The Use of Prosthetic Vacuum Socket Suspensions: A Comparison of a Modified Bicycle Pump to Commercially Available Options

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Abstract

There are approximately 35-40 million people requiring orthotic and prosthetic services in developing countries (World Health Organization, 2017). Elevated vacuum, as a form of socket suspension, has been documented to decrease limb volume change, improve amputee proprioception, circulation, comfort, gait symmetry, and overall quality of life of amputees (Gholizadeh, Lemaire, Eshraghi, 2016). While these systems may benefit many amputees in developing countries, the high cost, accessibility, and maintenance of current elevated vacuum systems are not a feasible option. The purpose of this study was to evaluate how a simple modified bicycle pump compares to commercially available vacuum pumps. Results from the study show that a modified bicycle pump can achieve a maximum vacuum level of 21.7 inHg (57.6 kPa), comparable to commercially available options, and can achieve 17 inHg (57.6 kPa), significantly faster than commercially available pumps at a price point of $15.00.

Key words: elevated vacuum, low-income, prosthetics, developing countries, bicycle pump, socket suspension

Introduction

Providing quality care for amputees in low income countries is a problem across the world largely due to low-income countries not having adequate resources or personal to deal with amputees (Harkins, McGarry, Buis 2008). Financial road-blocks as well as the lack of skilled practitioners create a major problem for amputees who could otherwise live a normal life (Strait, 2006). There are many obstacles to overcome in providing quality prosthetic care in low income countries. According to the WHO, there are approximately 35-40 million people requiring orthotic prosthetic services in developing countries and more than 75% of developing countries have no training programs for orthotic and prosthetic programs (World Health Organization, 2017). Additionally, only 5-15% of people who could benefit from an orthosis or prosthesis have access to them (World Health Organization, 2017).

There are several published research studies outlining the benefits of elevated vacuum. Elevated vacuum has been shown to decrease limb volume change, improve amputee proprioception, circulation, comfort, gait symmetry, and overall quality of life (Gholizadeh, Lemaire, Eshraghi, 2016). The lifetime cost of a unilateral transtibial prosthesis in the United States ranges from $0.5- $1.8 million US dollars (Highsmith et al. 2016). While these systems would benefit many amputees in developing countries, the high cost, accessibility, and maintenance of current elevated vacuum systems are not a feasible option.

For elevated vacuum systems to be a realistic option for socket suspension for amputees in low income countries, the systems must be low cost and readily accessible. Adapting already available equipment may offer a sustainable solution at a low cost. Bicycles have long been a source of transportation for low income countries, and simple hand pumps are readily available for tire maintenance and can be obtained for a relatively low price. Using a modified bicycle pump could provide the means of which to obtain the necessary vacuum levels needed for socket suspension.

Research by Xu, Bloswick, Zhao, & Merryweather (2017), stated that increased vacuum pressure correlated with improved comfort and residual limb relief. Their research recommended vacuum pressure of 15-20 Hg, and suggests low vacuum levels have negative effects of gait symmetry and should be avoided (Xu, Blowswick, Zhao, & Merryweather 2017). Increased elevated vacuum was also shown to have a significant effect on hip external rotation, and on external knee adduction moments (Xu, Blowswick, Zhao, & Merryweather 2017). Higher vacuum improved gait symmetry in step length and stance duration as opposed to no vacuum (Xu, Blowswick, Zhao, & Merryweather 2017). Residual limb pistoning can be mitigated with elevated vacuum. Reducing pistoning protects the residual limb from sheer forces, but also increases proprioception of the prosthesis.

Elevated vacuum showed advantages over pin suspension and suction suspension systems by creating greater negative pressure environments during swing phase, and lowering positive pressure impact during stance phase (Xu, Blowswick, Zhao, & Merryweather 2017). This is significant because skin breakdown occurs from positive pressure, not negative pressure (Xu, Blowswick, Zhao, & Merryweather 2017).

