Evaluation of a Prototype Hybrid Vacuum Pump to Provide Vacuum-Assisted Suspension for Above-Knee Prostheses

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Vacuum-assisted suspension (VAS) of prosthetic sockets utilizes a pump to evacuate air from between the prosthetic liner and socket, and are available as mechanical or electric systems. This technical note describes a hybrid pump that benefits from the advantages of mechanical and electric systems, and evaluates a prototype as proof-of-concept. Cyclical bench testing of the hybrid pump mechanical system was performed using a materials testing system to assess the relationship between compression cycles and vacuum pressure. Phase 1 in vivo testing of the hybrid pump was performed by an able-bodied individual using prosthesis simulator boots walking on a treadmill, and phase 2 involved an above-knee prosthesis user walking with the hybrid pump and a commercial electric pump for comparison. Bench testing of 300 compression cycles produced a maximum vacuum of 24 in-Hg. In vivo testing demonstrated that the hybrid pump continued to pull vacuum during walking, and as opposed to the commercial electric pump, did not require reactivation of the electric system during phase 2 testing. The novelty of the hybrid pump is that while the electric system provides rapid, initial vacuum suspension, the mechanical system provides continuous air evacuation while walking to maintain suspension without reactivation of the electric system, thereby allowing battery power to be reserved for monitoring vacuum levels. [DOI: 10.1115/1.4030507]

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Introduction

Prosthetic sockets are secured to the limb by suspension mechanisms of which there are many types, including mechanical (straps, pin locking liners) and suction (liners, one way valves, vacuum pumps) systems. Introduced and adopted in the late 1990's, vacuum pumps used to suspend a socket on the residual limb are referred to as VAS [1]. Pumps create a negative pressure differential relative to atmospheric pressure by evacuating air from between the surface of a liner clad residual limb and the interior of a prosthetic socket [1]. Evidence of the suggested benefits of VAS over suspension techniques such as suction and pin-locking liners have been described as: reducing residual limb volume fluctuations that compromise socket fit [1–4], improving gait symmetry [1], reducing residual limb pistoning [1,5], and facilitating limb healing [3,6–9]. In particular, VAS has been proposed as an effective suspension strategy for short residual limbs [10] and brimless sockets that may enhance user comfort [11,12].

Current pump designs are either mechanical or electrical [13]. The advantage of mechanical pumps is that there is no need to charge or replace batteries, they are less noisy, they are mostly maintenance free and field serviceable if issues arise, and will work continuously as long as the user is walking. Mechanical pumps require multiple steps with the prosthesis to reach the recommended vacuum [14], delaying achievement of optimal suspension and coupling. For example, according to the manufacturer the Otto Bock Harmony® P3 should reach 15 in-Hg within 50 steps. A smaller pump like the Össur Unity™ may take even more time to evacuate the same volume to the same vacuum pressure. Loss of active vacuum when not walking can lead to the need to re-establish vacuum, potentially contributing to trauma of the residual limb soft tissues. Mechanical pumps are infrequently used in transfemoral prostheses possibly because their flow rate is insufficient to rapidly evacuate the relatively larger air space as compared to a transtibial socket. With larger volumes, such as are found in transfemoral sockets or double wall socket designs, establishing the required vacuum level before walking may be even more crucial.

Electric pumps pull and monitor vacuum even while not walking. This allows them to initiate vacuum before walking, ensuring that the residual limb is completely seated in the socket and avoiding suspension issues that contribute to skin problems. For example, clinically, prosthesis users complain that when sitting for a period of time, socket fit is altered and they need to reseat their limb into the socket when they resume standing. Reseating has the tendency to allow the liner to move away from the residual limb creating a suspension issue that contributes to skin abrasion. The ability to maintain vacuum and a correct position within the socket at all times is particularly critical for users that have sensitive skin, significant bony prominences or open sores. The disadvantages of electric pumps are that they are noisy, need charging, and are not easily field serviced.

