Dynamic Effectiveness Evaluation of Elevated Vacuum Suspension

Maria J. Gerschutz, PhD, Michael L. Hayne, MS, James M. Colvin, MS, Jeffery A. Denune, CP

ABSTRACT

Introduction: The functional purpose of lower-limb prosthetic suspension systems is to adhere the prosthesis to the residual limb of the individual with amputation. Elevated vacuum suspension, a recent advancement in suspension systems, creates subatmospheric pressure between the prosthetic socket and the interface material. This form of suspension has clinically demonstrated superior prosthetic linkage. The purpose of this study was to dynamically evaluate distal displacement for vacuum and suction suspension. Vacuum was assessed at three different levels (8 in Hg, 14 in Hg, and 20 in Hg). In addition, the relationship between distal displacement and vacuum pressure fluctuations was compared.

Materials and Methods: For five subjects with transfemoral amputation, an inductive sensor was used to measure the distal displacement during ambulation. Simultaneous vacuum pressure responses were collected for comparison.

Results: The average distal displacement was 2.65 (1.21) mm for suction suspension, 0.80 (0.40) mm for vacuum at 8 in Hg, 0.21 (0.15) mm for vacuum at 14 in Hg, and 0.05 (0.04) mm for vacuum at 20 in Hg. Direct correlations were also determined between fluctuations in vacuum pressure and the amount of distal displacement providing insight regarding the dynamics within a vacuum suspended prosthetic socket.

Conclusions: Vacuum suspension significantly reduced the amount of vertical displacement compared with suction displacement, and a linear correlation was determined between pressure fluctuations and distal displacement with vacuum suspension.
(*J Prosthet Orthot*. 2015;27:161–165.)

KEY INDEXING TERMS: prosthesis, vacuum, suspension, socket

The purpose of a suspension system is to minimize the disconnect or relative motion between the residual limb and the prosthesis.[1] Many types of suspension systems are available for lower-limb prostheses. Some include a pin lock system, a sealing sleeve, suction, and elevated vacuum. A direct comparison of suspension systems is difficult to achieve due to the specific socket fabrication requirements for each system. However, if adequate suspension is attained, the individual with amputation is less likely to experience tissue breakdown or skin irritation and more likely to experience improvements in comfort, confidence, gait, and prosthesis control.[2,3]

Traditionally, the effectiveness of suspension systems was investigated using imaging techniques. Several studies utilizing x-ray measurement techniques reported a wide range of distal displacement of the tibia bone relative to the socket, 2 mm to 36 mm, depending on the measurement reference site and suspension system.[1,3,4] A study by Söderberg et al.[5] took a more invasive approach to measure displacement with Roentgen stereophotogrammetric measurements of tantalum bone markers. The study compared bone movement and motion of four suspension systems under simulated conditions. The authors reported that the airtight sleeve with expulsion valve (suction) exhibited the least amount of vertical displacement, approximately 7 mm, relative to the tibia when compared with a supracondylar suspension, patella tendon bearing strap, and distal pin suspension.

The previously mentioned research studies were conducted using radiological methods and under static simulated conditions. Sanders et al.[6] utilized a different approach by dynamically measuring displacement with a photoelectric sensor. The study focused on the feasibility of the noncontact measurement technique and reported a single clinical trial. The subject with transtibial amputation experienced an average displacement of 41.7 mm between swing and stance phase relative to wool socks. The subject's prosthesis incorporated a neoprene sleeve. The photoelectric sensor is not ideal for measuring displacement associated with vacuum or suction suspension because use of the photoelectric sensor requires removal of a portion of the socket to achieve direct access to the interface material, whereas vacuum/suction suspension requires closed and airtight sockets.

Most of the previously mentioned research studies focused on comparing different suspension systems or different prosthetic socket designs, but all lacked the inclusion of elevated vacuum suspension. Board et al.[2] investigated the difference between suction suspension and vacuum suspension. The study statically simulated the force exerted during swing phase and conducted a comparison against the unloaded baseline condition. Using x-rays, the study reported a displacement between the liner and socket of 5 (2) mm for suction suspension and 1 (1) mm for vacuum suspension. In the study, vacuum was assessed at 23 in Hg (−78 kPa relative to atmospheric pressure).

