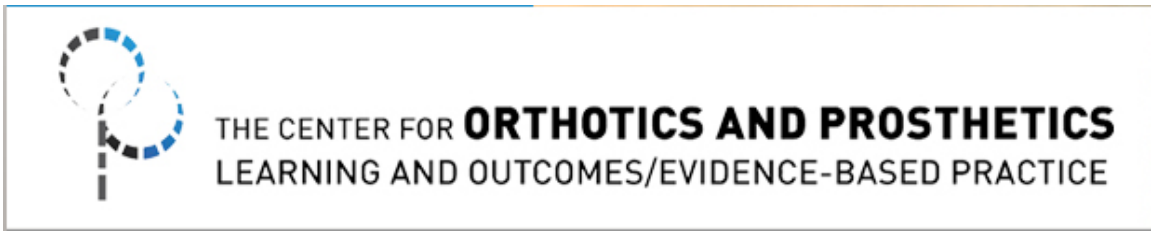

Comparison of Liner Assisted Suspensions in Transtibial Prosthetics

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Abstract

Volume loss of the residual limb when patients are active, compromises the fit of the prosthetic socket, requiring adjustment of the prosthesis throughout the day. This compromised fit can lead to increased pistoning of the socket, which causes pressure and shear stresses at the bony prominences resulting in wounds and limited activity. Vacuum suspension maintains residual limb volume, thus reducing pistoning. With multiple suspension options, practitioners need to be able to quantify patients' outcomes with various systems.

This study was designed to determine which outcome measures will give clinicians the best feedback on patient success or restriction with 4 types of liner assisted suspension systems. The protocol consisted of five 2-week phases, which required the subjects to alternate between their current prosthesis and a study prosthesis. Test conditions included locking pin, suction, elevated vacuum, and the dynamic vacuum liner system. At the end of each phase, the researchers conducted the following outcome measures: mEFAP, TAPES, PEQ, activity level, and knee ROM. 5 subjects enrolled and 2 subjects have completed the protocol to date. With varied prosthetic histories and current medical conditions, each subject presented unique results. Notable results were found with the TAPES, PEQ, activity level, and knee ROM.

Introduction

Persons with amputation experience volume loss of the residual limb when active, compromising fit of the prosthetic socket. This requires adjustment of the

prosthesis throughout the day and addition of interface, such as socks, to improve the fit. This compromised fit can lead to increased pistoning of the socket, and increased pressure and shear stresses at the bony prominences of the residuum (Highsmith 2007). These pressures and stresses may cause wounds and result in the person limiting or discontinuing activity. Research has investigated volume loss and wound healing with use of vacuum assisted suspension.

Street (2007) explains that volume loss is due to an elevated pressure in the socket which forces interstitial fluid out of the limb and back into the bloodstream and lymphatic vessels. Board (2001) and Goswami (2003) measured volume changes of the residual limb related to ambulation and compared the results of subjects using suction suspension vs. vacuum assisted suspension. Vacuum assisted sockets resulted in a net volume gain of 3.7% as opposed to the net volume loss of 6.5% experienced with the use of suction suspension. Beil (2002) found this volume gain to be related to interface pressures between the skin and liner. Persons with vacuum assisted sockets experience a 27% increase in negative pressure on the residual limb in swing and a 7% decrease in positive pressure in stance. This increases the draw of fluid into the residual limb and reduces the drive of the fluid out of the residual limb. The decrease in positive pressure may be attributed to the reduced pistoning experienced with the vacuum assisted socket.

The reduced pistoning of the residual limb in relation to the socket as well as the resulting decrease in positive pressures and decreased residual limb volume loss may promote increased activity. Beil also reports that subjects with a more conical

residual limb, the greatest amount of taper from the proximal to distal end, experienced the greatest negative pressure impulse values in swing phase. This was hypothesized to be due to vertical displacement of the liner in relation to the residual limb.

With little to no volume loss occurring in vacuum suspension, a better overall fit is achieved in the socket. This fit provides patients with increased proprioception and control over the prosthesis (Street 2007). It has also been shown that vacuum assisted suspension promotes wound healing. Patients who are affected by open wounds, folliculitis, or cysts on their residual limb are often required to spend time without wearing their prosthesis to allow for healing. Brunelli (2009) reports that patients with a transtibial amputation and previous wound healing failure of the residual limb had improved healing with use of a vacuum suspension system. The patients with the vacuum suspension also performed at higher locomotion capabilities than those with a patellar tendon bearing prosthesis.

While the research has presented benefits of vacuum suspension, there is little research that provides indications for this suspension over other types. As such, the objectives of this pilot study are to:

1. To identify trends and distinguish characteristics that may indicate or contraindicate people with unilateral transtibial amputations for specific liner assisted suspension systems.
2. To determine the most appropriate outcome measures for a larer study of the same design.