A hybrid vacuum pump that incorporates both an electric and mechanical pump is proposed as a modular prosthetic component to generate VAS of transfemoral prosthetic sockets irrespective of the state of the user while maximizing battery life and minimizing noise. It would act such that the electric pump operates initially to rapidly draw a threshold vacuum with the mechanical pump maintaining that vacuum during prosthesis use when air slowly leaks back into the interface. Importantly, during daily activity the electric pump ensures that vacuum suspension is maintained during stationary periods (e.g., standing and sitting) and the mechanical pump maintains suspension during ambulation (e.g., walking and transfers). This technical note describes the design of a hybrid vacuum pump and demonstrates operational feasibility.

Materials and Methods

Hybrid Pump Design. A prototype hybrid prosthetic pump, dubbed the Northwestern University Hybrid Integrated Prosthetic Pump Initiative (HIPPI) was fabricated (Fig. 1), including a rubber bladder to act as the mechanical pump system, electronics for the electric pump system, and housing that was built from polycarbonate–acrylonitrile-butadiene-styrene (PC-ABS) plastic using an additive manufacturing (fused deposition modeling) 3D printer (Stratasys, Eden Prairie, MN). Although the PC-ABS housing is porous, the sealed bladder of the mechanical system is attached to the volume of interest via tubing and does not require

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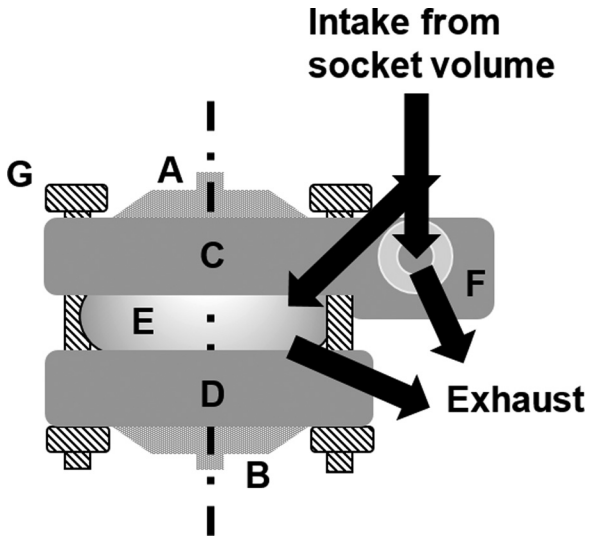

Fig. 1 Schematic of the hybrid pump design. Constituent parts include: (*a*) proximal female pyramid adapter, (*b*) distal male pyramid adapter, (*c*) proximal housing plate, (*d*) distal housing plate, (*e*) bladder pump (mechanical system), (*f*) electric pump (electric system), and (*g*) threaded posts (×4). The threaded posts act as guide rails during cyclical compression and extension of the bladder. The solid arrows indicate air flow from the socket volume during operation.

the housing to be airtight but only act as compression plates. The mechanical and electric pump systems attach to the desired evacuation volume through a parallel connection and a system of one-way valves. The mechanical system pulls air from the evacuation volume as the bladder expands, and forces this air through an exhaust as the bladder compresses during load-bearing. The electric system pulls air from the evacuation volume through a pump that is activated by a DC motor and can be programmed to reach an upper vacuum pressure threshold when activated and reactivate when a defined lower threshold is reached. Pyramid adapters (Otto Bock, Duderstadt, Germany) were fixed to the proximal and distal ends of the pump housing to allow for integration within a modular prosthetic system. The concept of the hybrid pump is that prior to walking the electric system would rapidly evacuate air to create a desired vacuum pressure for socket suspension, and during walking when leakage of the vacuum is likely to occur, the mechanical system is continuously engaged to maintain a sufficient level of vacuum pressure. A patent has been granted on the hybrid pump design [15].

