Comparison of Liner Assisted Suspensions in Transtibial Prosthetics: A Pilot Study

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Amputation and Volume loss

- Persons with amputation experience volume loss
  - Increased pistoning of limb inside the socket
    - Pistoning is vertical displacement
  - Increased pressure and shear stresses at the bony prominences
  - Pressure and shear
    - Wounds
    - Pain
    - Infection
    - Re-amputation
    - Decreased activity

(Highsmith 2007)
Importance?

• How do we accommodate for volume loss?
  ○ Socks
  ○ Socket modification
  ○ Suspension system

• How do we know what is appropriate?
Outcome Measures

- Quantify the difference between groups due to differing interventions
  - Quantitative and qualitative
  - Surveys, questionnaires, timed tests
  - Justification for device types
  - Helps formulate prosthetic prescription recommendations
Test Conditions

- **Elevated Vacuum:**
  LimbLogic® VS
  Pump turned ON
  - Maintains a specified level of vacuum; can be changed

- **Suction:**
  LimbLogic® VS
  Pump turned OFF
  - One way expulsion valve
Test Conditions

- **Dynamic Vacuum Liner (DVL)**
  - Elevated vacuum
What is Vacuum?

- Vacuum suspension
  - Created in 1999 (Board 2001)
  - Removes air molecules from inside of the socket
  - Negative pressure
    - Holds the socket on the limb
    - Increases contact of liner to socket walls (Street 2007)
Donning the Socket
Forms of Vacuum

- **Suction**
  - Air is expelled during weight bearing through one way expulsion valve
Forms of Elevated Vacuum

- LimbLogic® VS

- DVL

LimbLogic® VS from Ohio Willow Wood®

Dynamic Vacuum Liner (DVL)
Dynamic Vacuum Liner

• The DVL consists of custom silicone liner and socket

• Vacuum created through the custom silicone liner and unique fabrication of the distal end of the socket
How do pressures affect the limb?

- **Positive pressure pushes fluid up out of the RL**
  - Causes a decrease in RL volume

- **Negative pressure draws fluid into the RL**
  - Keeps RL volume stable
Research on Vacuum Suspension

- Elevated vacuum suspension
  - Promotes wound healing
  - Decreased volume loss
  - Decreased RL volume loss
  - Decreased positive pressures

= may promote increased activity

(Brunelli 2009, Beil 2007)
Research of Vacuum Systems

- **Comparison of RL volume in two vacuum systems**
  - Suction: *Decreased* 6.5%
  - Elevated Vacuum: *Increased* 3.7%

- **Pressure Changes**
  - Vacuum sockets
    - 27% *Increased* negative pressure during swing
    - 7% *Decreased* positive pressure during stance

(Board 2001, Goswami 2003, Beil 2002)
Outcome Measures

Trinity Amputation and Prosthesis Experience Scales (TAPES)

- Measures perceived restriction and satisfaction levels
- Subscales:
  - Athletic Activity Restriction
  - Functional Restriction
  - Weight Satisfaction
  - Functional Satisfaction

- Can be used to measure quality of life in rehab and give insight into nature of disability
- Only some of the subscales were applicable to study

(Gallagher 2004, Deans 2008)
Outcome Measures

Prosthesis Evaluation Questionnaire (PEQ)

- Measures perceived quality of life and satisfaction level
- Subscales:
  - Utility
  - Residual limb health
  - Frustration
- Validated survey; used in several studies
Outcome Measures

StepWatch™ Activity Monitor (SAM)

- Microprocessor-controlled step counter
- Outcomes:
  - Average steps/day
  - Peak activity index

- Found to be more accurate than self-reported activity

(Coleman 2004, Stepien 2007)
Outcome Measures

Modified Emory Functional Ambulation Profile (mEFAP)

- 4 timed tasks
  - Walking 5-meters on a hard surface
  - Walking 5-meters on a carpeted surface
  - Timed Up and Go Test (TUGT)
  - Ascending and descending 5 steps

- Measures time elapsed to traverse common environmental terrains
  - Only been conducted on persons with stroke
  - With or without the use of an assistive device
Aims

- To identify trends and distinguish characteristics that may indicate or contraindicate people with unilateral transtibial amputations for specific liner assisted suspension systems

- To determine the most appropriate outcome measures for future study

- To calculate effect size estimates which can be used to adequately power larger studies
Methods

