

## Methods for characterization of mechanical and electrical prosthetic vacuum pumps

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**Abstract**—Despite increasingly widespread adoption of vacuum-assisted suspension systems in prosthetic clinical practices, there remain gaps in the body of scientific knowledge guiding clinicians' choices of existing products. In this study, we identified important pump-performance metrics and developed techniques to objectively characterize the evacuation performance of prosthetic vacuum pumps. The sensitivity of the proposed techniques was assessed by characterizing the evacuation performance of two electrical (Harmony e-Pulse [Ottobock; Duderstadt, Germany] and LimbLogic VS [Ohio Willow Wood; Mt. Sterling, Ohio]) and three mechanical (Harmony P2, Harmony HD, and Harmony P3 [Ottobock]) prosthetic pumps in bench-top testing. Five fixed volume chambers ranging from 33 cm<sup>3</sup> (2 in.<sup>3</sup>) to 197 cm<sup>3</sup> (12 in.<sup>3</sup>) were used to represent different air volume spaces between a prosthetic socket and a liner-clad residual limb. All measurements were obtained at a vacuum gauge pressure of 57.6 kPa (17 inHg). The proposed techniques demonstrated sensitivity to the different electrical and mechanical pumps and, to a lesser degree, to the different setting adjustments of each pump. The sensitivity was less pronounced for the mechanical pumps, and future improvements for testing of mechanical vacuum pumps were proposed. Overall, this study successfully offers techniques feasible as standards for assessing the evacuation performance of prosthetic vacuum pump devices.

**Key words:** electrical prosthetic pump, elevated vacuum, mechanical prosthetic pump, negative pressure, prosthetic pump, prosthetic pump performance, prosthetic vacuum, socket evacuation, vacuum assisted suspension, vacuum pump.

## INTRODUCTION

Prosthetic suspension refers to the mechanism by which the prosthetic socket is secured onto the residual limb of a person with an amputation, with poor suspension resulting in relative motion between the prosthetic socket and residual limb [1]. Vacuum-assisted suspension (VAS) of prosthetic sockets uses electrical or mechanical pumps to create a negative pressure differential, relative to the atmospheric pressure, between the interior of a prosthetic socket and the surface of a liner-clad residual limb. Since VAS was introduced and adopted in the late 1990s, investigations of VAS have focused on lower-limb prosthetic applications and the effects of vacuum on residual-limb volume [2–5], socket suspension [2], socket fit and interface pressures [6–7], gait kinematics, and residual-limb health [8–9]. These studies suggested VAS improves the

**Abbreviations:** ISO = International Organization for Standardization, Li-Ion = lithium-ion, VAS = vacuum-assisted suspension.

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limb health of prosthesis users by minimizing trauma-inducing relative motion between the socket and residual limb, as well as by promoting tissue hydration, evidenced by reduction in fluctuations in residual-limb volume.

The high numbers of reports in related professional journals [10–11], as well as in prosthetic trade magazines [12–13], suggest an increasingly widespread use of VAS in prosthetic clinical practice, as well as a concomitant increase in the number of commercially available pumps for achieving VAS in prosthetic socket systems. However, other than manufacturer specifications, we have no knowledge of any guidelines in the way of standardized pump performance characterization that may assist clinicians' decision-making. This is in contrast to the large number of characterization studies on other commercially available prosthetic devices and components, such as prosthetic feet [14–15], shock absorbing pylons [16–17], prosthetic knees [18–19], liners, and interface materials [20–22].

Hence, the purpose of this study was to develop techniques to characterize the performance of prosthetic vacuum pumps. Important performance metrics considered included the pumps' evacuation rates to specific vacuum levels and maximum evacuation capabilities based on repeated evacuation of leakage-free containers. The approach described in this article represents a first step toward understanding vacuum pump characteristics in chambers with known leakage (a more clinically relevant scenario). The sensitivity of the proposed techniques was assessed by characterizing the evacuation performance of several commercially available electrical and mechanical pumps.

## METHODS

### Equipment

Based on input from a certified prosthetist (author RC) regarding the level of use in prosthetic practice, two electrical (Harmony e-Pulse [Ottobock; Duderstadt, Germany] and LimbLogic VS [Ohio WillowWood; Mt. Sterling, Ohio]) and three mechanical (Harmony P2, Harmony HD, and Harmony P3 [Ottobock]) prosthetic pumps (**Table 1**) were purchased and their evacuation performance evaluated. In both electrical pumps, a lithium-ion (Li-Ion) battery powered a direct current motor, which ran a small capacity pump. Microprocessor circuitry within the pump monitored the vacuum pressure in the prosthetic socket system and reactivated the pump if the vacuum pressure level decreased below a prescribed threshold.