3. To calculate effect size estimates which can then be used to adequately power larger studies to ensure that practically relevant differences can be detected.

Patient based outcome measures quantify differences in groups due to differing interventions. Outcome measures can be surveys, questionnaires, interviews, and ambulation profiles. There are a number of outcome measures available that have been validated and may be appropriate for different populations of patients. Research has shown that there is a need for further studies using outcome measures to justify necessity of prosthetic suspension types for individual patients.

The pilot study focuses on objective and subjective outcomes to determine correlations to each subject's level of success with three different suspension types. There is a lack of empirical evidence in the literature to indicate or contraindicate persons with amputations for a specific suspension system. Therefore, the researchers used a number of outcome measures to begin collecting information which will more adequately support these clinical decisions.

Data included residual limb shape, tissue type, subject activity level (measured with a step activity monitor), knee range of motion, Modified Emory Functional Ambulation Profile (mEFAP), and subjective feedback of the Prosthetic Evaluation Questionnaire (PEQ) and Trinity Amputation and Prosthesis Experience Scales (TAPES) surveys. Researchers compared the subjects' original prosthetic suspension with suction and vacuum assisted suspension systems.

To date the mEFAP has only been conducted on persons with gait dysfunction due to stroke. It has been validated for inter-rater reliability, test-retest validity, and sensitivity to change. The mEFAP has not been used as a whole in prosthetic research, however, 4 of the 5 timed tasks are established outcome measures in prosthetics. The mEFAP can be used to evaluate patient progress with the use of a new suspension system over a variety of terrains (Wolf 1999, 2001).

Since the Prosthetic Evaluation Questionnaire (PEQ) was created in 1997, it has been used in several studies with regards to persons with lower limb amputations. Because it encompasses topics such as mobility, function, psychosocial experiences, and well being, all facets of having an amputation and using a prosthesis are examined (Legro 1998). A similar outcome measure, Trinity Amputation and Prosthesis Experience Scale (TAPES) explores the quality of life (QoL) with regards to having an amputation and using a prosthesis. This has also been used in previous studies and authors have concluded that although it also evaluates several categories of QoL, all subscales may not be applicable for all studies (Deans 2008). The subscales have not been validated individually, however this should be a focus in the future.

The TAPES and PEQ are validated instruments for measuring prosthetic satisfaction and prosthesis-related quality of life (Legro 1998, Gallagher and McLachlan 2000, 2004). We have decided to focus on the following subscales of the TAPES: athletic activity restriction, functional restriction, weight satisfaction, and functional

satisfaction. Of the PEQ subscales, we focused on the utility, residual limb, and frustration subscales.

Use of the StepWatch™ Activity Monitor has become more prevalent in research, and has offered insight to the rate of activity for individuals (Coleman 2004). Stepien (2007) reported on the reliability self-reported activity data versus the use of step activity monitors. The step activity monitors were able to measure steps per day and also steps per minute, allowing the authors to measure perceived activity intensity of the subjects. It was found that people with amputations did not accurately self-report their daily activity. Stepien concludes that the step activity monitor is a good objective measure of activity level and will assist in recommending the appropriate prosthesis for each patient.

Methods

Protocol

The study protocol is 10 weeks long, segmented into five 2 week phases. This multiple baseline study design requires subjects to alternate between their original prosthesis and two test conditions in an A-B-A-B-A design (Figure 1).

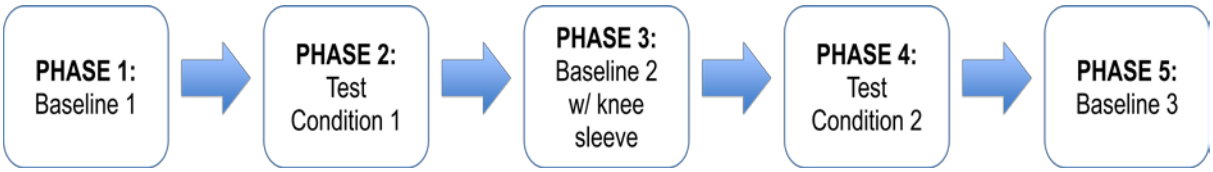

Figure 1. Study design

Subjects started out on their own prosthesis, then spent two weeks on a study prosthesis. They then switched back to their own prosthesis, with the addition of a

suspension sleeve, then switched to a study prosthesis with a different test condition, and finished out the protocol with two weeks of wearing their own prosthesis again.

