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Technical Notes on Elevated Vacuum Suspension: Amputee Patient Outcomes Evaluating Patient Verbal Opinion and Pressure Data

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I. Purpose

This review is intended to fulfill two purposes. The first purpose is to describe the factors that can affect real time pressure data collected from lower limb prosthetic sockets utilizing elevated vacuum suspension. The second purpose of this paper is to summarize the current results of Ohio Willow Wood's work with vacuum suspension for lower extremity amputees. The patient outcomes have been evaluated using qualitative data, such as amputee feedback, and quantitative data, such as real time vacuum pressure data.

II. Background

Quantitative, real time, vacuum pressure data is being used to increase the current level of understanding of the operational functionality of elevated vacuum. There are a number of factors that affect the level of vacuum in a prosthetic socket. A few include ambulation, patient physiology, and socket design.

Not surprisingly, ambulation results in pressure fluctuations in the prosthetic socket. These vacuum pressure fluctuations decrease with an increase in the average vacuum pressure in the socket. Figure 1 compares vacuum pressure fluctuations at 8 inHg, 12 inHg, and 18 inHg for an ambulating amputee.¹

¹ Due to the practicalities of collecting real time pressure data, such as continuously varying average pressures caused by leaks, it is not possible to collect data from multiple patients at exactly the same average vacuum pressure. For analysis, data from patients was sorted by the upper level of the controlled vacuum range. For this reason, when a vacuum level is used, this refers to the maximum level in the control window of 5 inHg and may not match exactly with the observed average value.

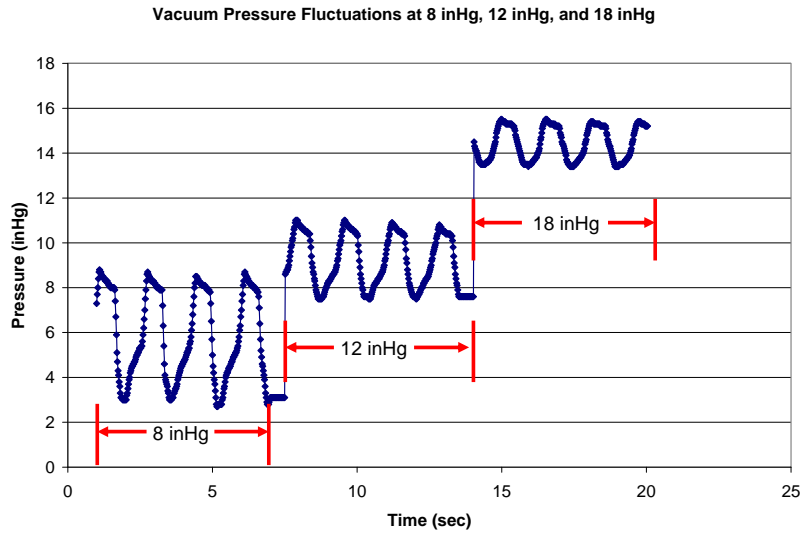


Figure 1: Vacuum pressure fluctuation at 8 inHg, 12 inHg, and 18 inHg. The vacuum pressure settings correspond to the upper level of the controlled vacuum range with the control window set at 5 inHg.

This vacuum pressure fluctuation pattern is a direct result of ambulation. During the swing phases (period of mid-air motion), the vacuum pressure increases as the weight and momentum of the prosthesis attempt to pull it off of the residual limb. In the stance phases (period of floor contact), the force of the body is acting downward on the prosthesis forcing the residual limb into the socket and causing the vacuum pressure to decrease. Figure 2 shows a plot of some typical real time data collected during these vacuum pressure fluctuations.