Bench Testing Protocol. Prior to in vivo testing, bench testing of the hybrid pump was performed using a materials testing system (Model 8800, Instron, Norwood, MA). The protocol for bench characterization was modeled upon a previously established protocol [13]. The pump was secured in the testing machine, preloaded to 20 N, and underwent 300 cycles of compression and release at a cyclical loading rate of 23 mm/s with two dwell periods of 0.16 s at minimum and maximum displacement, a simulated cadence of 100 steps/min. The vector of applied load coincided with the longitudinal axis of the pump and was measured with an integrated uniaxial load-cell. The compression displacement was 10 mm, which represented effective bottoming out and full compression of the bladder. The pump was attached to a sealed canister of 6.36 $in.^3$ volume to simulate the average evacuation volume to create VAS in a transfemoral prosthetic socket [13]. A digital vacuum pressure gauge (model 2L760, DigiVac; Matawan, NJ) measured the real-time pressure level in the sealed canister. Bench testing was performed three times to estimate the average time and number of "steps" required to achieve a vacuum pressure of 17 in-Hg, a common vacuum pressure for socket suspension as recommended by vacuum pump manufacturers

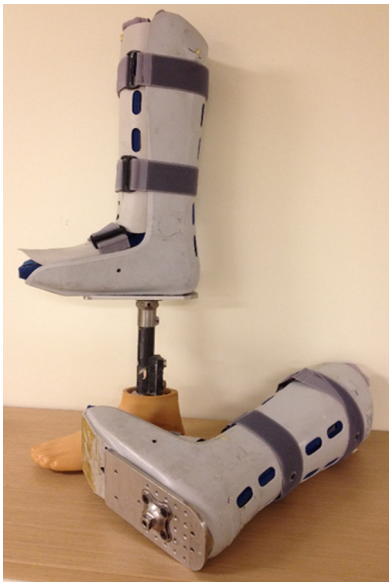

Fig. 2 Walking simulator boots. Prosthetic components attach distal to the foot plate and mimic transtibial prosthesis use.

[13], as well as the initial linear rate of pressure creation as approximated by a linear best fit and the maximum force attained during cyclical testing.

In Vivo Phase 1: Walking Simulator. The first phase of in vivo testing involved a single participant (35 yrs, 185 cm, 78 kg) walking on a treadmill with walking simulator boots (Fig. 2) and the hybrid pump installed between the plantar surface of the right leg boot and a prosthetic foot. A prosthetic foot and pylon were attached to the left leg boot and adjusted to eliminate leg length discrepancy. Athletic trainer shoes were donned on each foot to improve plantar surface friction with the treadmill belt. The pump was attached to the same sealed canister as used during bench testing and the digital vacuum pressure gauge was used to measure real-time pressure in the canister. Prior to walking, the electric system was used to create vacuum in the canister and, when the pressure reached approximately 17 in-Hg, the subject walked for 10 minutes at a speed of 0.53 m/s (a speed that was considered comfortable and safe by the participant). This in vivo testing was used to determine if the prototype would sustain the loads encountered during operation and if the mechanical system would continue to create vacuum during walking when under operational loads. Real-time pressure level in the sealed canister was collected during testing as measured by the digital vacuum pressure gauge (DigiVac).

In Vivo Phase 2: Transfemoral Prosthesis User. The second phase of in vivo testing involved a unilateral transfemoral prosthesis user (54 yrs, 183 cm, 97.5 kg, left side amputation due to trauma) walking on a treadmill under two conditions:

(1) the original prosthetic setup consisting of a KX06 knee (Endolite, Miamisburg, OH), highlander foot (Freedom Innovations, Irvine, CA), subischial socket with a Relax 3 C liner (Medi, Whitsett, NC), and the LimbLogic electric pump (Ohio WillowWood, Mt. Sterling, OH), and
(2) the original socket integrated with a 3R60 knee (Otto Bock, Duderstadt, Germany), solid ankle cushioned heel foot (Kingsley Mfg. Co., Costa Mesa, CA) and the hybrid pump installed between the distal end of the socket and the knee joint (Fig. 3).

For both pump units, the electric system was programmed to create a maximum vacuum setting of approximately 17 in-Hg and the minimum allowable vacuum before reactivation was set at