The use of the suspension sleeve in all three test conditions may affect the results. Anecdotally, some patients have not accepted the suction or vacuum systems because the suspension sleeve limited their range of motion (ROM). In order to eliminate the possibility of this limited ROM causing variability in the results, subjects are to wear the sleeve with their own prosthesis in phase 3. The results of phase 3 can then be compared to phases 1 and 5 to determine the effects of the sleeve.

Each subject was initially evaluated and then returned at the end of each 2 week phase to perform certain outcome measure tests. Each subject wore a StepWatch™ Activity Monitor (SAM) [OrthoCare Innovations, LLC, Mountlake Terrace, WA] over the course of the entire study to obtain activity level data for each condition. This data was cross-referenced with an activity journal kept by each subject. The purpose of the activity level was to compare self-reported activity to that of the SAM.

Test conditions

The study involved three test conditions total, and each subject was randomly assigned to two of these three conditions. Testing all three conditions for each subject would have required more time than the study allowed. Table 1 shows the assignment of test conditions to each subject.

Table 1. Test condition assignments.

Subject	Test Condition A	Test Condition B
1	Vacuum	Suction
2	Vacuum	Dynamic Vacuum Liner
3	Suction	Dynamic Vacuum Liner
4	Suction	Vacuum
5	Suction	Dynamic Vacuum Liner

Test Condition 1: Vacuum assisted suspension. Test condition 1 is elevated vacuum with use of the LimbLogic™ Vacuum System (LLVS) [Ohio Willow Wood, Mount Sterling, OH]. Use of the LLVS required that patients wear an Alpha cushion liner and suspension sleeve.

Test Condition 2: Suction suspension. Test condition 2 used the same study prosthesis as test condition 1, but the LLVS pump remained off. This allowed for suction suspension to be achieved with use of the one way valve of the system. Subjects wore an Alpha cushion liner and suspension sleeve.

Test Condition 3: Dynamic vacuum liner (DVL). Test condition 3 consists of a custom silicone liner (Evolution Labs) and socket. The system creates vacuum through the custom silicone liner and unique fabrication of the distal end of the prosthetic socket (Fig 2). Once the patient dons the liner and bears weight into the socket, the distal end of the liner compresses and acts as a

diaphragm over the distal chamber. The liner pushes the air out of the socket through a one-way expulsion valve, causing negative air pressure in the socket that secures the socket to the limb and maintains total contact. Ambulation maintains this negative pressure as it flexes the diaphragm and continues to expel air (Jeff Hoerner, Biomotions LLC).

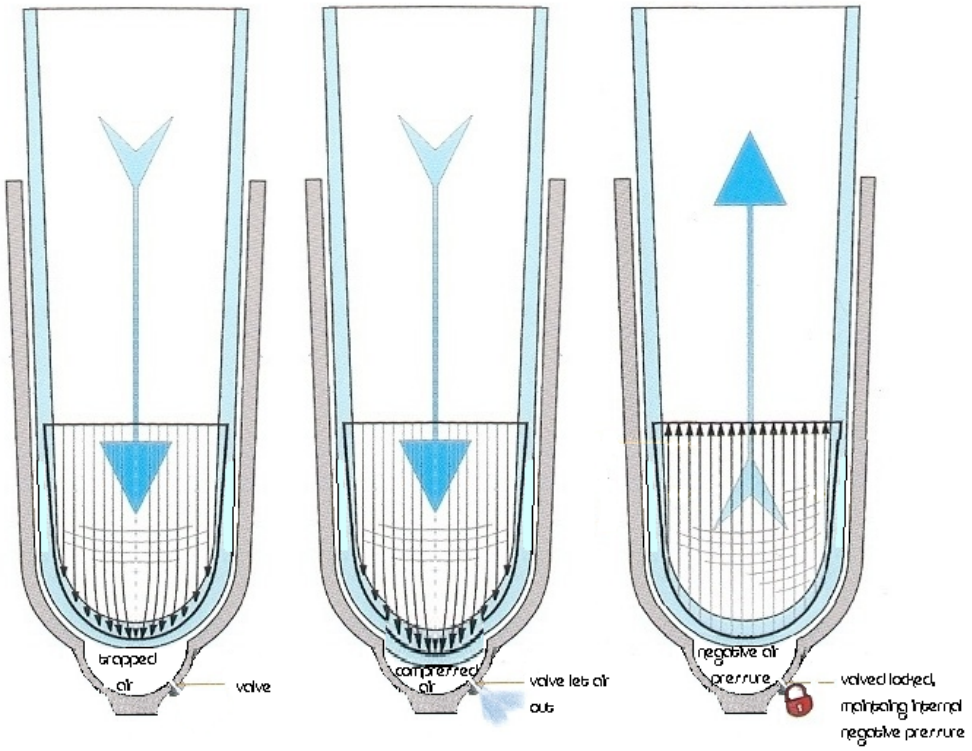

Figure 2. The DVL system.