Research published by Beil, Street, & Covey, (2002) compared socket interface pressures between total-surface weight-bearing suction sockets and vacuum-assisted sockets. Results from their study showed that vacuum-assisted sockets created statistically significant lower positive pressure impulses and lower peak pressures during stance phase compared to the weight-bearing suction sockets, and greater negative pressure impulses during swing phase with the vacuum-assisted socket compared to the weight-bearing suction socket (Beil, Street, & Covey, 2002). The researchers concluded that the pressure levels created during stance and swing phase with the vacuum assisted socket reduced fluid fluctuation within the limb, resulting in users eliminating daily residual limb volume loss (Beil, Street, & Covey, 2002).

Board, Street, & Caspers, 2001, measured volume fluctuation and pistoning of transtibial patients in total surface 41 weight bearing suction sockets with and without vacuum. 10 participants' residual limb |volumes were measured prior to a 30 minute walk and immediately afterwards. Results of the measurements showed that using vacuum participants gained an average of 3.7 of residual limb volume compared to losing an average of 6.5 of residual limb volume (Board, Street, & Caspers, 2001). Additionally, Xrays showed that the limb pistoned 4mm less under vacuum, and the tibia pistoned 7mm less under vacuum (Board, Street, & Caspers, 2001). Their research concluded that maintaining residual limb volume and reducing pistoning using vacuum accounts for a more symmetrical gait then not using vacuum (Board, Street, & Caspers, 2001).

Ferraro, 2011, used a survey to evaluate different prosthetic suspension systems. Activity Balance Confidence scores were shown to be significantly higher with participants using vacuum suspension with a 95% confidence level compared to pin suspension (Ferraro, 2011). The survey also showed that skin issues such as blistering and skin breakdown decreased and walking time increased with the use of vacuum (Ferraro, 2011).

Research was conducted comparing the various commercially available prosthetic vacuum pumps including the Harmony e-Pulse, LimbLogic VS , Harmony P2, Harmony HD, and Harmony P3 (Komolafe, et al., 2013). The researcher's completed laboratory testing using fixed volume chambers sized, 12.54 in^3 (205 cm^3), 8.52 in^3 (140cm^3), 6.46 in^3 (106cm^3), 4.59 in^3

(75cm^3), and 2.69 in^3 (44cm^3). Data was collected showing the differences between the electrical and mechanical pumps, times to achieve 17 inHg (57.6 kPa) in each of the different fixed chambers, and battery life between the electrical pumps. This data can be used as comparative data to evaluate new systems.

In relation to assistive technologies, including prosthetics and orthotics, this report outlines when properly equipped to the participant and the participants' environment that assistive technologies are beneficial in promoting independence and participation (World Health Organization/ World Bank, 2011). A study was highlighted out of Uganda, a low-income country, that showed that assistive technology that aided in mobility increased community participation in education and employment (World Health Organization/ World Bank, 2011). The report also outlined the difficulty in obtaining accurate data.

Pupulin, (2001) lays out several issues that the developing world is facing including; prosthetic and orthotic services are usually only available in large cities, services tend to lean more towards prosthetic services even though there is a greater need for orthotic services, there are not enough prosthetic and orthotic professionals working in developing countries, category 1 professionals are need to train, educate and equip others, there are not enough orthotic and prosthetic schools to meet the demand for needed professionals, funds are limited for those who do wish to become an orthotic or prosthetic professional, and when if a local student is trained they cannot secure employment in their own country so they leave. Pupulin, (2001) suggests that awareness, collaboration, reinforcement of existing organizations that provide orthotic and prosthetic services, workshops that are located close to hospitals, and multi-disciplinary approach including surgeons, physiotherapists, and occupational therapists are important steps to brining recognition to the importance of orthotic and prosthetic services in developing countries.

The purpose of this study was to evaluate how a simple modified bicycle pump compares to commercially available options including two electrical elevated vacuum systems (Harmony e-Pulse [Ottobock; Duderstadt, Germany] and LimbLogic VS [Ohio WillowWood; Mt. Sterling, Ohio]) and three mechanical elevated vacuum pumps (Harmony P2, Harmony HD, and Harmony P3 [Ottobock; Duderstadt, Germany]). Data was collected to demonstrate how the modified bicycle pump compares to commercially available options by measuring the two dependent variables of time (sec) to evacuate air pressure level to 17 inHg (57 kPa) and maximum evacuation capabilities in inHg (kPa). The dependent variable is the modified bicycle pump. The cost of the modified bicycle was also calculated and compared to published research by Komolafe et al., (2013). This study will show if a modified bicycle can produce enough vacuum to provide adequate socket suspension, and how the evacuation time compares to commercially available elevated vacuum pumps currently used for socket suspension.