The three mechanical pumps were designed to be installed in-line with the prostheses and engaged the weight of the user to generate vacuum pressure through two distinctly different activation mechanisms. The two "piston-actuated" mechanical pumps (Harmony P2 and Harmony HD) pulled air from the socket to the pump chamber during stance phase on the prosthetic limb while walking (i.e., when the prosthesis was loaded). The pumps could be configured for different user weights through adjustments of the tension of an elastomer rod within the pumps (**Table 2**). Conversely, the "compressible bladder" mechanical pump (Harmony P3) pulled air from the socket to the pump bladder during swing phase of the prosthetic limb while walking (i.e., when the prosthesis was

**Table 1.**

Description of vacuum pumps tested.

Pump	Description
<b>Electrical</b>	
Harmony e-Pulse (Ottobock)	<ul style="list-style-type: none"> <li>• 2.20 Wh nominal battery energy.</li> <li>• 61 kPa (18 inHg) maximum negative pressure level.</li> </ul>
LimbLogic VS (Ohio WillowWood)	<ul style="list-style-type: none"> <li>• 2.04 Wh nominal battery energy.</li> <li>• 68 kPa (20 inHg) maximum negative pressure level.</li> </ul>
<b>Mechanical</b>	
Harmony P2 (Ottobock)	<ul style="list-style-type: none"> <li>• Patient weights of 50–100 kg (110–220 lb).</li> <li>• Vacuum capability of 51–85 kPa (15–25 inHg).</li> </ul>
Harmony HD (Ottobock)	<ul style="list-style-type: none"> <li>• Patient weights of 100–150 kg (220–330 lb).</li> <li>• Vacuum capability of 51–85 kPa (15–25 inHg).</li> </ul>
Harmony P3 (Ottobock)	<ul style="list-style-type: none"> <li>• Patient weights of 45–100 kg (100–220 lb).</li> <li>• Functional rings denoted 0–4 in order of increasing resistance to compression.</li> <li>• Vacuum capability of 51–85 kPa (15–25 inHg).</li> </ul>

**Table 2.**  
Weight settings for mechanical pumps.

Setting	Number of Turns out (counterclockwise) from Fully Inserted Position *	Harmony P2	Harmony HD	Harmony P3		
		Corresponding Patient Weight (lb/kg)		Functional Ring (n)	Body Weight (kg)	Load (lb)
1 <sup>†</sup>	4.5	120/50	220/100	0	45–50	100–110
2	4.0	140/60	240/110	1	50–60	110–130
3	3.5	160/70	260/120	2	60–73	130–160
4 <sup>†</sup>	3.0	180/80	280/130	3	73–86	160–190
5	2.5	200/90	300/140	4	86–100	190–200
6 <sup>†</sup>	2.0	220/100	320/150	—	—	—

\*Manufacturer instructions: To adjust settings, locate blue cup inside pump shaft, screw in completely using 3/8" Allen wrench. Set elastomer rod by backing out blue cup completely to release pressure on rod, then turning clockwise by suggested number of turns.

<sup>†</sup>Settings used for benchtop testing. Settings 1, 4, and 6 were weight settings assessed in study.

unloaded). In this case, the pump was configured for different user weights using bladders of varying resistance to compression (i.e., functional rings denoted “0” to “4” in order of increasing resistance in **Table 2**). In both mechanisms, air was pushed out from the pump chamber during the alternate phase of walking, i.e., during swing phase for the piston-actuated pumps and during stance phase for the compressible bladder pump.

For the purpose of this study, a well-fitted subschial prosthetic check socket was fabricated for an average-sized male subject with a transfemoral amputation. The air volume space between the inner surface of the doffed check socket and an appropriately sized liner was estimated at 98 cm<sup>3</sup> (6 in.<sup>3</sup>) based on a linear interpolation of the relationship from a previous characterization of the evacuation time of the LimbLogic VS pump using known volumes. Scaling about this reference, five fixed-volume chambers were manufactured from PVC (polyvinyl chloride) tubing and end-caps (ranging from 33 cm<sup>3</sup> [2 in.<sup>3</sup>] to 197 cm<sup>3</sup> [12 in.<sup>3</sup>]). These chambers were used during evacuation testing of the prosthetic pumps to simulate varying air volume spaces of transfemoral sockets, although the range of volumes, in particular the smaller volumes, may also be relevant to transtibial sockets. Exact volumes of the chambers were calculated by dividing the weight of the mass of water required to fill the chambers by the density of water.