Outcome Measures

At the end of each 2 week phase, outcome data was collected. Researchers used subsections of the Prosthetic Evalutation Questionnaire (PEQ) and Trinity Amputation and Prosthesis Experience Scales (TAPES) to gather subjective data. We

also conducted the Modified Emory Functional Ambulation Profile (mEFAP). And data from the SAM was downloaded at the end of each phase. The PEQ and TAPES were filled out with regards to the prosthesis and suspension worn for the previous two week phase.

Prosthesis Evaluation Questionnaire (PEQ). The PEQ is a survey filled out by the subject, to rate the subject's perceived quality of life and satisfaction level with the prosthesis. We have decided to focus on the following subscales: utility, residual limb health, and frustration.

Trinity Amputation and Prosthesis Experience Scales (TAPES). The TAPES is a survey completed by the subject, to rate the subject's perceived restrictions and satisfaction level with the prosthesis. We have decided to focus on the following subscales: Athletic Activity Restriction, Functional Restriction, Weight Satisfaction, and Functional Satisfaction.

Modified Emory Functional Ambulation Profile (mEFAP). This is an easily administered test used to measure time elapsed to traverse common environmental terrains. The mEFAP comprises 5 individually timed tasks performed over different environmental terrains. The researchers chose to focus on 4 of the 5 tests. The subtasks include:

1. Walking 5-meters on a hard surface (tile)
2. Walking 5-meters on a carpeted surface
3. Rising from a chair, walking 3 meters, and returning to a seated position (Timed Up and Go Test)

4. Ascending and descending 5 steps

StepWatch™ Activity Monitor (SAM). The SAM is a microprocessor-controlled step counter. The pager-sized device is attached to the ”ankle” of the prosthesis. This device is able to record steps/minute over the course of each two week phase.

Evaluation and Study Prosthesis Fabrication

The initial appointment included a pre-screen of the subject and an explanation of what involvement in the study would entail. We then obtained informed consent. Once informed consent was obtained, we began evaluation of the patient. We took the subject's medical and prosthetic history. The subject's body composition was measured with a Dual Energy X-ray Absorptiometry scanner (DEXA) [GE Medical Systems, Diegem, Belgium].

We then evaluated the residual limb, took measurements, and scanned the limb with the Ohio Willow Wood T-ring capture system. We applied the appropriate modifications for a total surface bearing socket design in TracerCAD. Ohio Willow Wood produced check sockets based on these scans. For the test condition 3, researchers took a plaster of Paris hand cast under vacuum. The cast was sent to Evolution Industries, Inc. for a custom silicone liner and check socket. For each appointment, there was a certified and licensed prosthetist available for proper fitting, dynamic alignment, and delivery of the prosthesis. The definitive sockets for test conditions 1 and 2 were fabricated and delivered on site. Jeff Hoerner of Biomotions, LLC, fabricated the DVL sockets for test condition 3.

Participants

Subjects were prescreened to verify that they met the inclusion criteria of the study. Subjects who met the criteria were people with unilateral transtibial amputations, ages 18 - 65, who weigh 300 lb (136 kg) or lower, who are at least one year post-amputation, who are classified at a K2-K4 activity level and who are currently ambulating in a prosthesis with either a locking pin or Seal-In suspension. Subjects were excluded if they had bilateral involvement, were at a K0 or K1 activity level, or used other suspension than a locking pin or Seal-In system in their current prosthesis.

We enrolled 5 subjects, who met the inclusion criteria, in the study. There were 3 females and 2 males. Subjects ranged in age from 43 to 61 years (mean 47.4 years). The subjects had had their amputations 2 to 31 years prior to the study (mean 9.4 years).

Two subjects have completed the protocol. One subject had to discontinue the study due to skin irritation issues. The remaining two subjects are both currently still completing the protocol.

Results

At this point, two of the five subjects have completed the study protocol. Subject three had to withdraw from the study due to skin sensitivity to the gel liner used with the study conditions. As such, we will only present the results of Subjects 1 and 2. It is important to have an understanding of the subjects' prosthetic history in order to make sense of the results.

Subject 1

Subject 1 is a 45 year old female. She had her leg amputated 6 years ago and her current prosthesis is the only prosthesis that she has had. As such, her socket is ill-fitting. No modifications have been made to the socket to accommodate for the shrinkage of her residual limb as it has matured. She wears about ___ ply socks each morning, adding socks throughout the day as she experiences volume loss of her residual limb. She is currently using a locking pin suspension system. Subject 1 has no insurance coverage and therefore has no access to a new prosthesis or components. She is a proficient K3 ambulator with her current prosthesis.