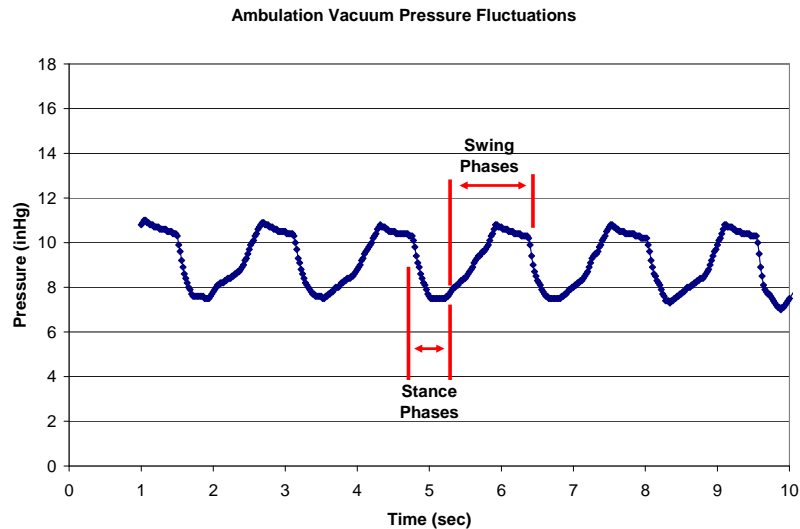


Figure 2: Ambulation vacuum pressure fluctuations at 12 inHg. Vacuum pressure increases during the swing phases (period of mid-air motion) and decreases during stance phases (period of floor contact).

Changes in motion, such as turning a corner, usually produce disturbances in the periodic waveform. Additionally, vacuum pump activations cause spikes in pressure. Figure 3 illustrates the pressure responses to both motion change and pump activation.

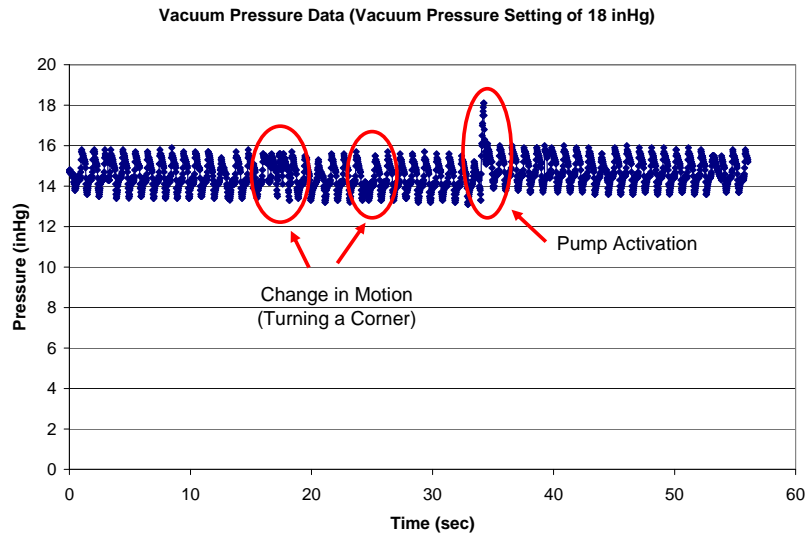


Figure 3: Vacuum pressure data at a setting of 18 inHg. Spikes indicate pump activations and disturbances in the waveform indicate directional motion change.

The observation of a steadily decreasing average vacuum pressure usually indicates a leak in a sealing component (Figure 4). Leaks generally result in increased activation of the pump which ultimately reduces battery life.

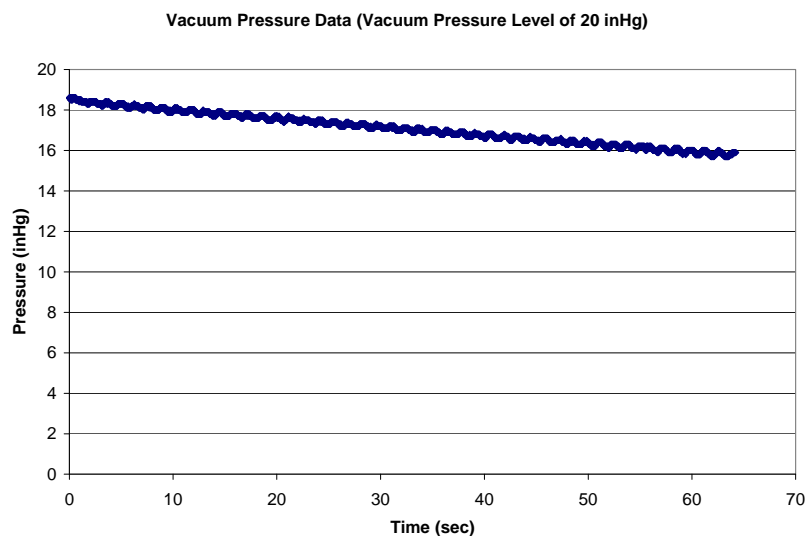


Figure 4: Vacuum pressure data at 20 inHg demonstrating the effects of a leak in the sealing components.