A servo-hydraulic materials testing system (8800 Controller, Instron; Norwood, Massachusetts) was used to apply periodic vertical loads, representative of a prosthesis user’s weight during walking, to the mechanical pumps. For both electrical and mechanical pump systems, vacuum pressure measurements were acquired

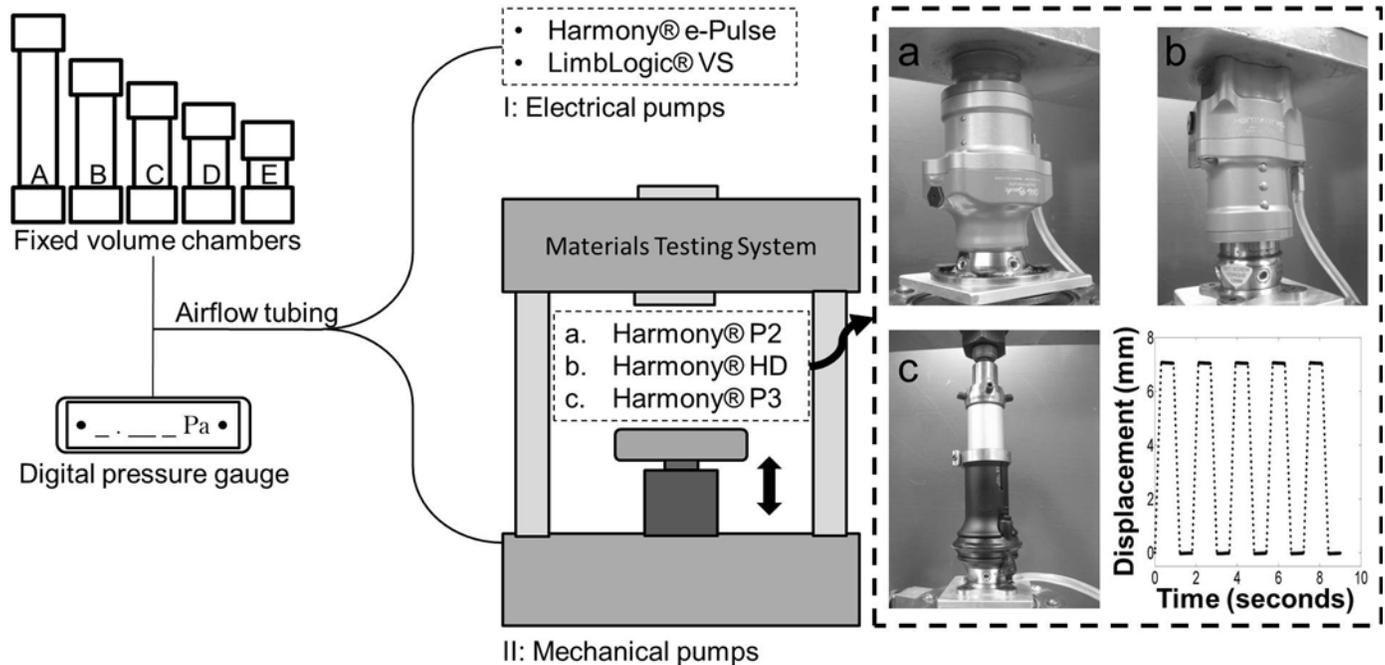
using a digital vacuum pressure gauge (model 2L760, DigiVac; Matawan, New Jersey) with a detection resolution of 0.27 kPa (0.08 inHg). The gauge was customized to a full scale output of 5 V at atmospheric pressure of the testing environment. Prior to each testing session, the gauge was calibrated for a maximum vacuum gauge measurement of –84.7 kPa (25 inHg) relative to the atmospheric pressure. For simplicity, the negative sign on the vacuum pressure levels will be omitted in the remainder of this report.

## Experimental Procedures

### Electrical Pump Testing

The setup for the performance testing of the two electrical pumps consisted of connecting each pump to one of the five fixed-volume chambers using airflow tubing (**Figure 1**). The pump was activated and the vacuum pressure within the connected chamber was monitored and recorded. After evacuation to a specified vacuum level, the airflow tubing was disconnected to return the chamber to the baseline pressure. This process was repeated for five trials of each electrical pump and chamber combination.

Preliminary assessment of the out-of-box capabilities of the two electrical pumps in this study indicated the maximum vacuum pressure level common to both pumps was 57.6 kPa (17 inHg). Consequently, for each chamber, the “evacuation time” of both electrical pumps was defined as the total time from initial pump activation (start-time) to achieving a vacuum pressure of 57.6 kPa (17 inHg) in that chamber (end-time).