Subject 2

Subject 2 is a 38 year old male. He underwent amputation of his leg 31 years ago. His current prosthesis is 1 to 2 years old and he uses a locking pin system. Subject 2 also uses socks to accommodate for volume loss of his residual limb throughout the day. He has insurance and a good relationship with his prosthetist, so he receives prosthetic maintenance and adjustments as needed. Subject 2 is a K4 ambulator and has experience with various types of suspension and components.

Self-Reported Activity Log

Subjects were provided with an activity log to keep of the course of the 10 week protocol. Subjects were asked to record their daily activity and to note whether it was low, medium or high intensity. They were also to note if they experienced any pain or discomfort with the prosthesis or had any problem with the condition of their residual limb.

Subject 1 reported that she suffered from a pinched nerve in her back over the entire 10 week protocol. She also experienced nerve pain at the distal end of her residual limb, most severely when wearing her own prosthesis, as opposed to the study prosthesis. Subject 1 reported more activity when wearing the study prosthesis in phases 2 and 4.

Subject 2 plays racquetball regularly. He wore his own prosthesis while playing, but did not wear the study prostheses because of limitations of the componentry. Subject 2 also reported that he was not working during phase 5, which significantly decreased his daily activity during that phase.

mEFAP Results

The results of the mEFAP timed tests were not noteable. The subjects' times across the five phases varied by a maximum of 4 seconds, with no patterns emerging from the data across the 4 tests.

TAPES Results

The first two subscales of the TAPES that we looked at were athletic activity restriction and functional restriction. Subject 1 reported the greatest restriction in phases 1 and 5, which were her own prosthesis. Subject 2 reported the greatest restriction in phase 3 (his own prosthesis with a knee sleeve) and reported no restriction with his own prosthesis in phases 1 and 5.

We also collected data from the weight satisfaction and functional satisfaction subscales. Subject 1 reported greatest satisfaction in phases 2 and 4 with the study

prosthesis. Subject 2 reported greatest satisfaction in phases 1 and 5 with his own prosthesis.

PEQ Results

We used the Utility, Frustration, and Residual Limb Health subscales from the PEQ. Subject 1 reported the greatest outcomes in phases 2 and 4 for all subscales. Subject 2 reported the greatest utility in phases 4 and 5. He reported the lowest frustration in phases 1 and 5, and the greatest residual limb health in phases 2, 4, and 5.

SAM Results

From the data output by the SAM, we focused on average steps/day and the Peak Activity Index. Subject 1 had highest the activity levels in phases 2 and 4, while subject 2 had the highest activity levels in phases 1 and 3.

Knee ROM

We also measured subjects' maximum knee flexion with each study condition. Full extension of the knee was measured as 0° and according to Neumann (2002), normal knee ROM is from 5° of hyperextension to 140° of flexion. Subjects 1 and 2 had the greatest maximum knee flexion in their own prostheses (phases 1 and 5) without a knee sleeve.

Discussion

The subjects' individual situations and varied prosthetic histories have affected the results and have limited our ability to make comparisons. With only two subjects completed, we were unable to perform statistical analyses, but there are patterns

across outcome measures. Once four subjects have completed the protocol, we hope to perform a power analysis to determine effect size estimates for a larger study.

Subject 1

Correlations can be found in the outcome measures across the phases (Figure 3). The PEQ, TAPES, and SAM activity level results follow the same pattern. The subject presented with high results and therefore, better outcomes in phases 2 and 4 with the study prosthesis. However, the subject's maximum knee flexion is inversely correlated to the other outcomes. This was unexpected, but supports the assumption that the socket fit was the most influential variable for this subject. The subject's perception of satisfaction and restriction with the prosthesis was most affected by the more intimate total contact fit of the study prosthesis vs. the 20 ply fit of her current prosthesis.