• Protocol
  ○ 5 two week phases
  ○ Multiple baseline study design
  ○ Subjects randomly assigned to 2 of 3 test conditions
  ○ Outcome measures:
    ▸ mEFAP
    ▸ TAPES/PEQ
    ▸ SAM
    ▸ Self-reported activity log
    ▸ Knee ROM
Phases

Baseline → Test Condition 1 → Baseline w/ Knee Sleeve → Test Condition 2 → Baseline
Methods

• Initial Appointments
  o Informed consent
  o Clinical and prosthetic history taken
  o Casted/Scanned for test condition socket
  o Fabricated custom test condition socket
  o Fittings and dynamic alignments with licensed and certified prosthetist
Subject recruitment

- **Inclusion Criteria**
  - Unilateral, transtibial amputation
  - Seal-in or locking liner suspension
  - At least 1 year post amputation
  - < 300lbs.
  - IRB approval
# Subjects

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Average

- Age – 47.4 yrs
- Time Since Amputation – 9.4 yrs

*Completed Protocol

**Subject discontinued study
Subject withdrew from study
Test Conditions

- **Elevated Vacuum:**
  LimbLogic® VS
  Pump turned ON

- **Suction:**
  LimbLogic® VS
  Pump turned OFF

- **Dynamic Vacuum Liner (DVL)**
Subject 1

• 45 yo female
• 6 yrs since amputation
• Current prosthesis 6 yrs old
• Poor socket fit
• Locking pin system

• No insurance coverage
  ○ Limited access to prosthetic componentry and supplies
• Experienced wearer
Subject 2

- 38 yo male
- 31 yrs since amputation
- Current prosthesis 1-2 years old
- Locking pin system

- Has insurance and good relationship with prosthietist
  - Regular prosthetic maintenance and adjustments
  - Experience with several types of suspension
- Very experienced wearer and can accommodate to different components and alignment
Self-Reported Activity Log

• Subject 1
  o Pinched nerve in back
  o Nerve pain at distal end of RL
  o More active with study prosthesis

• Subject 2
  o Plays racquetball
    ✷ Didn’t wear study prosthesis
  o Didn’t work during phase 5
## Phase Designations

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<td>EV Elevated Vacuum</td>
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mEFAP Results

Subject 1

Subject 2

Bar charts showing time in seconds for different conditions.

Conditions:
- 5m Tile Floor
- 5m Carpet
- 3m TUGT
- 5 Steps

Time (s)
TAPES Restriction Subscales Results
TAPES Satisfaction Subscales

Results

Subject 1

Subject 2
PEQ Subscale Results

Subject 1

Subject 2
Activity Results
(Average Steps/Day)

Subject 1

Subject 2
Peak Activity Index

Subject 1

Subject 2
Knee ROM

- ROM
  - Full extension = 0°
  - > angle = > knee flexion
  - Normal Knee ROM
    - -5° - 140° (Neumann)
Maximum Knee Flexion

Subject 1

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Discussion

- Different subject profiles
- No statistical significance
- Patterns in the data across outcome measures
Discussion

• Relation to the literature
  ○ “... since all patients had a troublesome prosthetic history, the results cannot be generalized to any extent.” (Van de Weg 2005)

• Power Analysis
Outcome Measures

- **mEFAP**
  - Designed for people with stroke
  - Individual tests used in prosthetics
  - Ceiling effect

- **PEQ & TAPES**
  - Used in literature
  - Significance not found with all subscales
  - Not all subscales are applicable

- **SAM**
  - Good indicator of activity level
  - Self-reported activity lacking
Clinical Relevance

• Vacuum suspension may not be appropriate for all patients
  o Shape and composition of limb
  o Skin sensitivity
  o Activity level
  o Knee ROM
  o Cognitive ability
  o Hand dexterity

• Subject 3 had to withdraw
Clinical Relevance

- Outcome measures can be performed in clinic
  - mEFAP
    - Early prosthetic wearer
  - PEQ/TAPES
    - Valuable results
  - SAM/Self-Report
    - SAM: objective & reliable
  - Knee ROM
    - Specific to pt. activity level
Limitations

- Subject situations
  - Health
  - Activity level
  - Age of px.
  - Fit of px.
- Componentry available to researchers
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- Ohio Willow Wood®


References