The purposes of this study were threefold: 1) to develop a dynamic measurement technique to quantitatively evaluate the distal displacement; 2) to assess the amount of distal displacement present when using different suspension systems and

MARIA J. GERSCHUTZ, PhD, is affiliated with Trine University, Angola, Indiana.

MICHAEL L. HAYNE, MS; JAMES M. COLVIN, MS; and JEFFERY A. DENUNE, CP, are affiliated with The Ohio Willow Wood Company, Mt Sterling, Ohio.

Disclosure: All authors are currently or previously employed at The Ohio Willow Wood Company.

Correspondence to: Maria Gerschutz, PhD, Trine University, One University Ave, Angola, IN 46703; email: gerschutzm@trine.edu

when using different vacuum pressure levels; and 3) to compare the relationship between distal displacement and vacuum pressure fluctuations.

METHODS

MATERIAL

An inductive sensor (BAW0029; Balluff, Florence, KY, USA) was used to measure the distal displacement. This model of inductive sensor outputs an analog voltage (0–10 V) corresponding to the distance from a metal target. The particular sensor used in this study had a range of 4 mm to 16 mm providing a total measurement span of 12 mm. Aluminum foil covering the distal end of the liner was used as the metal target due to its ability to conform to the residual limb's distal shape. The thinness of the aluminum foil also minimized any interference with socket fit. The inductive sensor was connected via cable to an oscilloscope (TDS 420A; Tektronix, Portland, OR, USA), allowing real-time data to be saved for postprocessing. In addition to the inductive motion measurements, pressure measurements were simultaneously collected wirelessly with the LimbLogic VS Communicator[7] (Ohio Willow Wood, Mt Sterling, OH, USA).

Transfemoral prosthetic sockets were altered to allow the inductive sensor to be placed at the most distal position. The sensor was held in position by a threaded nut embedded in a PVC fitting and secured with an additional threaded nut. A picture of the socket fabrication is shown in Figure 1. The metal target's placement on the liner was situated such that it was perpendicular to the sensor head. Sensor calibration measurements and verification of sensor placement within the measurement range were conducted for each individual socket. The calibration process utilized spacers with known thicknesses to determine the linear correlation between the sensor's voltage response and distance. During the calibration process, the practical resolution of the relative motion was determined to be 0.01 mm.

Airflow from the socket passed through a barb fitting, which was installed through the socket wall and then connected to

Figure 1. Fabricated socket with induction sensor and vacuum port.

Table 1. Patient characteristics (n = 5 subjects)

Measure	Mean (SD)	Range
Age, y	51 (18)	26–71
Body mass, kg	85.7 (21)	62–116
Residual limb length, cm	26.7 (4.8)	7.6–12.6
Post amputation, y	9 (3.7)	5–15
Activity level	K3	K2–K3

the inlet of a LimbLogic VS (Ohio Willow Wood, Mt Sterling, OH, USA) by a hose. When the pump was disabled, this assembly allowed the air in the socket to be expelled through the one-way valve located in the vacuum pump, thus achieving suction suspension. In contrast, vacuum suspension was achieved through the activation of the LimbLogic VS. In this way, the fabricated sockets allowed both suction and vacuum suspension to be evaluated with the same prosthetic components.

The LimbLogic VS allows for the selection of vacuum pressure settings in increments of 1 in Hg. This vacuum setting corresponds to the peak vacuum level drawn by the pump. However, the vacuum level in the socket was allowed to drift to as much as 5 in Hg below this setting before the vacuum pump activated to bring the vacuum level back up to the set point. Using this assembly and mode of control, distal displacement was randomly assessed at four different treatment levels: suction (no active vacuum), vacuum at 8 in Hg (–27.1 kPa), vacuum at 14 in Hg (–47.4 kPa), and vacuum at 20 in Hg (–67.7 kPa).