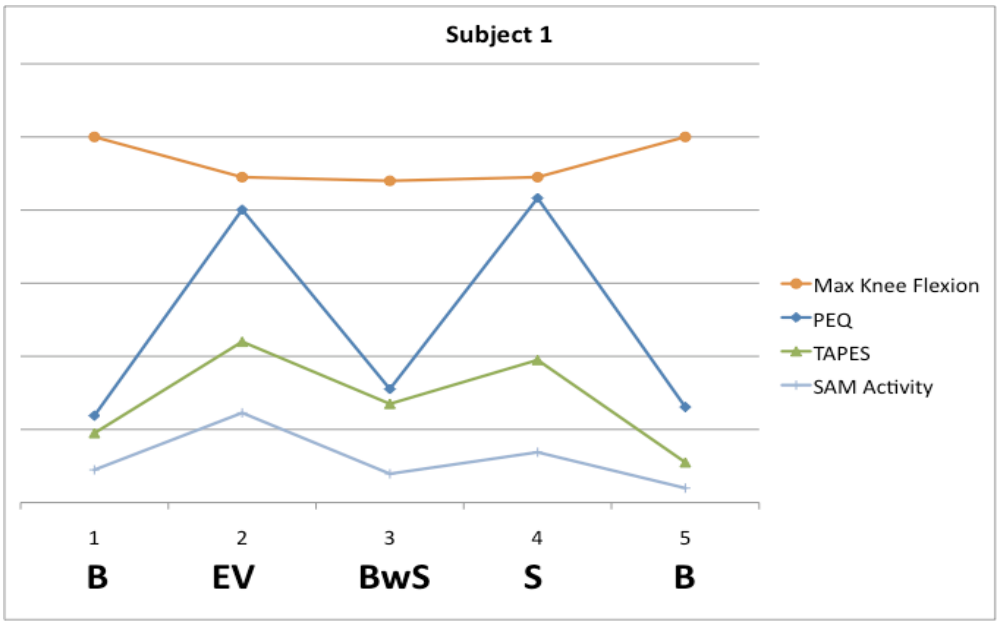

Figure 3. Outcome measure results for Subject 1.

Subject 2

The researchers also found patterns in the data for Subject 2 (Figure 4). For purposes of the discussion, the researchers decided to exclude the data from phase 5. As the subject was not working during this phase, his results were notably affected. Hypothetically the results of phases 1 and 5 should be identical as they were both the baseline condition. The subject's activity level and maximum knee flexion were highest in phases 1 and 3 with the subject's own prosthesis. However, the subject reported the highest results for residual limb health in phases 2 and 4 with the vacuum study conditions. This is supported by the literature (Brunelli, 2009).

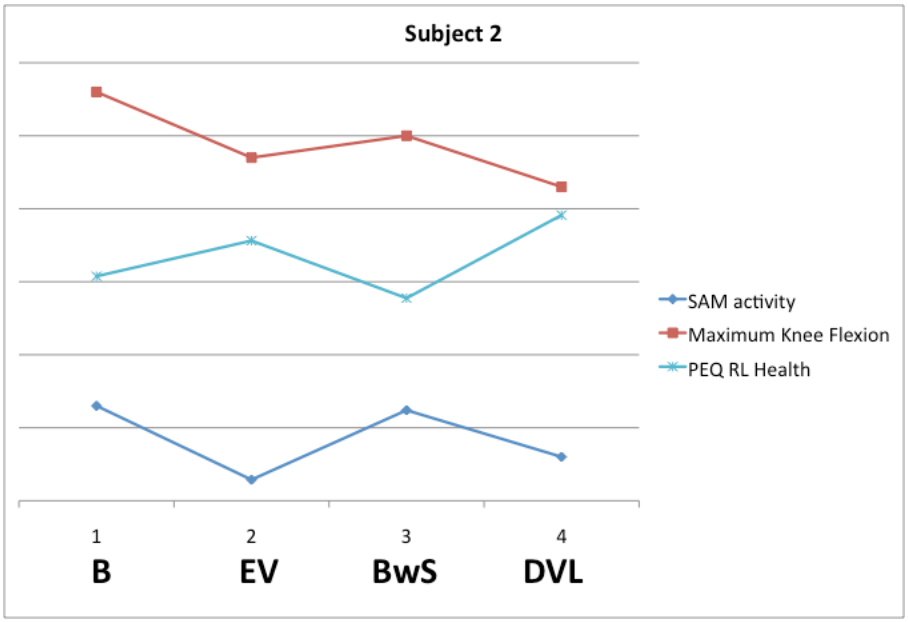

Figure 4. SAM activity, maximum knee flexion, and RL health results for Subject 2.

The results of the PEQ and TAPES present the lowest outcomes in phase 3 (Figure 5). This condition is the subject's baseline with a knee sleeve. The researchers believe that this is because the subject was most used to being active and performing his ADL's with his own prosthesis. The requirement of wearing a knee sleeve limited his knee range of motion and affected the subject's perception of satisfaction and restriction with the prosthesis.

