



Prevention of Diabetic Foot Ulcers

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Foot problems are an important cause of morbidity and mortality in patients with diabetes.

Diabetes is significant. In some countries, up to 25% of the population has it, due to obesity.

Diabetes and Amputations

Diabetes is the cause of 80-90% of the amputations in the western world. Every 30 seconds a limb is lost due to diabetes.

Amputations are preceded by a foot ulcer in 84% of the cases.

Amputation rate:

- 20% of diabetic patients will have an ulcer
- Out of those, 20% will undergo an amputation

Additional amputations:

- 9% to 20% of patients experienced an additional second-leg amputation within 1 year
- 28% to 51% have a second amputation within 5 years of the initial amputation

Mortality rate:

- Peri-operative mortality averages 5.8%
- 5-year mortality rate is 39% to 68%

Therefore, relief of mechanical pressure (offloading) is critical. Ideal footwear for a diabetic patient decreases weight-bearing pressure and shear forces.



WCICT2017

20-21 June | Manchester, UK

Diabetic Ulcer Formation

Etiology for foot ulcers

(Cross sectional studies)

- 55% pure neuropathic
- 34% neuro ischemic
- 10% pure ischemic

The neuropathy has autonomic, sensory and motor aspects that lead, eventually, to infection, abnormal pressure points and ulcers.

If there is good blood supply, we should be able to prevent and treat these wounds, avoiding amputation.

30% of the foot doesn't bear weight (arch) – heavy weight is therefore distributed in smaller area – under the metatarsal heads and on the heel. Those are the places ulcers form.

Elevated plantar pressures in combination with other factors cause ulceration:

- Role of ongoing mechanical trauma
 - Lack of innate sensory feedback
- High foot pad pressures
- Neuropathy-induced muscle imbalance
- Biomechanical dysfunction
- Structural deformities

Air Cushioned Shoes

KyBoot – an air cushioned shoe. You're standing on an unstable surface – how does this affect you? What happens if we give the patients this unstable surface to stand on?

Relevant benefits to address:

- Shock absorption
- Proprioception - sense of knowing where your body part is in space. The most common symptom of reduced proprioception is poor balance, leading to falls
- Balance
- Better (more equal) distribution of pressure
- Propulsion
- Muscle strengthening (while walking)



- Blood flow improvement (by muscle activation)
- Prevention of falls

Compare to other shoe technology: APOS therapy shoes. The biomechanical device works to retrain muscles around the knee by adjusting the center of pressure - changing the way your foot interacts with the ground. By changing the foot's point of contact with the ground, the device shifts the forces acting on the damaged knee. Over time, this helps to restore better alignment and develop improved gait (walking) patterns. This, in turn, can help you live better with osteoarthritis and other chronic conditions of the knee.

Air Cushioned Shoe Study

Goals

We wanted to compare the:

- Pressure distribution
- Changes in the movement of the center of pressure
- Shock absorbing capabilities

of the KyBoot in comparison with regular shoes in healthy and diabetic subjects

To test, we pressure mapped our feet, standing in the shoes > clear max pressure decrease of 35%.

We ran the study again with another subject, to confirm the findings > max pressure decrease of 13%.

Participants

- 10 healthy people and 11 diabetic patients
- All ulcer free and intact cognition
- No other diseases that would influence range of motion, gait, strength, balance

Methods

- In-sole Pressure Sensors (Tactilus Human Interface Stretch System) recorded the pressure distribution and changes in center of pressure inside the shoes
- With the help of the GaitRite System we determined walking speed, length of stride and step and several other gait parameters
- We took measurements in stance and walk



- The test subjects were asked to complete a questionnaire on comfort of wear and satisfaction

Results

Maximum average pressure was reduced significantly in the air cushioned shoes (Kyboot) - by 13%

<http://www.kybun.com/products-and-stores/kybun-products/kyboot.html>

Maximal contact area was increased by 2% with Kyboot.

Movement of center of pressure had decrease of 19% with Kyboot.

The movement from the center of pressure was lower with the air cushioned shoes - it's like standing on a balance board.

Patients reported better comfort in comparison to regular shoes. For those who had pain with regular shoes, there was a significant reduction of pain using the Kyboot.

Conclusions

1. The air cushioned shoes reduce average pressure and distribute the pressure more effectively than regular shoes in gait → reduced risk of ulceration
2. The step length is significantly increased with the air cushioned shoes (propulsion without increased pressure)
3. The air cushioned shoes could be beneficial for diabetic patients and in some cases could offer an alternative to shoes provided by the Ministry of Health and thus save money
4. We do not suggest (yet) the KyBoot™ to diabetic patients with significant deformities, as we didn't examine it in the current study.
5. KyBoot™ shoes reduce pain and improve comfort during stance and gait

Additional plus of Kyboot: they look like regular shoes, therefore compliance in wearing them is higher in patients. Patients don't want ugly, heavy shoes.

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