Inadequately sealed vacuum systems generate unusually frequent pump activations. Figure 5 illustrates the increase in pump activations resulting from improper donning techniques and leaks. An increase in the frequency of pump activations reduces pump performance, battery life, and possibly amputee satisfaction.

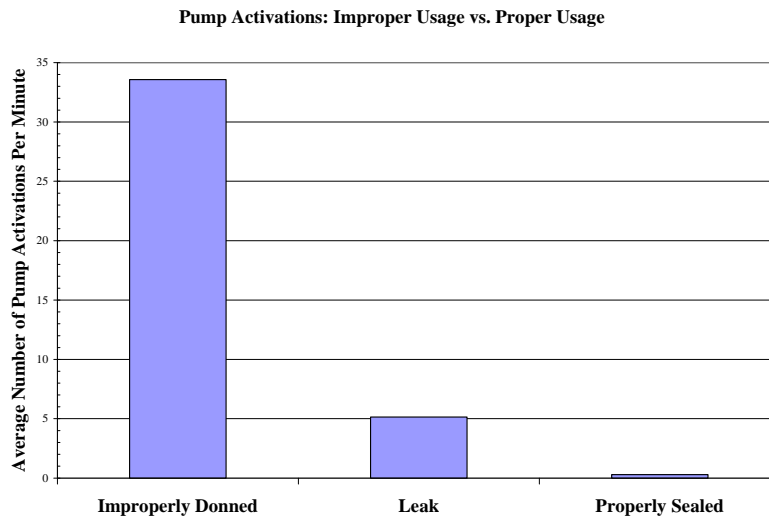


Figure 5: Pump activations per minute with an improperly donned system, a system with a leak, and a properly sealed vacuum system.

III. Vacuum Level Preference Study

A cross-sectional study containing 22 lower extremity amputees with LimbLogic Vacuum Systems (LLVS) was performed to evaluate patient preferences with regard to vacuum level in elevated vacuum suspension sockets.

Study design:

- 13 transtibial amputees and 9 transfemoral amputees
- Patient experience with elevated vacuum suspension: average 7 months (max: 2.5 yrs, min: 1 month)
- Vacuum pressure settings: 8, 10, 12, 14, 16, 18, and 20 inHg while ambulating²

Amputees have trouble differentiating between vacuum pressure settings across even short periods of time unless the change is drastic (see below). However, over time patients tend to determine a personal optimal ambulation vacuum pressure setting. The preferred vacuum levels during ambulation vary widely among patients. Figure 6 charts the preferred ambulation vacuum pressure setting for the 22 amputees. 16 out of 22 (72.7%) of amputee patients prefer a vacuum setting at or above 14 inHg. In addition to differences in preference between patients, some amputees (14 out of 22 (63.6%)) also opt to modify the vacuum pressure settings to match their current activity (sitting, walking, strenuous activity, etc.). Therefore, the ability to change the vacuum pressure setting allows the amputee to achieve the highest level of personal comfort and functionality.

² Vacuum pressure settings below 8 inHg are not tested due to limited usage among the amputees and the very high variance in the vacuum pressure fluctuations at these levels.

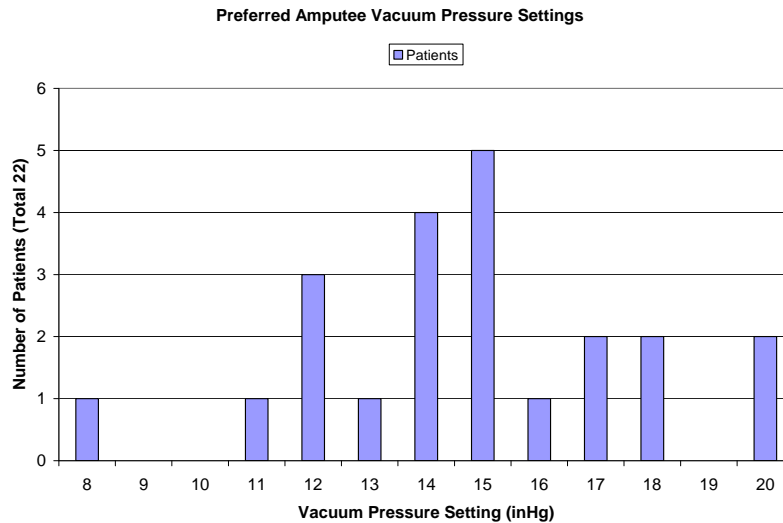


Figure 6: Preferred ambulation amputee vacuum pressure setting for 22 amputees (Transtibial and Transfemoral Amputees)