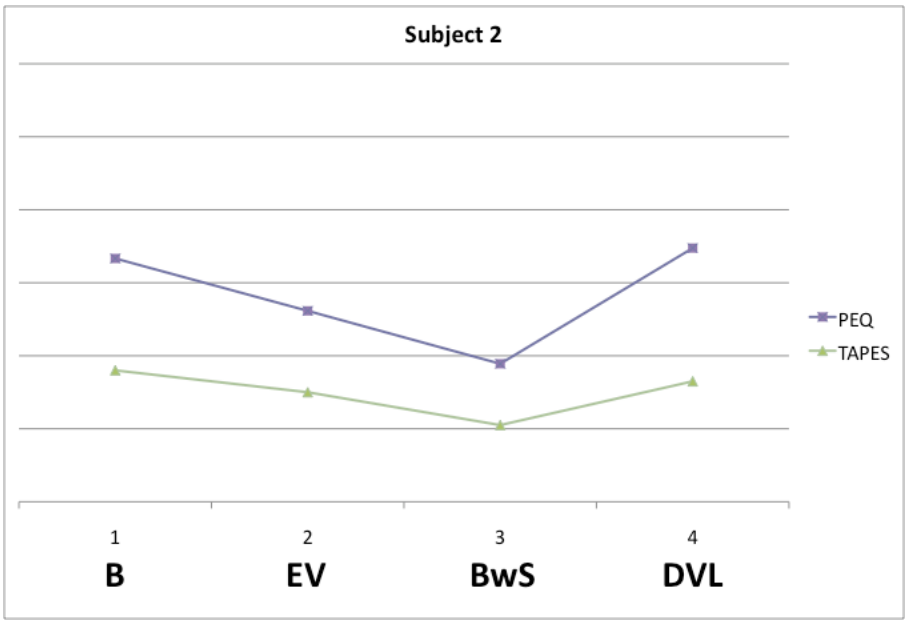

Figure 5. PEQ and TAPES results for Subject 2.

Outcome Measures

The researchers found that not all outcome measures provided meaningful results for the study design.

mEFAP

The mEFAP, while designed for patients with stroke, has been used as individual timed tests in prosthetics research. We found a ceiling effect with our subjects as

they were experienced walkers. The results varied by a maximum of 4 seconds for any given timed test, and showed no pattern across phases for either subject. As such, we don't recommend this outcome measure for a study of the same design.

PEQ/TAPES

The PEQ and TAPES were used in many studies in the literature. Significant results were not found with all subscales, and we also found varied results with the individual subscales. We found that not all the subscales were applicable to our study design. As such, we recommend using specific subscales in a larger study of the same design.

Activity Level

The StepWatch™ Activity Monitor was an objective and reliable measure of he subjects' activity. This is supported by the literature. The self-reported activity log, while valuable in understanding the subjects' health and residual limb issues, was not a reliable measure of activity level. The subjects were not diligent in keeping the log or recording the intensity of activity each day.

Clinical Relevance

The researchers recognize that all persons with amputations are not candidates for vacuum suspension systems. Practitioners must keep in mind the patients' shape and composition of their residual limb, skin sensitivity, activity level, knee range of motion, hand dexterity, and cognitive ability. The researchers found this evident as Subject 3 had to withdraw from the study due to skin irritation related to the gel

liners and both Subjects 2 and 3 were restricted in their daily activities by the knee sleeve limiting their achievable maximum knee range of motion.

The use of functional outcome measures has just recently become more common. Not only are they useful for research purposes, but many of them are simple enough to be used in the clinical setting. They offer quantifiable justification for new technology in the prosthetic industry, which is necessary for insurance approval. In addition, outcome measures can be used to monitor patient progress and to obtain feedback in a subjective manner.

Based on the results of this study, the researchers recommend the mEFAP for early prosthetic wearers and patients undergoing rehabilitation. It is not appropriate for experienced prosthetic patients. The PEQ and TAPES offer valuable results as patients progress in wearing their prosthesis or try out different components or suspension systems. And the StepWatch™ Activity Monitor provides objective and reliable feedback on patient activity levels. Knee range of motion is also an important variable to keep in mind. Limitations in knee range of motion due to the prosthesis can greatly affect the patient's perception of the prosthesis as it affects their daily activities. These outcome measures offer greater insight to the lifestyle and priorities to the individual that will aid in determining the most appropriate style of prosthesis.

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Appendix I

IRB Approved Consent Form

Appendix II

TAPES/PEQ Patient Questionnaire

Section I: Base your responses on the prosthetic suspension system that you have worn for the past 2 weeks.

