EchelonVAC

Building on the established hydraulic technology of Echelon, EchelonVAC incorporates the use of an elevated vacuum system, allowing for increased suspension and a healthier residual limb environment. The hydraulic motion of the ankle acts like a pump, creating a vacuum between the socket and residual limb. This makes for a more secure attachment of the prosthesis, reducing the amount of movement (pistoning) present and increasing the safety and comfort of the user.

This vacuum also creates a negative pressure around the residual limb. Numerous studies have shown this pressure difference to be extremely beneficial in the management of wounds such as ulcers, a common ailment of amputees; promoting healthier skin and tissue at the residuum. The vacuum also helps to reduce the amount of volume fluctuation that occurs in the limb, ensuring a correct socket fit is maintained and reducing the risk of pain.

Improvements in Clinical Outcomes using Echelon compared to ESR feet

Improvement in **SAFETY**

- Reduced risk of tripping and falls
  - Increased minimum toe clearance during swing phase[1,2]
- Improving standing balance on a slope
  - 24-25% reduction in mean inter-limb centre-of-pressure root mean square (COP RMS)[3]

Improvement in **ENERGY CONSUMPTION**

- Reduced energy expenditure during walking
  - Mean 11.8% reduction in energy use on level ground, across all walking speeds[4]
  - Mean 20.2% reduction in energy use on slopes, across all gradients[4]
  - Mean 8.3% faster walking speed for the same amount of effort[4]

Improvement in **MOBILITY**

- Improved gait performance
  - Faster self-selected walking speed[2,5-7]
  - Higher PLUS-M scores than FlexFoot and FlexWalk style feet[8]
- Improved ground compliance when walking on slopes
  - Increased plantarflexion peak during level walking, fast level walking and cambered walking[9]
  - Increased dorsiflexion peak during level walking, fast level walking and cambered walking[9]
- Less of a prosthetic “dead spot” during gait
  - Reduced aggregate negative COP displacement[5]
  - Centre-of-pressure passes anterior to the shank statistically significantly earlier in stance[5]
  - Increased minimum instantaneous COM velocity during prosthetic-limb single support phase[5]

  - Reduced peak negative COP velocity[7]
  - Reduced COP posterior travel distance[7]
- Improved ground compliance when walking on slopes
  - Increased plantarflexion range during slope descent[10]
  - Increased dorsiflexion range during slope ascent[10]

Improvement in **RESIDUAL LIMB HEALTH**

- Helps protect vulnerable residual limb tissue, reducing likelihood of damage
  - Reduced peak stresses on residual limb[11]
  - Reduced stress RMS on residual limb[11]
  - Reduced loading rates on residual limb[11]

Improvement in **LOADING SYMMETRY**

- Greater contribution of prosthetic limb to support during walking
  - Increased residual knee negative work[6]
- Reduced reliance on sound limb for support during walking
  - Reduced intact limb peak hip flexion moment[6]
  - Reduced intact limb peak dorsiflexion moment[6]
  - Reduced intact ankle negative work and total work[6]
  - Reduced intact limb total joint work[6]
- Better symmetry of loading between prosthetic and sound limbs during standing on a slope
  - Degree of asymmetry closer to zero for 5/5 amputees[3]
- Reduced residual and sound joint moments during standing of a slope
  - Significant reductions in both prosthetic and sound support moments[12]
- Less pressure on the sole of the contralateral foot
  - Peak plantar-pressure[13]
- Improved gait symmetry
  - Reduced stance phase timing asymmetry[14]

Improvement in **USER SATISFACTION**

- Patient reported outcome measures indicate improvements
  - Mean improvement across all Prosthesis Evaluation Questionnaire domains[15]
  - Bilateral patients showed highest mean improvement in satisfaction[15]
- Subjective user preference for hydraulic ankle
  - 13/13 participants preferred hydraulic ankle[13]

Improvements in Clinical Outcomes using EVS compared to other suspension types

Improvement in **SAFETY**

- Fewer falls and less chance of multiple falls
  - No trans-tibial EVS users reported multiple falls, while 75% of the non-EV users did[16]
- Better balance in functional clinical tests

  - Significant improvements in the Berg Balance Scale (BBS), the Four Square Step Test (FSST) and the Timed-Up-and-Go (TUG) test[17]
- Better balance reported in patient-reported outcome measures
  - Improvements in the Activity Balance Confidence (ABC) scale questionnaire[18]

Improvement in **MOBILITY**

- Fewer gait compensations[19-21]
- Knee contact forces not significantly different to those of able-bodied controls[22]

Improvement in **SUSPENSION**

- Decreased pistoning
  - Reductions of over 69% and 83%, compared to suction[21,23] and pin-lock[24] suspensions, respectively, with other researchers and practitioners reporting similar observations[18,19,25,26]
- Maintain residual limb volume
  - Suction suspension = mean 6.5% loss in volume; EVS = mean 3.7% increase in volume (N.B. it is possible that the increase may have been due to the fact that these individuals attended the clinic wearing their regular prostheses before using the EVS system)[21]
  - Other studies have since confirmed the observation that residuum volume loss is prevented by EVS[19,27-30]