Methodology

Instruments

Five fixed volume chambers were fabricated (Fig.1) using 1" Schedule 40 PVC pipe. A volume of 6 in^3 (98.3 cm^3) was determined to be a standard displacement for a well fitting sub-ischial socket for an averaged size male (Komolafe et al. 2013). In a similar set up at as the Komolafe et al. study the chamber volumes are 12.54 in^3 (205 cm^3), 8.52 in^3 (140cm^3), 6.46 in^3 (106cm^3), 4.59 in^3 (75cm^3), and 2.69 in^3 (44cm^3).

[Insert Figure 1 About Here]

A vacuum pressure gauge (model PEM135, Winters Instruments; Toronto, Canada), (Appendix 1), was used to measure vacuum pressure on each chamber. The vacuum pressure gauge was attached to a 1" PVC threaded cap that screws on to the fixed volume chambers (Fig. 2.)

A commonly available Schrader bike valve (model S-684-4, Milton Industries; Chicago, IL), (Appendix 2) was also attached to a 1" PVC threaded cap that screws on to the fixed volume chambers (Fig. 2.)

[Insert Figure 2 About Here]

A simple and cheap bicycle hand pump (model Air Master 60- Psi Hand pump, Air Master; China) (Appendix 4), was chosen for modification.

A polypropylene check valve (model 1/4" Ball Cone Spring Check Valve, Grainger Industrial Supply; St. Paul, MN) (Appendix 3) was used in the modification.

Procedures

Modifications to the bicycle pump included reversing the washer and seal in the pump shaft, removing the existing check valve, and replacing it with a new one in the reversed direction.

[Insert Figure 3 About Here]

[Insert Figure 4 About Here]

First, the cap to the pump cylinder was removed to expose the seat and washer (Fig. 3). The washer and rubber seal were removed and reversed from the washer being on top of the rubber seal (Fig. 4) to the rubber seal being on top of the washer (Fig.5). Switching this allows the pump to drawl air on the upstroke, rather than push air on the down stroke.

[Insert Figure 5 About Here]

Second, the built in check valve that came with the pump was removed by unscrewing the hose and removing metal housing that contained it (Fig. 6).The rubber portion of the valve was removed and the internal part of the valve fitting was drilled out to allow more airflow (Fig. 7).

[Insert Figure 6 About Here]

[Insert Figure 7 About Here]

Third, the new check valve was attached to the pump using vinyl tubing (Fig. 8) and attached to the fixed chamber.

[Insert Figure 8 About Here]

Each fixed volume chamber was tested with the same vacuum pressure gauge, Schrader valve, and modified bicycle pump. Each chamber was tested five consecutive times.

Data Analysis and Calculations

This study was designed to compare a modified bicycle pump to commercially available vacuum options including the Harmony e-Pulse, LimbLogic VS, Harmony P2, Harmony HD, and Harmony P3. The basic methodology was replicated from Komolafe et al., 2013 study. Fixed volume chambers were fabricated at 12.54 in^3 (205 cm^3), 8.52 in^3 (140cm^3), 6.46 in^3 (106cm^3), 4.59 in^3 (75cm^3), and 2.69 in^3 (44cm^3). The modified bicycle pump was tested on how long (sec), and how many pumps were needed to reach a vacuum pressure of 17 inHg (57.6 kPa) similar to the Komolafe et al., 2013 study. Analysis of Variance (ANOVA) was used to determine differences in evacuation time (seconds) for the modified bicycle pump in comparison to the commercial pumps. The time to evacuate each fixed chamber with the modified bicycle pump was compared to the results published in the Komolafe et al., 2013 study.