IV. Differentiation Between Different Vacuum Levels

This task has been investigated from two different angles. The first is an evaluation of a patients’ ability to distinguish between different vacuum levels in an elevated vacuum suspension system. The second is a statistical evaluation of the measurable difference between two vacuum pressures during ambulation.

Study design:

- 13 transtibial amputees and 9 transfemoral amputees
- Patient experience with elevated vacuum suspension: average 7 months (max: 2.5 yrs, min: 1 month)
- Vacuum pressure settings: 8, 10, 12, 14, 16, 18, and 20 inHg while ambulating³

A. Patient’s Ability to Distinguish Between Vacuum Pressure Levels

Initial anecdotal observations indicated that many if not most patients were unable to distinguish between vacuum suspension pressure levels under a short duration of time and especially for pressures below 14 inHg. To evaluate this observation, eleven patients were fitted with elevated vacuum suspension systems and asked to judge the difference between different vacuum settings between 8 and 20 inHg. Majority of the patients, 7 out of 10 (63.6%), were unable to distinguish between vacuum differences of less than 5 inHg. One patient, not included in the statistic above, could not distinguish between any vacuum settings in the entire range.

B. Analysis of Variance (ANOVA) of Real Time Vacuum Data at Different Vacuum Levels

A single-factor ANOVA with a 95% confidence interval post hoc Tukey multiple comparison test was used to evaluate vacuum variation due to ambulation over the range of pressure settings from 8 to 20 (inHg). Not surprisingly, for vacuum levels at

³ Vacuum pressure settings below 8 inHg are not tested due to limited usage among the amputees and the very high variance in the vacuum pressure fluctuations at these levels.

or below 12 inHg, the large variations in vacuum due to ambulation made it difficult or even impossible to differentiate between different average vacuum levels with a high degree of confidence. Figure 7 is an example of the real time data obtained from ambulating patients at seven different average vacuum levels.

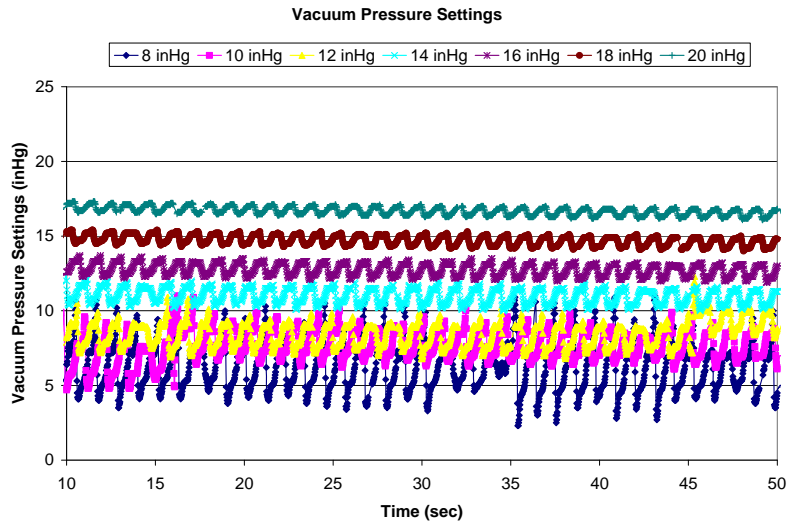


Figure 7: Ambulating vacuum pressure settings. Vacuum pressure data from 8 inHg to 12 inHg are not significantly different (overlap) for 19 out of 22 (86.4%) amputees. Vacuum pressure data from 14 inHg to 20 inHg are significantly different (do not overlap) for 15 out of 22 (68.2%) amputees.