**Figure 1.**

Schematic of experimental test setup for electrical and mechanical pumps showing fixed volume chambers, digital pressure gauge, and servo-hydraulic materials testing system. Volumes of five PVC chambers used for testing from left to right are (A) 205 cm<sup>3</sup> (12.54 in.<sup>3</sup>), (B) 140 cm<sup>3</sup> (8.52 in.<sup>3</sup>), (C) 106 cm<sup>3</sup> (6.46 in.<sup>3</sup>), (D) 75 cm<sup>3</sup> (4.59 in.<sup>3</sup>), and (E) 44 cm<sup>3</sup> (2.69 in.<sup>3</sup>). Inserts show fixture attachment within materials testing machine for (a) Harmony P2, (b) Harmony HD, and (c) Harmony P3. Bottom right insert is displacement loading profile for mechanical pump tests.

The discovery of inconsistent evacuation times for the electrical pumps over consecutive days suggested the performance of the pumps was dependent on level of battery charge. Accounting for this dependency by performing all evacuations with the pumps connected to an alternating current power supply was not possible because the Harmony e-Pulse pump was unable to be simultaneously activated and charged. Instead, a series of exhaustive tests (i.e., testing each pump to complete battery charge depletion) was performed to quantify the dependence of both pumps' evacuation performance on battery discharge. The exhaustive testing for each pump involved evacuating the 106 cm<sup>3</sup> (6.46 in.<sup>3</sup>) chamber repeatedly to 57.6 kPa (17 inHg), allowing only time to return the chamber to the baseline atmospheric pressure between each evacuation trial, until the Li-Ion battery of the pump was depleted.

#### *Mechanical Pump Testing*

The performance of the two piston-actuated mechanical pumps (Harmony P2 and Harmony HD) was

assessed at three different settings of manufacturer-prescribed elastomer rod tension adjustments, while the performance of the compressible bladder mechanical pump (Harmony P3) was assessed for the five weight-rated functional rings (Table 2). Prior to testing, each functional ring was "precompressed" for 15 min using a compression tool provided by the manufacturer and was allowed to equilibrate to the testing temperature and humidity environment for a minimum of 24 h before testing. To simulate the in vivo compressive cyclic loads exerted on the pumps during walking, the pumps were loaded using the hydraulic piston ram of the material testing system. Airflow tubing was used to connect the installed pumps to the fixed volume chambers and the digital vacuum pressure gauge (Figure 1).

The piston ram was configured to compress the two piston-actuated pumps by 7 mm, at a cyclic loading rate of 23 mm/s and the compressible bladder pump by 5 mm at the same cyclic loading rate. These values represent the manufacturer's displacement recommendations for optimal pump performance [23] and an approximate

prosthetic-limb cadence of 100 steps/min, with a 50:50 proportion of single- and double-limb stance support. The numbers of loading-unloading cycles applied to each mechanical pump were determined from pilot data and identified as the number of cycles at which continued activation of the pumps created a negligible increase in vacuum pressure. Consistently for all pump weight settings and chamber combinations, three trials of 200 loading-unloading cycles were applied to the piston actuated pumps and three trials of 300 loading-unloading cycles applied to the compressible bladder pump.