Results and Discussion

The type of pump influenced the pattern of time it took to evacuate the chambers. Analysis of Variance (ANOVA) with a Greenhouse-Geisser correction revealed a statistically significant difference in evacuation time (seconds) for the modified bicycle pump in comparison to the commercial pumps. Table 1 demonstrates the raw data (mean ± SD) in seconds for evacuation time (sec.) and maximum vacuum level (Hg) relative to the modified bicycle pump. The mean average of the modified bicycle pump was 1.98 seconds with standard of 0.81 seconds.

[Insert Table 1 About Here]

The results are extremely significant at a .05 level of significance. The effective sizes are as follows: P3= 3.08, HD= 3.12, P2= 3.25, e-Pulse= 2.5, and Limb Logic= 2.34. The time to evacuate was significantly quicker with the modified bicycle pump compared to all of the commercial options. Across all the different fixed volume chambers, the modified bicycle pump was able to achieve 17 inHg (57.6 kPa) in less than 3.5 seconds, compared to a range of 5.1- 90 secs for all other pumps and chambers.

[Insert Table 2 About Here]

The maximum vacuum that the modified bicycle pump reached was 21.7 inHg (73.5 kPa). This result is comparable to commercially available options. The P2 and HD achieved higher vacuum at 26.41 inHg (89.4 kPa) and 26.1 inHg (88.4 kPa), respectively. The P3, Limb Logic, and e-Pulse achieved lesser vacuum levels then the modified bicycle pump at 20.05 inHg, 20.00 inHg (67.9 kPa), and 18.00 (61.0 kPa) inHg, respectively. The evacuation times of the modified bicycle pump are significantly significant at the .05 level and are clinically meaningful as the effect size is much greater than .8, which is considered large.

[Insert Table 3 About Here]

Raw data for the modified bicycle pump showing, evacuation times, number of pumps, and maximum achieved vacuum levels is shown below, as well as a graph showing the mean evacuation time averages including the confidence intervals.

[Insert Table 4 About Here]

[Insert Table 5 About Here]

An additional aim of the project was to provide a low cost elevated vacuum pump solution for low-income countries. Equipment was chosen that had lower price point, then other options in an attempt to keep the modified pump as cheap as possible. The breakdown of the prices are seen below:

Modified Bicycle Pump: (Hand Pump: $8.99 + Polypropylene check valve: $5.50) = $14.49

Commercial Options

Harmony P2: $2,276.00

Harmony P3: $2,115.00

Harmony HD: $2,239.00

e-Pulse: $1,685.00

Limb Logic: Price not publically available

The data collected from this study shows that the modified bicycle pump achieves 17 inHg (57.6 kPa) of vacuum significantly faster than all commercial options. Additionally, the maximum level achieved by the modified bicycle pump is on par with commercial options reaching functional socket suspension levels. Statistical tests cannot be on the mean maximum vacuum levels, because the standard deviations for the commercial pumps values are not available. The commercial pumps had a maximum vacuum range of 18 inHg (61.0 kPa) to 26.1 inHg (88.4 kPa), and the modified bicycle pump had a mean maximum vacuum of 21.7 inHg (73.5 kPa).

Conclusion

This study was initiated because to develop a low cost elevated vacuum solution that could potentially be used in low-income countries. Since bicycles and bicycle pumps are readily available all over the world for a relatively low cost it seemed like a worthwhile endeavor to see a modified bicycle pump could be a viable option. Reviewing the research on elevated vacuum the Komolafe et al., (2013) study proved to be a realistic approach to measuring and acquiring useful data. The primary question posed was to see if a modified bicycle pump could provide enough vacuum for socket suspension.

Results from the testing showed that an average vacuum level of about 21.7 inHg (73.5 kPa), (on par with commercial options) can be achieved regardless of amount of air that needs to be evacuated within a couple seconds. The cost of the modified bicycle pump was about $15.00. It should be noted that similar pumps were found online for a reduce price of $5.00, and other check valves were located for about $2.00 which would effectively cut the price in half. These options were not tested, although other brands should be a consideration.