CLINICAL TESTING

The study enrolled five subjects with transfemoral amputation. Subjects participated in the study under a signed test-subject agreement form. Subject characteristics are located in Table 1. Individuals with transfemoral amputations were chosen over individuals with transtibial amputation due to the restriction of the sensor placement and necessary prosthetic componentry. All subjects were fitted with a zero-ply total surface bearing socket with lowered trimlines. Sockets were fitted and approved by a certified prosthetist. Trimlines were lowered below the ischium according to subject comfort. Both types of suspension, vacuum and suction, were implemented with the LimbLogic VS.

Subjects were asked to don the Alpha AK liner. Before donning the socket, the metal foil target was placed on the distal end of the liner using double-sided adhesive tape. The placement of foil on the outside of the liner provided a direct comparison to the variation in vacuum pressure. Both types of suspension utilized an Alpha sealing sleeve. A sealed system was achieved by reflecting the liner over the socket brim, thus allowing the gel interface material of the sleeve to come in contact with the gel interface material of the liner. With the subject standing, the sensor was threaded into position and the corresponding treatment was applied. The subjects were asked to walk in place between parallel bars for 20 seconds. Simultaneous displacement and vacuum pressure responses were collected. The measurement setup remained the same for all treatments. Each treatment was allowed to stabilize before measurement. Stabilization was defined as obtaining the designated vacuum pressure level with a pump cycle activation over 1 minute.

Both the displacement and vacuum pressure response data were processed by calculating the absolute deviation, maximum minus minimum, for a single step cycle. The average deviation for seven steps was reported. Within each subject, the average amount of distal displacement was statistically compared across the treatment levels using analysis of variance at a 95% confidence level. Pearson statistical correlation values were also calculated between the average distal displacement, and the vacuum pressure fluctuations within each subject. Vacuum pressure fluctuations refer to the difference between the maximum vacuum pressure and the minimum vacuum pressure for a single gait cycle.

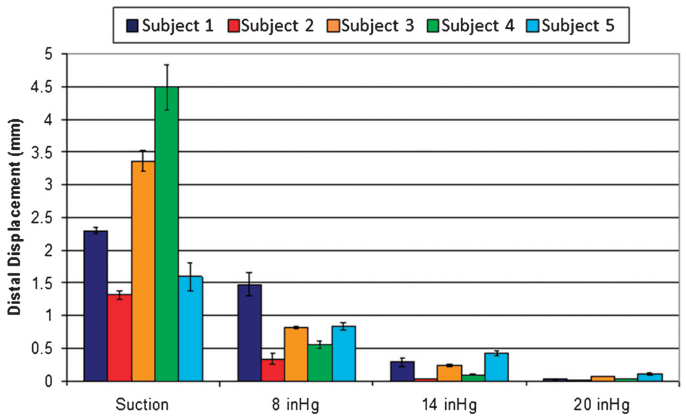

Figure 3. Average distal displacement for five subjects under the treatment levels of suction, vacuum at 8 in Hg, vacuum at 14 in Hg, and vacuum at 20 in Hg. Error bars correspond to standard error.

RESULTS

A sample of the simultaneous distal displacement data, in millimeter, and vacuum pressure data, in inch mercury, is displayed in Figure 2. All reported values refer to the amount of absolute deviation, maximum minus minimum, for each measurement. The maximum displacement occurred during periods where the limb was suspended in the air and the minimum displacement occurred during stance phases. For the vacuum pressure response, the swing phases resulted in an increase in the magnitude of relative pressure differential; stance phases resulted in a decrease.

For each subject, the average amount of distal displacement and the corresponding standard deviation for the four different treatment levels are located in Figure 3. Suction had an overall average displacement of 2.65 (1.21) mm. The overall average displacement was 0.80 (0.40) mm, 0.21 (0.15) mm, and 0.05 (0.04) mm for vacuum at 8 in Hg, 14 in Hg, and 20 in Hg, respectively. Within each subject, statistical comparison and post hoc Tukey's test determined a statistical significance for all treatment levels at a 95% confidence level.