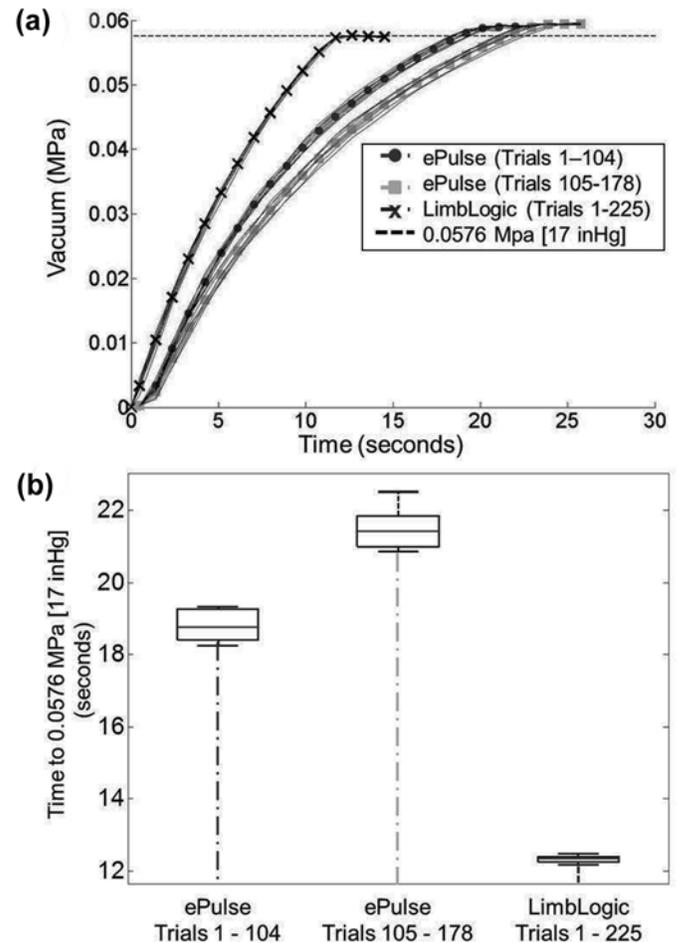
### Data Analysis and Calculations

The vacuum pressure data generated by the mechanical pumps exhibited a step-like profile, increasing as the pumps were loaded and staying approximately constant upon removal of load. The data were resampled to isolate the vacuum pressure value at the start of the loading-unloading cycle, effectively reducing the data to a single data point per cycle. Unlike the electrical pumps, where the maximum vacuum pressures were controlled by microprocessor circuitry, the maximum vacuum pressures generated by the mechanical pumps were potentially dependent on the number of cyclic activations of the pumps. In an attempt to address this dependence, a theoretical maximum vacuum capacity was calculated and reported for each mechanical pump. This calculation involved a linear extrapolation of the terminal region of the asymptotic trending vacuum pressure data to three times the total testing duration of that trial. For all electrical and mechanical pump trials, the evacuation times to a vacuum pressure of 57.6 kPa (17 inHg) were measured and averaged over the number of repeated trials for all pump, setting, and chamber combinations.

## RESULTS

### Electrical Pump Testing

Exhaustive testing of the electrical pumps demonstrated the Harmony e-Pulse had a total of 178 evacuations before complete battery depletion, with a 14 percent increase in time to evacuate to 57.6 kPa (17 inHg) over the entire course of the test (**Figure 2(a)**). We noted a distinct change in the time to evacuate between the first 104 trials and the subsequent 74 trials (**Figure 2(b)**), with consistent evacuation times within each group of trials (standard deviation of 0.40 and 0.54, respectively). By



**Figure 2.**

Electrical pump battery depletion test results. **(a)** Plot of vacuum pressure vs time for two grouped evacuation trials of Harmony e-Pulse and single group evacuation trial of LimbLogic VS. **(b)** Boxplot indicating substantially lower median activation time for LimbLogic VS compared with both groups of data from Harmony e-Pulse.

comparison, the LimbLogic VS achieved a total of 225 evacuations using only half a full battery charge (as indicated by the pump battery meter) before exhaustive testing was terminated. There was a 2.4 percent total increase in evacuation time to 57.6 kPa (17 inHg) over the course of the test.

The average time to evacuate all five chambers to 57.6 kPa (17 inHg) for the LimbLogic VS was 11.57 s, while the Harmony e-Pulse required 18.04 s (56% more time) to evacuate the same chambers (**Table 3**). For both electrical pumps, linear equations were able to describe

**Table 3.**

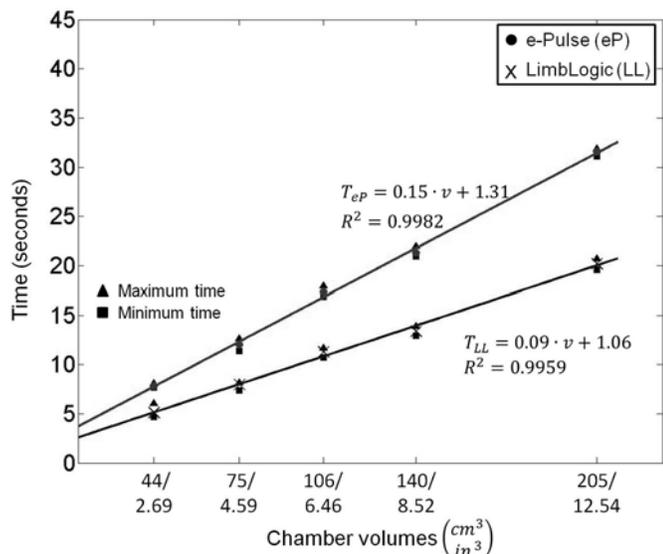
Electrical pump results. Standard evacuation pressure level was set at 57.6 kPa (17 inHg).