As can be seen in the Figure 7, the increase in vacuum variation at lower vacuum levels leads to significant overlap of the vacuum pressures. For 86.4% of amputees (19 out of 22) real time data collected during ambulation at any two vacuum settings at or below 12 inHg can not be distinguished from each other. Additionally, the results indicate that 68.2% of amputees (15 out of 22) displayed a distinguishable difference in vacuum settings between the range of 14 to 20 inHg. It is an interesting correlation that most amputees (72.7%) preferred vacuum pressure settings at or above 14 inHg (Figure 6). These results indicate that the average vacuum level affects not only the actual pressure dynamics inside of the socket, but also the patients' perception of vacuum. The variability of the exact pressure where vacuum can be reliably perceived and the degrees to which vacuum fluctuations are affected by ambulation are patient and prosthesis dependent. For these reasons, it is desirable to be able to adjust vacuum pressure settings according to individual patient needs. In addition, the inability of many patients to judge vacuum levels brings into question the efficacy of manually activated vacuum suspension systems, especially when used at lower vacuum pressure levels.

Effects of Patient Anatomy and Prosthetic Design on Vacuum Pressure Fluctuations

As seen in Figures 1-4 and Figure 7, when an amputee ambulates, vacuum pressure in their prosthetic socket fluctuates. In preliminary studies, the amplitude of these fluctuations has been found to be correlated with some degree to the following physical parameters:

- The ratio between residual limb length and distal residual limb circumference: Direct correlation, as the ratio increases the vacuum pressure fluctuations tend to increase.
 - Transtibial correlation value $r = 0.94$ for ten patients⁴ at 14 inHg
 - Transfemoral correlation value $r = 0.88$ for nine patients at 14 inHg
- The type of residual limb tissue: Direct correlation, firmer tissue tends to increase vacuum pressure fluctuation.
 - Correlation value $r = 0.92$ for nine transfemoral patients at 14 inHg
- The prosthesis Weight: Direct correlation, an increase in prosthesis weight results in an increase in vacuum pressure fluctuations (Affects the swinging phases and more predominate in transfemoral amputees)
 - Average Correlation value $r = 0.988$ for two transfemoral patients
- The amputee's gait pattern: Observations indicate that smoother gait patterns produce smaller vacuum pressure fluctuations.

Summary of Observations to date

This study focuses on patient outcomes regarding elevated vacuum.

Outcome conclusions include:

- 72.7% of amputee patients (16 out of 22 amputees) prefer a setting greater than 14 inHg.
- When given the option, 63.6% of amputee patients (14 out of 22) choose to modify the vacuum pressure according to activity (sitting, walking, strenuous exercise etc.) or daily comfort
- Vacuum pressure fluctuations decrease with an increase in vacuum pressure settings.
 - This is not to say that the highest vacuum available is the best choice. For example, an amputee's comfort and pump energy efficiency are not necessarily optimal at the higher vacuum levels that lead to smaller pressure fluctuations.
- Vacuum pressure waveform varies with activity
 - **Walking**
 - Vacuum pressure increases during swing phases and decreases during stance phases
 - **Change in motion (i.e. turning a corner)**
 - Disturbances in the periodic (quasi-sinusoidal) waveform
 - **Standing Still**
 - Steady pressure value
- When the pump activates, the pressure spikes to the upper vacuum pressure setting.
- Leak rate and system performance evaluation
 - The observation of a steady decrease in average pressure indicates a leak in a sealing component. The rate of this leak indicates the quality of the system seal.

⁴ Three transtibial patients were not included in this analysis due to incomplete physical parameters

- A high frequency of pump activations also indicates a leak in the system or improper usage (donning) of the elevated vacuum system.
 - High pump activations resulting from improper usage reduce pump performance, battery life, and possibly amputee satisfaction
- Vacuum pressure settings
 - For 86.4% of amputees, operation at average levels of vacuum below 14 inHg renders attempts to measure the difference between average vacuum levels statistically insignificant. This makes it hard to distinguish between different levels of vacuum.
 - For 68.2% of amputees, operation at average levels of vacuum at or above 14 inHg renders attempts to measure the difference between average vacuum levels statistical significant. This makes it possible to distinguish between different levels of vacuum.
- Vacuum pressure deviations are correlated to some degree with:
 - the ratio between limb length and distal circumference
 - tissue type
 - prosthesis weight
 - gait pattern



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