The correlation between vacuum pressure fluctuations and distal displacement is illustrated in Figure 4 for one subject across all treatment levels. Similar correlation curves are displayed in Figure 5 for all subjects across the three vacuum pressure settings (8 in Hg, 14 in Hg, and 20 in Hg). Pearson correlation values ranged from $r = 0.986$ to $r = 0.997$. The individual correlation values are indicated on Figure 5. It is instructive to consider that the slopes of these lines correspond to units of pressure divided by distance and are therefore a form of a scaled stiffness. In this light, it is not surprising that there is variation in these slopes when one considers the variations in limb geometry across subjects.

DISCUSSION

The inductive sensor successfully measured the distal displacement experienced during suction and vacuum suspension. Although the sensor measurement range of 12 mm is probably insufficient for the comparison of other types of suspension systems, it was suitable for the comparison between suction and vacuum suspension.

For the five transfemoral subjects, vacuum suspension exhibited significantly less distal displacement compared with

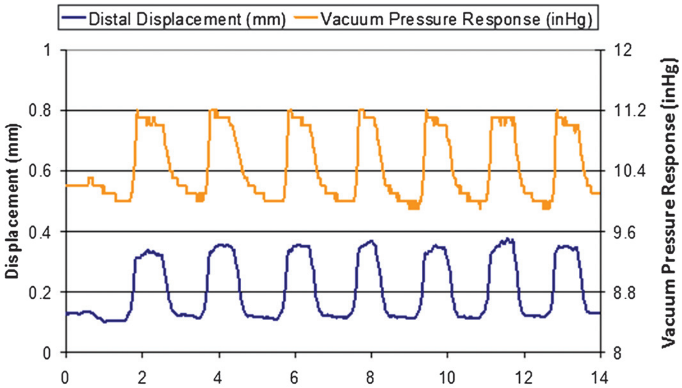

Figure 2. Displacement measurements and vacuum pressure responses for a given subject with vacuum set at 14 in Hg.

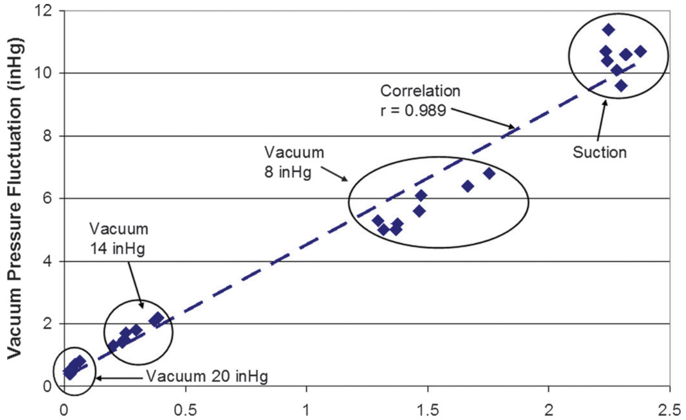

Figure 4. Correlation between pressure fluctuations and distal displacement.

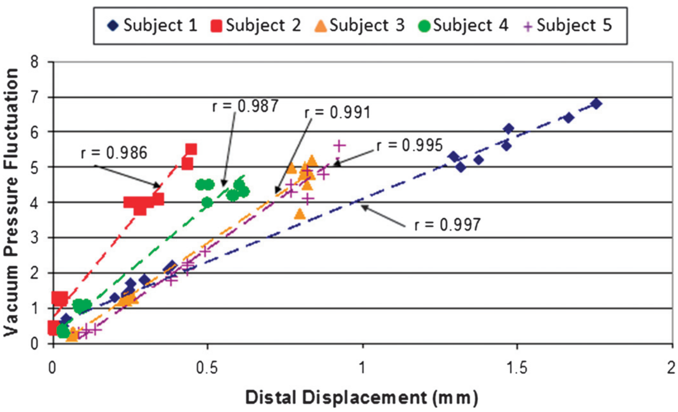

Figure 5. Correlation analysis between pressure fluctuations and distal displacement for all five subjects across the three vacuum pressure settings (8 in Hg, 14 in Hg, and 20 in Hg).

suction suspension. Although each subject experienced different amounts of displacement, the average decrease in distal movement from suction to vacuum at 8 in Hg was 1.8 mm. Comparing the different vacuum pressure levels, distal displacement significantly decreased with increasing vacuum levels. On average, the amount of distal displacement decreased by 0.6 mm from 8 in Hg to 14 in Hg and by 0.2 mm from 14 in Hg to 20 in Hg. Although the distal displacements experienced with a vacuum pressure setting of 20 in Hg were significantly different from the displacements experienced during 14 in Hg of suspension for all the subjects, the amount of distal displacement may not be clinically significant for some of the subjects. Subject perception of small incremental changes is unknown and dependent on the individual subject, and the exact relationship between specific levels of displacement and discomfort or harm has not been well documented.