Chamber Volume (cm <sup>3</sup> /in. <sup>3</sup> )	Time to Evacuate (s)	
	LimbLogic VS	Harmony e-Pulse
205/12.54	20.16	31.56
140/8.52	13.38	21.32
106/6.46	11.28	17.37
75/4.59	7.95	12.06
44/2.69	5.10	7.86
Mean ± Standard Deviation	11.57 ± 5.74	18.04 ± 9.13

most of the variability in the evacuation times as a function of the five chamber volumes ( $R^2 > 0.99$ ) (**Figure 3**). The best-fit lines of evacuation times plotted against chamber volume showed the LimbLogic VS had a smaller slope compared to the Harmony e-Pulse despite having a similar y-intercept.

### Mechanical Pump Testing

Across the three manufacturer-prescribed elastomer rod tension settings and for the same chamber volumes at those settings, neither the Harmony P2 nor the Harmony HD pumps showed substantial differences in their evacuation times to 57.6 kPa (17 inHg), the number of activa-

**Figure 3.**

Electrical pump results showing average evacuation time vs exact chamber volumes. Evacuation times of Harmony e-Pulse (superior line,  $T_{eP}$ ) are consistently higher than evacuation times of LimbLogic VS (inferior line,  $T_{LL}$ ).

tion cycles required, or their theoretical maximum vacuum capacity (**Table 4**). The Harmony P3 pump showed a consistent trend of increasing evacuation times to 57.6 kPa (17 inHg), increasing number of activations required, and a decreasing theoretical maximum vacuum capacity with increasing resistance to compression (i.e., functional rings denoted “0” to “4”).

A comparison of the maximum forces exerted by the hydraulic piston ram during application of the programmed compressive displacement to the Harmony P2 and Harmony HD pumps showed no sensitivity to the chamber volume within the three elastomer rod settings. However, across the three settings, there were clear differences, generally trending, with the exception of results of setting 1 of the Harmony P2 pump, to increasing maximum force with increasing resistance to compression of the elastomer rod (**Figure 4**). The Harmony P3 pump performed with less consistency within and across the different resistances to compression.

### DISCUSSION

The purpose of this study was to develop techniques to characterize the performance of vacuum pumps intended for clinical application within prostheses. Such characterizations offer insights to guide clinician selection of devices and components. To assess the sensitivity of the proposed techniques, several commercially available vacuum pumps were characterized in a series of benchtop tests.

### Electrical Pump Battery Depletion Testing

Results of the exhaustive battery testing indicated a slight increase in evacuation time of sequential trials, suggesting a dependence of pump performance on total battery charge. The substantially higher number of total evacuations of the LimbLogic VS pump than the Harmony e-Pulse was likely because of the quality of the battery and other components of the pumps. In spite of this dependence, both pumps performed consistently for the first 100 evacuation trials of the 106 cm<sup>3</sup> (6.46 in.<sup>3</sup>) chamber volume.

### Electrical Pump Testing

Selection of 57.6 kPa (17 inHg) as a standard vacuum pressure level for measuring evacuation time was based on a preliminary assessment that determined the maximum

**Table 4.**  
Mechanical pump results.

Measure	Harmony P2 (Settings)			Harmony HD (Settings)			Harmony P3 (Functional Rings)				
	1	4	6	1	4	6	0	1	2	3	4
Time to Evacuate to 57.6 kPa (17 inHg) (s)	42.72	42.59	42.71	42.47	43.31	43.06	39.50	41.78	53.31	62.12	79.17
Number of Cycles to 57.6 kPa (17 inHg) (units)	26	25	25	26	25	25	25	27	34	39	50
Maximum Vacuum Gauge Pressure (kPa/inHg)	80.39/ 23.74	89.43/ 26.41	89.43/ 26.41	88.93/ 26.26	88.38/ 26.10	88.69/ 26.19	75.11/ 22.18	70.40/ 20.79	67.90/ 20.05	65.15/ 19.24	63.16/ 18.65

vacuum pressure level common to both electrical pumps. The LimbLogic VS consistently outperformed the Harmony e-Pulse in time to evacuate each chamber, averaging 56 percent less time to achieve a vacuum level of 57.6 kPa (17 inHg) (**Figure 3**). For both pumps, linear equations were able to describe most of the variability in evacuation times as a function of the different chamber volumes. Despite having similar  $y$ -intercepts, the LimbLogic VS had a smaller slope than the Harmony e-Pulse pump, suggesting a higher base functional performance because increases in volumes resulted in smaller increases in evacuation time.