It is difficult to compare this study to other studies because no human trials were conducted. A working prototype could be fabricated and fit to present as case study in the future. The only comparisons that can be made is the statistical analysis between the modified pump and commercial options outlined. Even this comparison is flawed for several reasons. Different materials, instrumentation, and equipment was used between this study and the Komolafe et al.,(2013) research, resulting in many uncontrolled differences and variables between the two.

There are limitations to this study and the functional application of using a modified bicycle pump. The timing for chamber evacuation is subject to human error. The exact time to reach 17inHg was calculated by a stopwatch and eyeballed. The number of pumps needed to reach the required vacuum level is also subject to human error especially the partial pumps. The accuracy of cutting the pipes to an exact length measurement is subject to human error, as well as the extra space caused by the fittings not threading all the way in, and the cavity in the space of the fittings themselves. This error is likely to increase the actual amount of volume in the chambers. The rate that the pump was used will vary according to who is pumping, and this variable will affect the statistical comparison analysis.

There are many other variables to consider as far as a functional application of this modified bicycle pump. It is unlikely that the exact same pump will be available throughout developing countries, and different pumps will be able to achieve different vacuum levels. Sealing the socket and the residual limb is usually accomplished by synthetic liners that are very costly and could be challenging to source and fund in developing countries. A cheaper method to seal the residual limb and socket would have to be accomplished to create a truly low cost elevated vacuum system.

The practicality of using a bicycle pump to achieve functional vacuum is not convenient. No one wants to carry around bicycle pump. Setting specific vacuum levels could be challenging for users to acquire. A smaller pump that was attached to the prosthesis would be more ideal. A few tests were trialed, using low cost materials, but vacuum levels did not exceed 12inHg using such a small pump. Further research in this area could be beneficial.

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Tables and Figures

Figure 1. Fixed chamber volumes: 12.54 in^3 (A), 8.52 in^3 (B), 6.46 in^3 (C), 4.56 in^3 (D), and 2.69 in^3 (E).

Figure 2. Vacuum Gauge and Schrader Valve attacked to PVC threaded caps.

Figure 3. Bicycle stem removed exposing washer and seal.

Figure 4. Configuration of washer and seal prior to modification.

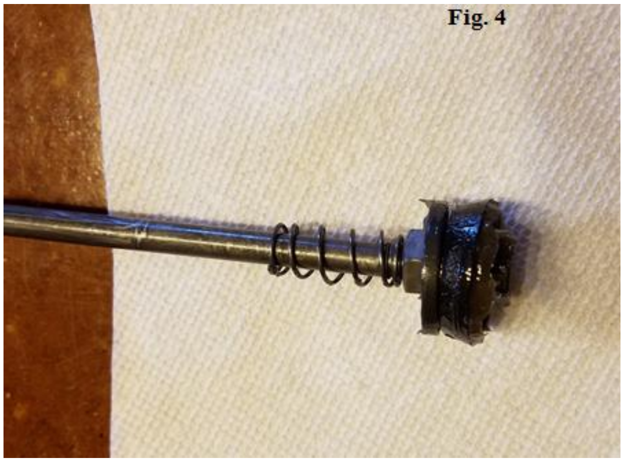


Figure 5. Orientation of seal and washer are reversed after modifications.

Figure 6. Location of built in check valve prior to modification.

Figure 7. Removal of built in check valve.

Figure 8. Modified bicycle pump with replaced check valve connected to a fixed volume chamber.

Table 1. Analysis of Variance (ANOVA) with a Greenhouse-Geisser correction revealed a statistically significant difference in evacuation time (seconds) for the modified bicycle pump in comparison to the commercial pumps.

Pump	Bicycle Pump	Harmony P3		Harmony HD		Harmony P2		e-Pulse		Limb Logic VS	
	M(SD)	M(SD)	ES	M(SD)	ES	M(SD)	ES	M(SD)	ES	M(SD)	ES
Evacutation Time (sec)	1.98 (0.81)	53.80 (23.75)	3.08	42.60 (18.41)	3.12	42.80 (17.74)	3.25	18.03 (9.13)	2.5	11.57 (5.75)	2.34
Maximum Vacuum (inHg)	21.7	20.05		26.1		26.41		18		20	
(kPa)	73.48	67.9		88.38		89.43		61		68	

Table 2. Bar Graph shows a comparison of each pump and how long it took to evacuate the different fixed chambers to 17 inHg (57.6 kPa).

