresses such as pressure and shear on the plantar surface of the foot should always be a part of diabetic foot ulcer management.

INVENTION DESCRIPTION/SOLUTION

A novel automated dual layer insole to modulate and distribute cyclic mechanical loading, for diabetic foot ulcer prevention is presented herein. This device simultaneously loads and unloads the selective areas of the foot by inflating and deflating individual actuators using compressed air. Automatic modulation is performed through a programmed control hardware which will cyclically relieve mechanical loading based on a prescribed duration and frequency. This approach will prevent plantar tissue from being overloaded, promote blood perfusion in offloaded areas and allow the tissue a chance to recover.

A preliminary prototype of pneumatic actuator system consisting of 14 active regions, with in-shoe pressure data of a healthy male subject (25 yrs, 185lbs, 5'10") is demonstrated herein. Figure below provides a depiction of the offloading effect on region #12 during one of these trials.



A) Region layout of the prototype. B) Static pressure distribution before region 12 was offloaded. C) Static pressure distribution while region 12 was offloaded. D) Picture of the actual prototype. E) The pressure differential between conditions B and C, clearly depicting the offloading effect at region 12. Unit in kPa

APPLICATIONS

- Prevention of diabetic foot ulcer/stress fractures
- Wound healing (in diabetic offloading boots and/or total contact casts)
- Pain relief in rheumatoid arthritis patients

KEY BENEFITS

- Reduce localized pressure and shear through improved fitting strategy
- Automated system that can alter the gait pattern without patient's intervention
- Facilitates the blood perfusion and reduces prolonged cyclic mechanical loading by periodically modulating and redistributing pressure and shear on the plantar surface of the foot

STAGE OF DEVELOPMENT

Prototype and tested

INTELLECTUAL PROPERTY STATUS

US Patent Pending



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