### Mechanical Pump Testing

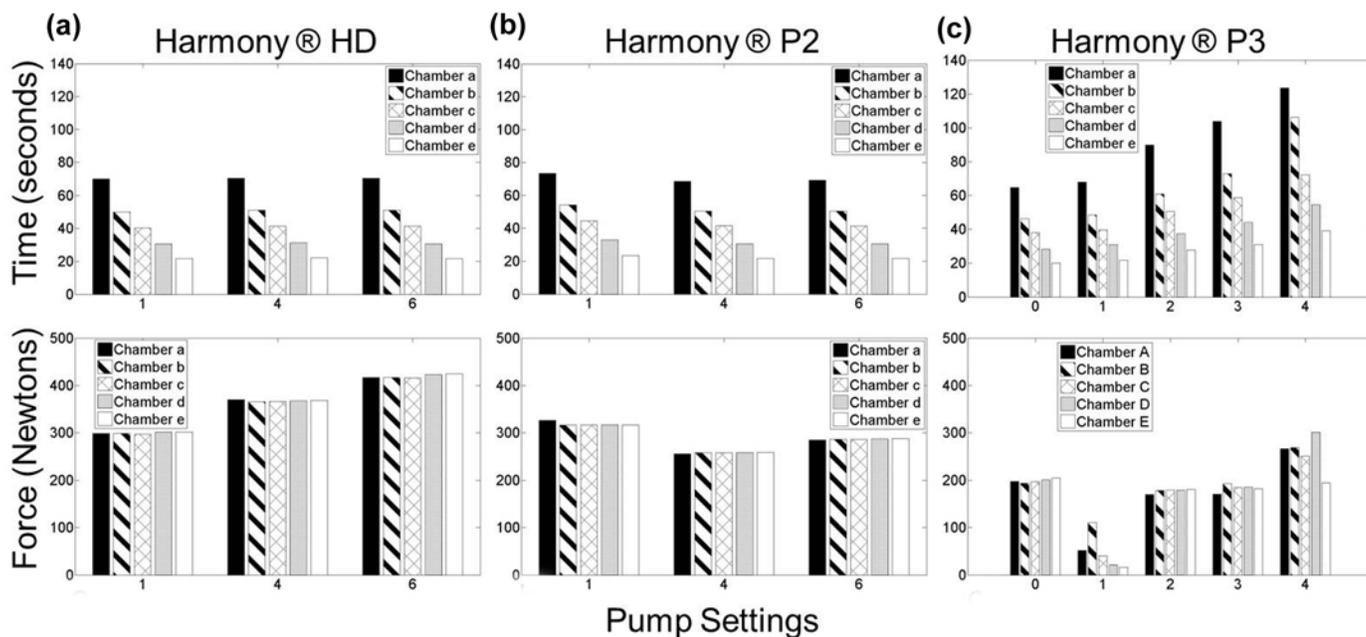
Our decision to adopt a benchtop approach to characterize the performance of the mechanical pumps allowed precise control of the loading variables. The pumps were actuated by the servo-hydraulic materials testing system using a displacement control paradigm. The amount of compression of the pumps, the cyclic loading rate, and the total number of loading-unloading cycles were determined prior to initiation of the test.

At the three weight settings tested for the Harmony P2 and Harmony HD pumps, there were no differences in pump performance within, as well as across, both pumps (**Table 4, Figure 4**). This misleading finding suggested the different elastomer rod tension adjustments had no effect on pump performance. Correct interpretation required consideration of the control paradigm used for loading of the mechanical pumps. Under a displacement control paradigm, the testing system adjusted the force applied at each weight setting to achieve prescribed displacements. We expected the applied force to increase with increasing resistance (i.e., setting  $1 < 4 < 6$ ) for both pumps. The results (**Figure 4**), with the inexplicable exception of the Harmony P2 pump at setting 1, followed these trends and demonstrated sensitivity of the pump performance to the different settings.

As previously described, the Harmony P3 pump used compressible bladders (functional rings) to pull air from the socket and generate vacuum pressure. With increasing resistance of the functional rings (from ring 0 to 4), the time and number of cyclic activations required to achieve 57.6 kPa (17 inHg) for each chamber also increased. Conversely, the theoretical maximum vacuum capacity was reduced. These results suggested the mechanism used to increase resistance was increased wall thickness of the bladders, effectively reducing the total volume of the bladders. Hence, with the stiffer bladders, the amount of air moved by the pump per activation cycle was reduced.

The testing of the mechanical pumps could be improved by use of machines for International Organization for Standardization (ISO) 22675 testing (ISO; Geneva, Switzerland) [24]. ISO 22675 testing machines are designed to test prosthetic feet in a heel-to-toe loading fashion that simulates walking. These machines also use force control to mimic the ground reaction forces during walking. Mechanical pumps could be placed in line with pylons and feet within these testing machines to obtain more realistic results. Manufacturers of mechanical vacuum pumps for use in prostheses could use similar metrics as described in this article, but with improved loading from ISO 22675 machines.

