AvalonK2VAC

AvalonVAC incorporates elevated vacuum suspension, Blatchford's hydraulic ankle technology and a keel designed specifically for the biomechanics of K2 users. The combination of the keel shape (similar to that of Navigator) and the hydraulic damping of the ankle unit allow shock absorption at initial contact and a smooth rollover. The keel length is designed for those with a shorter step length, to allow the progression of the body centre-of-mass over the end of the toe. Elevated vacuum suspension (EVS) creates a more secure socket fit and promotes improved residual limb health.

Improvements in Clinical Outcomes using Avalon compared to non-hydraulic feet

Improvement in **MOBILITY**

- Improved gait performance
  - Faster self-selected walking speed[1]
  - Smoother centre-of-pressure progression[1]
- Keel and ankle designed for Activities of Daily Living
  - Easier sit-to-stand[2]

Improvement in **LOADING SYMMETRY**

- Mean 34% reduction in stance phase timing asymmetry[3]
- Maximum 86% reduction in stance phase timing asymmetry[3]
- More symmetrical inter-limb loading[1]

Improvement in **USER SATISFACTION**

- Patient reported outcome measures indicate improvements
  - Mean improvement across all Prosthesis Evaluation Questionnaire domains[4]

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-EVS users did[5]
- 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[6]
- Better balance reported in patient-reported outcome measures
  - Improvements in the Activity Balance Confidence (ABC) scale questionnaire[7]

Improvement in **MOBILITY**

- Fewer gait compensations[8-10]
- Knee contact forces not significantly different to those of able-bodied controls[11]

Improvement in **SUSPENSION**

- Decreased pistoning
  - Reductions of over 69% and 83%, compared to suction[10,12] and pin-lock[13] suspensions, respectively, with other researchers and practitioners reporting similar observations[7,8,14,15]
- 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).[10]
  - Other studies have since confirmed the observation that residuum volume loss is prevented by EVS[8,16-19]

Improvement in **RESIDUAL LIMB HEALTH**

- Healthier residual limb tissue and skin
  - Higher trans-cutaneous oxygen measurement after activity[20]
  - Decreased trans-epidermal water loss after activity[20]
  - Decreased attenuated reactive hyperemia[20]
- Reduced interface pressures
  - Pressures reduced by a mean of 4% compared to suction suspension[21]
  - Pressure impulses reduced by a mean of 7.5% compared to suction suspension[21]
- Improved wound management
  - Continued prosthesis use while the wounds healed[22-24]
  - Wounds heal more quickly with EVS than other suspension methods[25]
- Less painful than other suspension methods
  - Expert opinion[8] and clinical case studies[26] agree that EVS is less painful and more comfortable than other suspension methods.
  - Improved Socket Comfort Score compared to other suspension methods[5]

Improvement in **USER SATISFACTION**

- Patients are more satisfied wearing their prosthesis[5,7,8,15,23,26-28]

Clinical Outcomes using the Avalon/Navigator keel design

With respect to **MOBILITY**

- Shorter keel allows for more consistent rollover radius of curvature, regardless of changing footwear[29]
- The most energy efficient radius of curvature for a rollover shape has been identified as 30% of the walker’s leg length. For a person of a typical adult height between 1.5m and 1.8m, this equates to approximately 245-290mm. The Avalon keel design has a rollover shape of ~250mm[29].

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[30]. 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[30], EVS gave an approximate 85% increase in peak vacuum magnitude and an approximate 67% reduction in the 'amplitude' of the vacuum measurement signal.

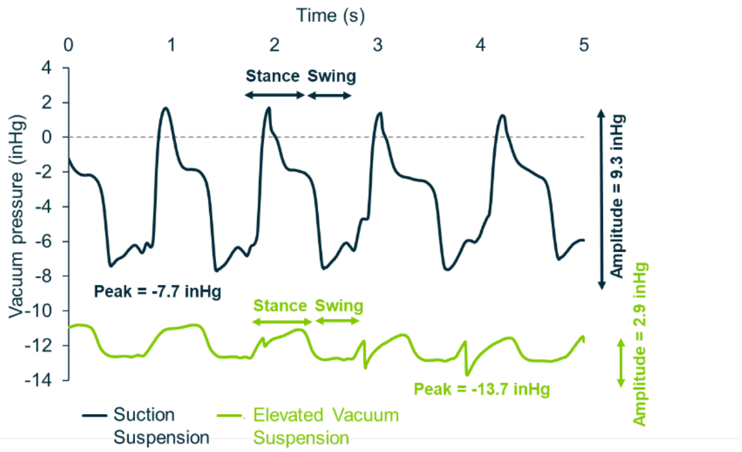

Figure 1: Negative pressure within the socket when walking using a one-way valve suction suspension (grey) and an elevated vacuum (EV) suspension. N.B. Data recorded with Echelon Vac system.

The difference in vacuum generated by the AvalonVAC, compared to that generated by the Echelon Vac, 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 Echelon Vac.

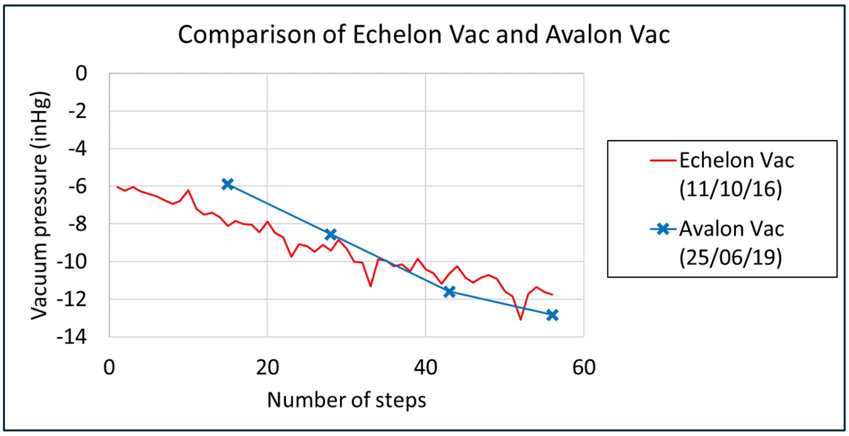

Figure 2: Comparison of the EchelonVAC and AvalonVAC vacuum generation by number of steps (regardless of walking speed).

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