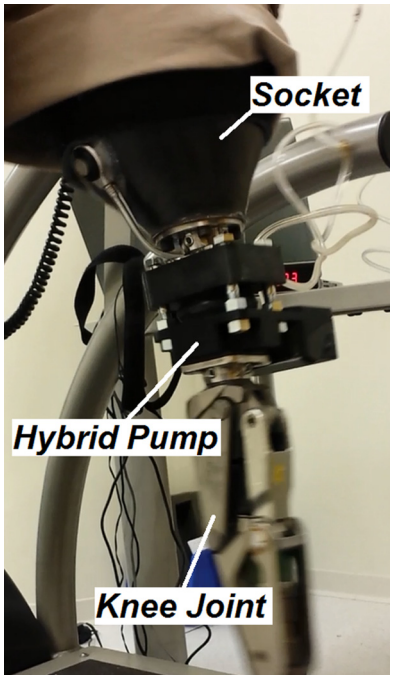

Fig. 3 Location of the hybrid vacuum pump for use within a transfemoral prosthesis. Pyramid adaptors fixed to proximal and distal ends of the pump housing were used for installation of the pump between the socket and knee joint, respectively.

13 in-Hg. Prior to walking, the electric system was used to create vacuum in the socket for suspension and when the pressure reached approximately 17 in-Hg, the subject walked for 10 min at a speed of 0.53 m/s (a speed that was considered comfortable and safe by the participant). This in vivo testing was used to determine if the prototype would sustain the loads encountered during operation in a transfemoral prosthesis when installed proximal to the knee joint, if the mechanical system would continue to create vacuum during walking when under operational loads, the time required to obtain 17 in-Hg vacuum pressure through the electric system, and the number of times the electric system reactivated due to the lower vacuum threshold being met. Real-time pressure level in the prosthetic socket was collected during testing as measured by the digital vacuum pressure gauge (DigiVac).

Ethical approval was obtained from the University Institutional Review Board and participants provided informed consent prior to in vivo data collection.

Results

An example of the bench testing results is presented in Fig. 4(*a*). The average maximum vacuum pressure was 24 in-Hg achieved after 112 cycles. On average, the desired vacuum pressure of 17 in-Hg was achieved after 13 cycles and the linear rate of evacuation was approximately 1.1 in-Hg/cycle. The average maximum force achieved during cyclical testing was 720 N.

Results from the walking simulator (phase 1) and transfemoral prosthesis user (phase 2) are presented in Figs. 4(*b*) and 4(*c*), respectively. The prototype sustained the loads applied during both in vivo testing scenarios. Testing with the walking simulator demonstrated that the electric system created an initial vacuum, while subsequent walking continued to increase vacuum pressure through activation of the mechanical system. During phase 2 testing, the commercial electric pump and hybrid pump achieved a maximum vacuum pressure of 18 in-Hg and 23 in-Hg, respectively. Using the electric system, the commercial pump and hybrid pump both achieved 17 in-Hg in approximately the same amount of time: 14 s. While the commercial pump was required to reactivate twice during the 10 min walk session, the additional vacuum