There were several practical limitations that curtailed the scope and generalizability of our findings. First, a single pump of each type was used to assess the techniques presented in this report. Findings from such a sample are not generalizable to all pumps of the same type, and a number of precautions were taken to mitigate potential errors introduced by the use of single samples. Both electrical pumps had less than 10 h of use, primarily usage for preliminary evaluation at commencement of our testing. Similarly, the three mechanical pumps were exposed to very limited use at the start of data collection. Brand new functional rings were purchased for the Harmony P3



**Figure 4.**

Mechanical pump results showing (top plots) time to evacuate chambers to 57.6 kPa (17 inHg) for pump settings (*x*-axis) and (bottom plots) maximum force exerted by testing system for each chamber evacuated: (a) Harmony HD, (b) Harmony P2, and (c) Harmony P3.

pump and were precompressed according to manufacturer recommendations. These precautions allowed the reasonable assumption that all pumps, batteries, and components remained true to their original technical specifications.

Second, the estimate of air volume space between the prosthetic socket's inner surface and the outer surface of the liner-clad residual limb was calculated from an average-sized male with a transfemoral amputation. To include a range of air volume spaces in our analysis, we used this estimate as a scaling reference for several fixed volume canisters, including smaller volumes that are likely relevant to air volume spaces found in transtibial prosthetic sockets.

Third, the ideal setup for the electrical and mechanical prosthetic vacuum pumps characterization would have simulated a gradual loss of vacuum gauge pressure (i.e., leakage), providing a more realistic representation of the everyday usage of prosthetic vacuum pumps. This would be of particular significance for the electrical pump battery depletion testing since the primary power mode of electrical pumps within minimally leaking socket systems would conceivably be a "stand-by" monitoring mode. In this mode, the electrical motor is deacti-

vated and battery power supply is limited to essential pump tasks for monitoring the vacuum gauge pressure within the socket system. An electrical pump with more efficient battery consumption in the stand-by monitoring mode may be capable of a higher number of overall evacuations for the same air space volumes and socket leakage rates. Our decision to assess pump performance based on repeated, complete loss of vacuum gauge pressure (i.e., full depletion) was due to the difficulty of developing a standard characterization of typical leakage. Repeated full depletion represents an unlikely worst case scenario and should be considered in the interpretation of performance findings determined using the proposed techniques.

Finally, although only one end of the two piston-actuated pumps was directly attached to the testing system (**Figure 1(a)** and **(b)**), both ends of the compressible bladder pump were directly attached to the testing system for the entire actuation cycle (**Figure 1(c)**). The difference in setup was due to the inability of the Harmony P3 pump to return to its original, uncompressed height after the loading (i.e., pump compression) phase of the actuation cycle. With increasing number of actuation cycles, the pump height gradually decreased until all evacuation functioning ceased

because of a fully compressed bladder, i.e., a “bottoming out” of the bladder. Attaching both ends to the testing system introduced a forcible, as opposed to a passive, restoration to the original bladder pump height during the unloading phase of the actuation cycle. Care was taken to ensure the compressible bladder pump was returned only to its uncompressed height, with negligible off-axial forces applied to the bladder while unloading. For these reasons, we expect the Harmony P3 pump to experience a bottoming out effect in clinical use and the actual performance, particularly regarding the maximum vacuum capacity, to be worse than our results suggest.

The proposed techniques offer objective assessments necessary for potential performance characterization guidelines of prosthetic vacuum pumps. They demonstrated sensitivity to the different commercially available electrical and mechanical pumps characterized in this study, and to a lesser degree, the pump settings. Overall, this study offers techniques feasible for general adoption as standards for assessing the evacuation performance of electrically controlled and mechanical prosthetic vacuum pumps.

## CONCLUSIONS

There are presently no performance guidelines to assist clinicians when selecting from among existing prosthetic vacuum pumps. If adopted by the prosthetics community, the proposed techniques will provide testing guidelines and standard performance metrics for prosthetic pumps that can enhance clinicians’ ability to make informed choices for patients using VAS.

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*Study concept and design:* O. Komolafe, S. Wood, R. Caldwell, A. Hansen, S. Fatone.

*Acquisition of data:* O. Komolafe, S. Wood, R. Caldwell.

*Analysis and interpretation of data:* O. Komolafe, S. Wood, R. Caldwell, A. Hansen, S. Fatone.

*Drafting of manuscript:* O. Komolafe.

*Critical revision of manuscript for important intellectual content:*

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*Obtained funding:* S. Fatone, R. Caldwell, A. Hansen.

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