Clinical Research Summary

The Benefits of Vacuum Compared to Other Suspension Methods

Elevated vacuum suspension systems manage limb volume fluctuation, a problem that people with limb loss are challenged with. Over time and on a daily basis, these volume changes can affect how the socket fits. When the limb volume increases, the socket becomes tighter, exerting pressure, restricting blood flow, and allowing for accumulated cell waste. When limb volume decreases, the socket is loose-fitting often causing pressure to bony prominences, which may result in pain and/or injury to the limb.[1]

Vacuum Compared to Pin Suspension

Ferraro (2011) conducted an outcomes study (n=13) comparing pin suspension to electronic vacuum suspension. All subjects used each suspension system for at least 30 days.[2] A validated measurement tool called the Activity-specific Balance Confidence (ABC) scale was used to evaluate the subject's confidence when performing certain activities (n=16) with regard to balance. Subjects taking the survey rated their confidence in performing each activity on a scale from 0 (no confidence) to 100 (completely confident).[3] A score below 67 indicates a risk for falling.[4]

Results: Four surveys were excluded from the final analysis; (survey not complete, subject did not use both suspension systems, vacuum system was not electronic, and incorrect amputation level). The ABC scores for the remaining 9 surveys were Vacuum Suspension (80±10) and Pin Suspension (65±20), resulting in a confidence level of 95% (p=0.0359) in favor of vacuum. Subjects (n=13) were also surveyed on a variety of related problems experienced with suspension systems. Results for pistoning, blisters, volume change, difficulty knee bending, redness, falls, and walking time, all favored vacuum suspension over pin suspension; however the results were not significant, possibly due to small sample size.[1]

An earlier study by Beil[5] (2004) compared pin suspension to suction suspension (n=9) by measuring impulse and peak pressures in the socket during ambulation. **Results:** During stance phase there was no difference between the two suspension methods (p=0.076); however, during swing phase, differences were significant (positive pressure impulses p=0.008, average positive pressure p-0.004, distal negative impulse p=0.053 and peak pressure p=0.026) demonstrating that pin suspension exerts an occlusive pressure on the proximal tissues of the residual limb, while at the same time generating considerable suction at the distal end of the socket, and that these pressures are likely causing both the persistent and the day-to-day skin issues witnessed with pin suspension users.

The Benefits of Vacuum Compared to Other Suspension Methods (cont.)

Vacuum compared to Suction Suspension

Board[6] (2001) conducted a randomized trial comparing suction suspension to vacuum-assisted suspension; evaluating changes in volume, tibia and liner pistoning, and stance phase and step length symmetry. **Volume:** Residual limb volume (n=10) was measured prior to and after a 30 minute treadmill walk, and a significant increase of 3.7% or 30 ml (p=0.007) was found when using vacuum as compared to a significant decrease of 6.5% or 52 ml when using suction. **Pistoning:** Pistoning of the tibia and liner (n=11) were measured using X-ray and extraction force and a significant decrease (p=0.000) in both tibia and liner pistoning was found in favor of the vacuum system. **Symmetry:** Gait symmetry (n=10) was assessed with video and found significant improvements in both stance phase symmetry (p=0.037) and step length symmetry (p=0.000). **Conclusion:** The authors concluded that while suction suspension fits well, it also causes volume loss due to the pressure that it exerts, which in turn worsens the fit, subjecting the skin to higher stresses and "shear forces" with potential for ulcers. Vacuum suspension, such as the Harmony®, retains correct fit, averts volume loss, and lessons pistoning in the socket; maintaining skin integrity, symmetry, and comfort.

Beil[7] (2002) also compared vacuum suspension to suction suspension (using total surface weight-bearing sockets) by measuring impulse and peak pressures during ambulation (n=9). **Results:** Findings were favorable for vacuum, both during stance phase (impulse p=0.00, peak p=0.003) and during swing phase (impulse p=0.000, average p=0.000, and peak 0.001). It is believed that lower pressures seen during stance when using the vacuum-assisted socket force less fluid out and greater negative pressures seen during swing increases the amount of fluid drawn into the limb, thereby preventing volume loss.

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