Distal displacement observed with suction suspension in this study was slightly lower but comparable to the values published in previous research studies. Söderberg et al.[5] reported 7 mm of displacement between the tibia and the socket. Board et al.[2] reported a displacement of 5 (2) mm with suction suspension in reference to the liner. Suction suspension in the presented study exhibited 2.65 (1.21) mm of distal displacement. On the other hand, the distal displacement exhibited in the presented study for vacuum suspension was, on average, less than the value reported by Board et al.[2] Board et al.[2] reported 1 (1) mm of distal displacement with a vacuum level at 23 in Hg (–78 kPa) compared with the presented study's averages of 0.80 (0.40) mm, 0.21 (0.15) mm, and 0.05 (0.04) mm for vacuum at 8 in Hg (–27.1 kPa), 14 in Hg (–47.4 kPa), and 20 in Hg (–67.7 kPa), respectively. Slight differences in values, for both the suction and vacuum comparisons to previous research studies, may be attributed to the location of measurement site, the implementation of dynamic measurements versus static simulation, the subjects' individual residual limb parameters, transfemoral versus transtibial subjects, socket fit, and measurement tool accuracy.

In analyzing a given level of vacuum, Boyle's law may aid in understanding the relationship between vacuum pressure fluctuations and distal displacement. Boyle's law is a specific case of the ideal gas law in which the number of moles and the temperature are assumed to be constant. This assumption is reasonable for vacuum suspension at a given vacuum pressure setting, at least for a short duration. This simplification of ideal gas law results in PV = K, where P, V, and K represent pressure, volume, and a constant, respectively. The relationship of Boyle's law is shown in Figure 2 with the simultaneous cyclic changes in the vacuum pressure and displacement curves. The relationship is also observed in Figure 4 with the individual data points at a given vacuum pressure setting.

The correlation analysis between pressure fluctuations and distal displacement displayed a direct correlation across the different levels of vacuum pressure. For a given subject, the amount of vacuum pressure fluctuation was linearly related to the amount of distal displacement across the different treatment levels as displayed in Figure 4 and Figure 5. The linearity between these two parameters provides a pathway to the prediction of the displacement present at any given vacuum pressure setting. Further reduction to a direct measure would likely require the consideration of prosthetic mass and kinematics, and hence the loading on the socket, as well as the geometry of the socket, including the cross-sectional area, and hence the area across which this loading is applied to the air volume being monitored.

As shown in Figure 5, most subjects had distinctly different trend lines. In light of the discussion above, this is not surprising. The individuality of each correlation may be dependent on but not limited to the type and amount of residual tissue, socket fit, size and shape of the residual limb, component selection, gait dynamics, and the degree of muscle activations. For further analysis, each subject was grouped according to residual limb tissue type. Tissue type was assessed by a certified prosthetist on a five-point scale: soft, soft-medium, medium, medium-firm, and firm. The categorization and correlation with tissue type is located in Figure 6. High correlations were exhibited with this categorization. The subjects with a firmer tissue type displayed higher pressure fluctuations than the subjects with medium