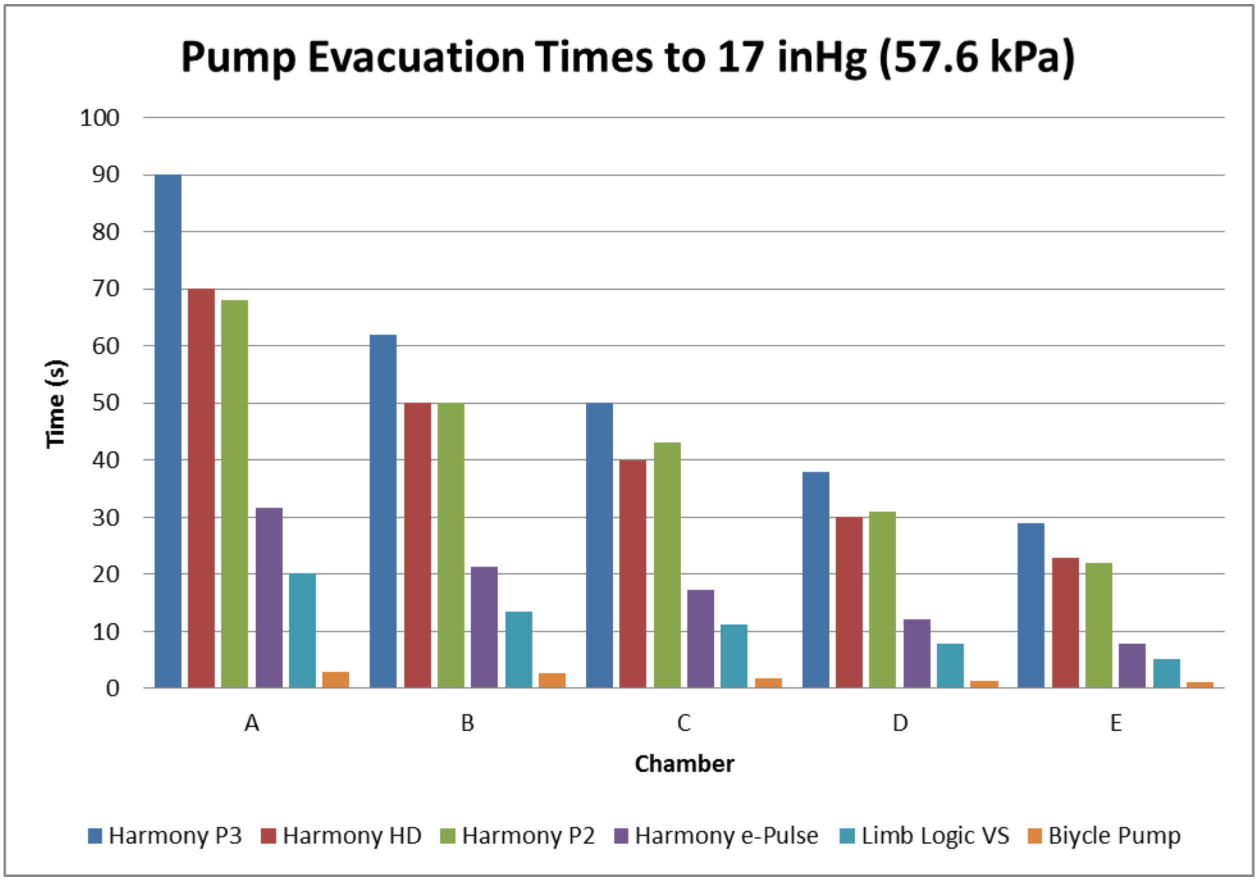


Table 3. Maximum vacuum levels.