Improvement in **RESIDUAL LIMB HEALTH**

- Healthier residual limb tissue and skin
  - Higher trans-cutaneous oxygen measurement after activity[31]
  - Decreased trans-epidermal water loss after activity[31]
  - Decreased attenuated reactive hyperemia[31]
- Reduced interface pressures
  - Pressures reduced by a mean of 4% compared to suction suspension[32]
  - Pressure impulses reduced by a mean of 7.5% compared to suction suspension[32]
- Improved wound management
  - Continued prosthesis use while the wounds healed[33-35]
  - Wounds heal more quickly with EVS than other suspension methods[36]
- Less painful than other suspension methods
  - Expert opinion[19] and clinical case studies[37] agree that EVS is less painful and more comfortable than other suspension methods.
  - Improved Socket Comfort Score compared to other suspension methods[38]

Improvement in **USER SATISFACTION**

- Patients are more satisfied wearing their prosthesis[18,19,26,34,37-38].

Other Internal unpublished Blatchford research

Vacuum levels generated:

When sensory control of the lower limb joints is lost, it is essential that the replacement behaves predictably. Consistency of performance is vital in providing prosthetic confidence. In terms of socket suspension method, this means providing the same good connection throughout a gait cycle, from one step to the next, and day-to-day, over the lifetime of the socket.

The difference between the vacuum levels generated by suction suspension, and that generated when using EVS, can be demonstrated by using a negative pressure gauge[40]. Figure 1 illustrates these measurements. Commonly, when the user bears weight on their prosthesis during stance phase, with suction suspension, the magnitude of the vacuum is low. When the leg is lifted into swing phase, the vacuum increases in magnitude, holding the socket to the residual limb. Comparatively, EVS retains a high level during stance phase – higher, in fact, than the peak swing phase vacuum with suction. Additionally, the difference between stance and swing phase is less pronounced, so that the vacuum level is more consistent throughout the gait cycle. For the amputee illustrated in the graph[40], EVS gave an approximate 85% increase in peak vacuum magnitude and an approximate 67% reduction in the 'amplitude' of the vacuum measurement signal.

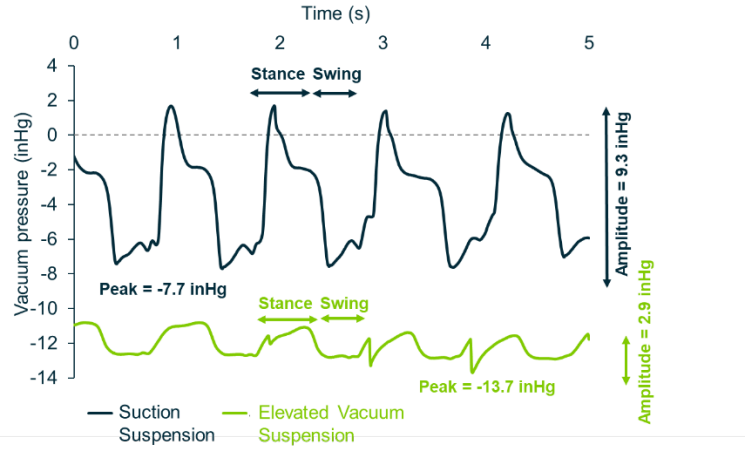

Figure 1: Negative pressure within the socket when walking using a one-way valve suction suspension (grey) and an elevated vacuum (EV) suspension. N.B. Data recorded with EchelonVAC system.

The difference in vacuum generated by the AvalonVAC, compared to that generated by the EchelonVAC, is shown in Figure 2. Despite differences in the method used (keel vs springs, different socket, different pressure gauge), when the same patient was asked to walk at 'K2 walking speed' (~2km/h, short steps), the trend of vacuum level to number of steps taken was comparable to when measured at 'K3 walking speed' (4-5km/h) with EchelonVAC.

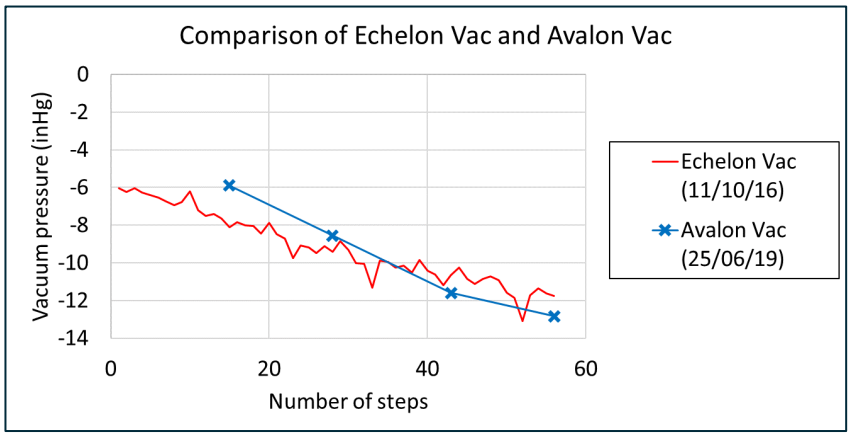

Figure 2: Comparison of the EchelonVAC and AvalonVAC vacuum generation by number of steps (regardless of walking speed)

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