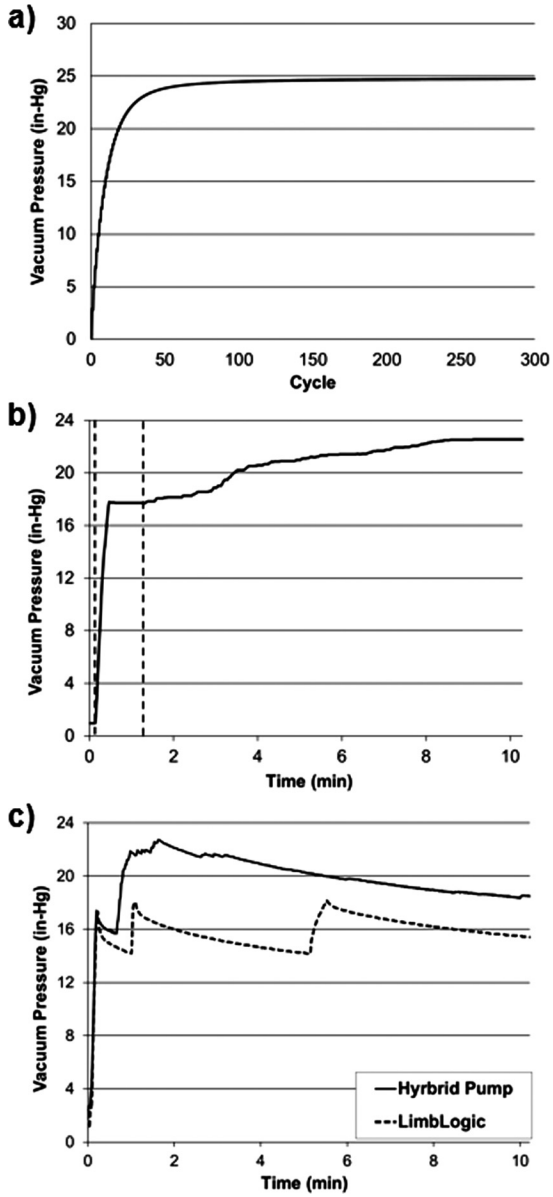

Fig. 4 Results from (*a*) bench testing, (*b*) in vivo walking with simulator boots (the first and second dashed vertical lines represent the initiation of the electric system and walking, respectively), and (*c*) in vivo walking of a transfemoral prosthesis user with a commercial electric pump (Ohio WillowWood LimbLogic) and the hybrid pump

created by the mechanical system during the initial portion of walking prevented the hybrid's electric pump from reactivating. Although vacuum was created and sustained by the mechanical system during the start of walking, this function appeared to be less effective as walking progressed and the hybrid pump demonstrated similar leakage to that of the commercial unit.

Discussion

This study described the proof-of-concept testing of a hybrid pump unit to be integrated with a transfemoral prosthesis for the purpose of VAS. Bench testing indicated that by solely using the mechanical pump system only 13 cycles (or steps) would be necessary to achieve the desired vacuum pressure of 17 in-Hg when maximum compression (10 mm) of the bladder occurs resulting from 720 N of force (approximately 92% of body weight for an 80 kg user) applied along the longitudinal axis of the unit. When the hybrid pump is installed within walking boots to simulate

integration with a transtibial prosthesis, the hybrid pump behaved as expected. The electric system initially created vacuum and walking continued to increase the vacuum pressure due to cyclical activation of the mechanical system. Importantly, the pump sustained the moments and loads applied during this form of testing, and the effectiveness of the mechanical system was not compromised during operation.

Results from in vivo testing with a transfemoral prosthesis user demonstrated promise for the utility of the hybrid pump. As expected, the hybrid pump was capable of achieving the desired level of vacuum similar to a commercial electric pump, and due to the creation of additional vacuum through activation of the mechanical system, prevented the electric system from reactivating. Reduced dependence on the electric system will save battery power and therefore reduce the frequency of battery charging. However, although the mechanical system created vacuum initially, this system became less effective as walking continued beyond approximately 1.5 min. One possible reason for this diminished function is a subtle modification in the participant's gait, which may have placed the hybrid pump under moments and loads not encountered during bench testing and when walking with the simulator boots. The use of a four-post system to guide the housing plates during bladder compression created a rocking motion (asymmetric compression) that restricted the bladder from achieving full compression and hence compromised its function. This issue will be addressed in subsequent design iterations to eliminate asymmetric compression during operation in a transfemoral prosthesis. Further evaluation of design iterations will also characterize the passive physical properties (i.e., stiffness and damping) of the hybrid pump and observe the effects of these properties on user performance [16,17] for design optimization.

Overall, this testing demonstrated the utility of a hybrid pump design, specifically for those users who may experience excessive time to create sufficient vacuum pressure for suspension when using only a mechanical pump due to their light weight (e.g., elderly), or who desire immediate use of their prosthesis postdonning (e.g., individuals who engage in sporting activity or the military). The use of a hybrid pump will quickly achieve the desired vacuum pressure such that the user may immediately begin walking with their device and this walking will sustain vacuum pressure due to continuous activation of the mechanical system. Importantly, as the mechanical system sustains adequate levels of vacuum pressure, this decelerates drainage of the battery in which power is only used to monitor vacuum pressure level and not for reactivating the electric system, which uses proportionally larger amounts of energy. Additionally, we have the ability to set the electric system to activate only when there is a critical loss of vacuum, further reducing battery demand. The pumps can also work independently if there is a malfunction with either individual system, creating a nice fail-safe. Although the hybrid pump appears to operate well for integration with a transtibial prosthesis, subsequent design iterations and testing will focus on improving its functional reliability for transfemoral prosthesis application.

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