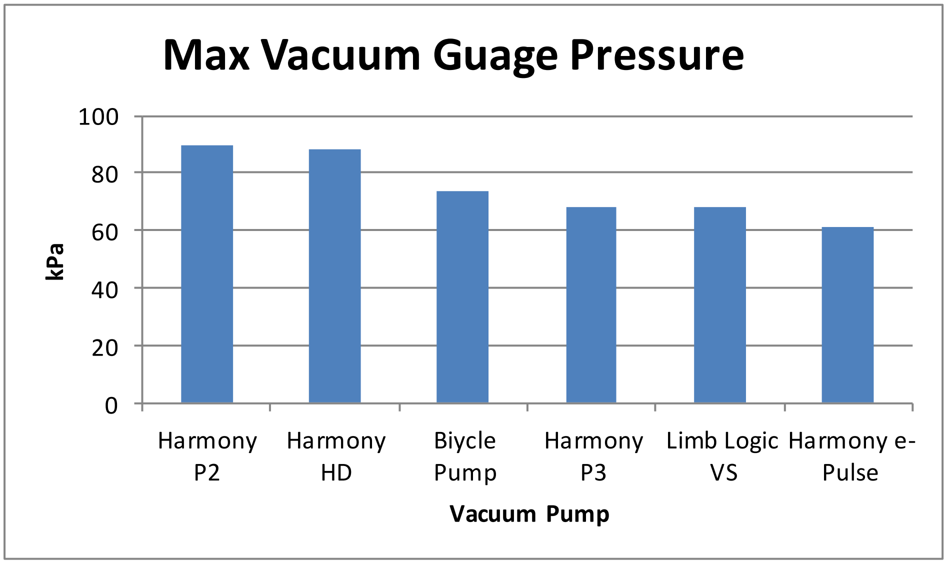
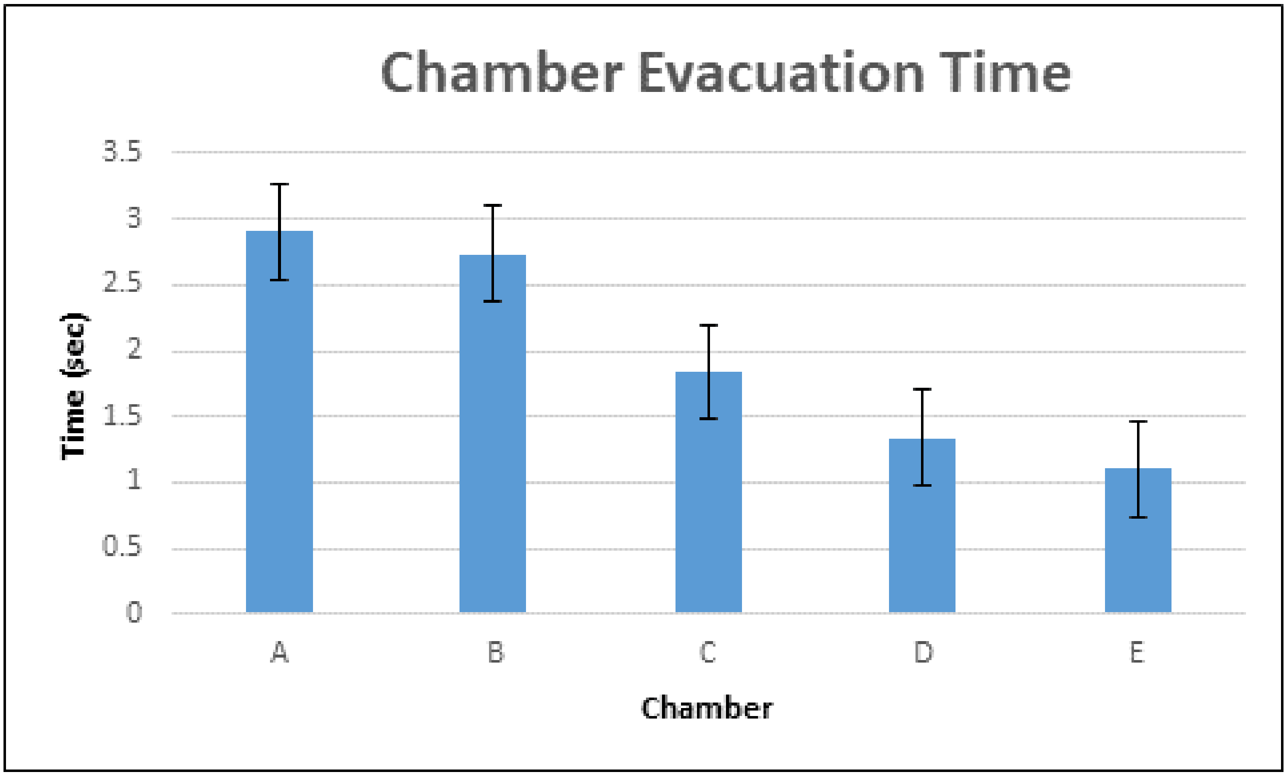