1. The following questions are about activities you might do during a typical day. Does this prosthesis limit you in these activities? If so, how much? *Please tick the appropriate box.*

	Yes, limited a lot	Limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports			
b. Climbing several flights of stairs			
c. Running for a bus			
d. Sport and recreation			
e. Climbing one flight of stairs			
f. Walking more than a mile			
g. Walking half a mile			
h. Walking 100 yards			

2. *Please tick the box* that represents the extent to which you are satisfied or dissatisfied with *each* of the different aspects of your prosthesis mentioned below:

	Very Dissatisfied	Dissatisfied	Neither Dissatisfied nor Satisfied	Satisfied	Very Satisfied
Weight					
Usefulness					
Reliability					
Fit					
Comfort					
Overall Satisfaction					

3. Do you experience residual limb pain (pain in the remaining part of your amputated limb)?

_____ Yes _____ No (If you answered No, **go to Section 2**)

4. With this prosthetic suspension system, how many times a week have you experienced residual limb pain?

_____/week

5. How long, on average, did each episode of pain last?_____

6. Please indicate the average level of residual limb pain experienced with this prosthetic suspension system on the scale below by ticking the appropriate box.

☐ Excruciating ☐ Horrible ☐ Distressing ☐ Discomforting ☐ Mild

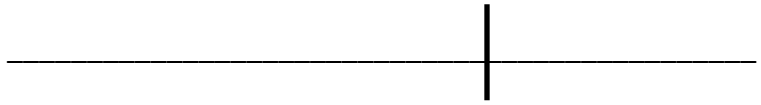
7. How much did residual limb pain interfere with your normal lifestyle (e.g. work, social and family activities) with this prosthetic suspension system?

☐ A lot ☐ Quite a bit ☐ Moderately ☐ A little bit ☐ Not at all

---

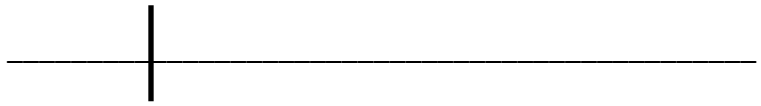
Section II: As you read each question, remember that there is no right or wrong answer. Just think of YOUR OWN OPINION on the topic and make a mark THROUGH the line anywhere along the line from one end to the other to show us your opinion.

EXAMPLE: How important is it to you to have coffee in the morning?



NOT AT ALL EXTREMELY IMPORTANT

Over the past two weeks, rate your morning coffee.



TERRIBLE EXCELLENT

OR check ____ I haven't drunk coffee in the past two weeks.

This example shows that the person who answered these questions feels that having coffee in the morning is important to him. He also thinks the coffee he has had lately has not been very good.

If he hadn't had any coffee in the past two weeks, he would have put a check by that statement instead of putting a mark on the line between TERRIBLE and EXCELLENT.

As in the example above, make a single mark across the line rather than using an X or an O. Please answer all questions.

1. **Over the past two weeks, rate your comfort while standing *when using your prosthesis.***

_____

TERRIBLE EXCELLENT

2. **Over the past two weeks, rate your comfort while sitting *when using your prosthesis.***

_____

TERRIBLE EXCELLENT

3. **Over the past two weeks, rate how often you felt off balance *while using your prosthesis.***

_____

ALL THE TIME NOT AT ALL

4. **Over the past two weeks, rate how much energy it took to use your prosthesis for as long as you need it.**

_____

COMPLETELY EXHAUSTING NONE AT ALL

5. **Over the past two weeks, rate the feel (such as temperature and texture) of the prosthesis (sock, liner, socket) on your residual limb (stump).**

_____

WORST POSSIBLE BEST POSSIBLE

6. **Over the past two weeks, rate the ease of putting on (donning) your prosthesis.**

_____

TERRIBLE EXCELLENT

7. **Over the past two weeks, rate how much you sweat inside your prosthesis (in the sock, liner, socket).**

_____

EXTREME AMOUNT NOT AT ALL

8. **Over the past two weeks, rate how smelly your prosthesis was at its worst.**

_____

EXTREMELY SMELLY NOT AT ALL

9. **Over the past two weeks, rate how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis.**

_____

ALL THE TIME NEVER

10. **Over the past two weeks, rate any rashes that you got on your residual limb.**

_____

EXTREMELY BOTHERSOME NOT AT ALL

OR check ___ I had no rashes on my residual limb in the last 2 weeks.

11. **Over the past two weeks, rate any ingrown hairs (pimples) that were on your residual limb.**

_____

EXTREMELY BOTHERSOME NOT AT ALL

OR check ___ I had no ingrown hairs on my residual limb in the last 2 weeks.

12. **Over the past two weeks, rate any blisters or sores that you got on your residual limb.**

_____

EXTREMELY BOTHERSOME NOT AT ALL

OR check ___ I had no blisters or sores on my residual limb in the last 2 weeks.

13. **Over the past two weeks, rate how frequently you were frustrated with your prosthesis.**

_____

ALL THE TIME NEVER

14. **If you were frustrated with your prosthesis at any time over the past 2 weeks, think of the most frustrating event and rate how you felt at that time.**

_____

EXTREMELY BOTHERSOME NOT AT ALL

OR check ___ I have not been frustrated with my prosthesis.