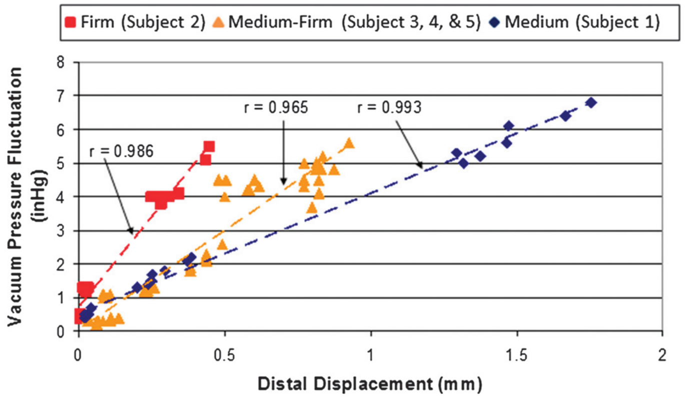

Figure 6. Correlation analysis between pressure fluctuations and distal displacement according to residual limb tissue type. Data include all five subjects across the three vacuum pressure settings (8 in Hg, 14 in Hg, and 20 in Hg).

tissue type for a given amount of distal displacement. Muscle activation may have a stronger effect on the pressure response for a subject with firmer tissue compared with a subject with medium tissue, providing some explanation for the observance of higher vacuum pressure fluctuations with firmer tissue. Distal displacement tended to be lower for subjects with firmer residual limb tissue types at a given vacuum pressure setting.

The nature of the study resulted in some limitations. First, the study focused on displacement measurements between the liner and socket, providing only one piece of information regarding the dynamic motion in a vacuum socket. Further insight can be provided with a study focusing on relative motion between the subject's residuum and the liner, and on bone displacement within the tissues. For safety reasons, subjects walked in place, resulting in lower forces being applied to the prosthesis. The available sample size was also small. Last, the subgroup analysis of different limb tissue types, designated by a certified prosthetist, is speculative and limited by the number of subjects. The subgroup analysis does suggest a potential area for further research.

This research provides some initial insight into one possible tool for quantifying the effectiveness of vacuum suspension, the linkage between the prosthetic socket and liner. Additional research is necessary to investigate the linkage between other elements, for example, between the liner and skin as well as between the residual tissue and the bone. As this study suggested, this information will be dependent on subject characteristics including the type of residual limb tissue, the size and shape of the residual limb, component selection, gait dynamics, and the presence of functional muscles. Future work will also be needed to determine the effects of prosthetic socket shape and volume on the correlation between displacement and vacuum pressure fluctuation.

CONCLUSIONS

In summary, vacuum suspension at any given vacuum level displayed superior reduction in vertical displacement compared with suction suspension. For all of the subjects, a vacuum pressure setting of 20 in Hg significantly reduced the amount of distal displacement compared with the other treatment levels. However, clinically significant differences may not be present between 14 in Hg and 20 in Hg for some of the subjects. The presented study demonstrated a subject-dependent linear relationship between distal displacement and vacuum pressure fluctuations as well as a correlation between the type of residual limb tissue and the slope of the associated pressure/motion line.

REFERENCES

1. Tanner JE, Berke GM. Radiographic comparison of vertical tibial translation using two types of suspensions on a transtibial prosthesis: a case study. *J Prosthet Orthot* 2001;13(1):14–17.
2. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthet Orthot Int* 2001;25(3):202–209.
3. Lilja M, Johansson T, Oberg T. Movement of the tibial end in a PTB prosthesis socket: a sagittal X-ray study of the PTB prosthesis. *Prosthet Orthot Int* 1993;17(1):21–26.
4. Narita H, Yokogushi K, Shii S, et al. Suspension effect and dynamic evaluation of the total surface bearing (TSB) trans-tibial prosthesis: a comparison with the patellar tendon bearing (PTB) trans-tibial prosthesis. *Prosthet Orthot Int* 1997;21(3):175–178.
5. Söderberg B, Ryd L, Persson BM. Roentgen stereophotogrammetric analysis of motion between the bone and the socket in a transtibial amputation prosthesis: A case study. *J Prosthet Orthot* 2003;15(3): 95–101.
6. Sanders JE, Karchin A, Fergason JR, Sorenson EA. A noncontact sensor for measurement of distal residual-limb position during walking. *J Rehabil Res Dev* 2006;43(4):509–516.
7. Gerschutz MJ, Haynes ML, Colvin JM, et al. A vacuum suspension measurement tool for use in prosthetic research and clinical outcomes: validation and analysis of vacuum pressure in a prosthetic socket. *J Prosthet Orthot* 2010;22(3):172–176.