Table 4. Time to evacuate fixed volume chambers, and number of pumps required.

Chamber	A		B		C		D		E	
Trial #	Time (sec)	Number of Pumps	Time (sec)	Number of Pumps	Time (sec)	Number of Pumps	Time (sec)	Number of Pumps	Time (sec)	Number of Pumps
1	3.23	5	2.62	4	1.95	2.5	1.28	2	1.22	1.5
2	2.75	4.25	2.79	4	1.94	2.275	1.55	2	1.07	1.25
3	2.94	4	2.85	4	2.01	2.75	1.36	2	1	1
4	2.86	4.5	2.8	3.75	1.68	2.75	1.29	2	1.14	1.5
5	2.77	4.5	2.62	3	1.61	3	1.22	2	1.1	1.75
Average Time (sec)	2.91	4.45	2.736	3.75	1.838	2.655	1.34	2	1.106	1.4
Maximum Pressure inHG		21.5		21.5		21.5		22		22

Table 5. Mean averages for the modified bicycle pump with confidence intervals.



Appendix

1.Winters Instruments: Winters PEM Series Steel Dual Scale Economy Pressure Gauge, 30"Hg Vacuum/kpa, 2" Dial Display, +/-3-2-3% Accuracy, 1/4" NPT Bottom Mount (Toronto, Canada)

Part Number	PEM135
Maximum Measurement	0-30"Hg Vacuum/kpa
Measurement System	Inch and Metric
UPC	628311200416
Brand Name	Winters Instruments
EAN	0628311200416
Item Diameter	2 inches
Material	Steel
Measurement Accuracy	+/-3-2-3%
Model Number	PEM135
Number of Items	1
Range	0-30"Hg Vacuum/kpa
Resolution	N/A
Size	0-30"Hg Vacuum/kpa
Special Features	Brass
Style	Bottom Mount
UNSPSC Code	41112412

2. Milton Industries: Milton (S-684-4) 1/4" MNPT Male Tank Valve (Chicago, IL USA)

Part Number	S-684-4
Item Weight	1.6 ounces
Product Dimensions	2 x 1 x 1 inches
Item model number	S-684-4
Size	Pack of 2
Item Package Quantity	1
Number Of Pieces	1
Number of Handles	1
Measurement System	Inch
Batteries Included?	No
Batteries Required?	No
National Stock Number	4820-01-443-1916

3. Grainger Industrial Supply: 1/4" Ball Cone Spring Check Valve, Polypropylene, Barb Connection Type (St.Paul, MN USA)

Technical Specs

- Item Ball Cone Spring Check Valve
- Material of Construction Polypropylene
- Size 1/4"
- Connection Type Barb
- Length 2"
- Width 1/2"
- Overall Height 1/2"
- Cap to Inlet Center 3-18/32"
- Max. Water Pressure 125 psi
- Cracking Pressure 1 psi
- Max. Temp. 140 Degrees F
- Mounting Position Vertical or Horizontal
- Seat Material Polypropylene
- Spring Material Stainless Steel
- Seal Material Viton

4. Air Master: Air Master 60-Psi Hand Pump (China)

Red Enamel Tire Pump, 60 PSI, No Gauge, 1-1/4" Barrel, Removable Top For Easy Maintenance.

Specifications

- Product Weight (pounds): 1.27
- Package dimensions (inches)
- Length: 17.8
- Width: 7.5
- Height: 1.5

- 20 inch air hose

- Quick Release Stem Fitting

- For bicycles, sport balls & most beach inflatables