RESEARCH OUTCOMES

Clinical Essentials for Vacuum Prostheses

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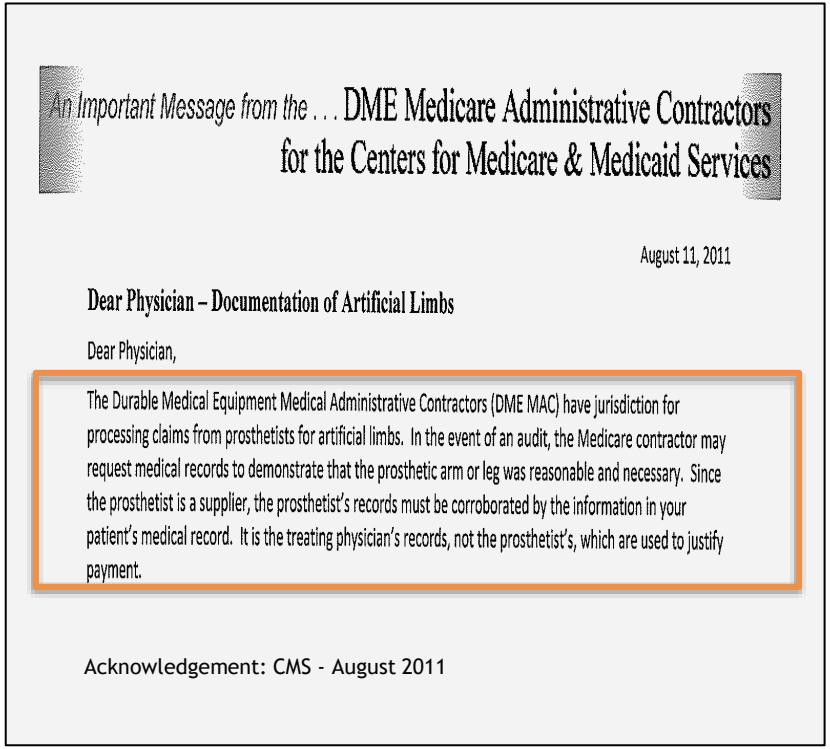
IMPORTANCE OF A PROPERLY FITTING SOCKET

- 98% of respondents (N=92) identified prosthesis fit as their primary concern (Legro ’99)
- Reports of high levels of dissatisfaction with prosthesis comfort (Pezzin ’04 and Klute ’09)
- Two surveys indicated a high prevalence of skin sores or irritation occurring within the socket, with fit likely being a contributing factor (Meulenbelt ’09 and Hagberg ’01)

MEDICARE GUIDELINES

- Medical notes
  - Complementary to referral source notes
  - Accommodates Allied Health Professional assessment(s)
- States the objective of your prosthetic decision
  - Treatment plan
- Details the physical assessment
  - Successful outcome measures
  - Mobility scores



An Important Message from the . . . DME Medicare Administrative Contractors for the Centers for Medicare & Medicaid Services

August 11, 2011

Dear Physician – Documentation of Artificial Limbs

Dear Physician,

The Durable Medical Equipment Medical Administrative Contractors (DME MAC) have jurisdiction for processing claims from prosthetists for artificial limbs. In the event of an audit, the Medicare contractor may request medical records to demonstrate that the prosthetic arm or leg was reasonable and necessary. Since the prosthetist is a supplier, the prosthetist's records must be corroborated by the information in your patient's medical record. It is the treating physician's records, not the prosthetist's, which are used to justify payment.

Acknowledgement: CMS - August 2011

Acknowledgement: Vega Healthcare Consultancy January 2014

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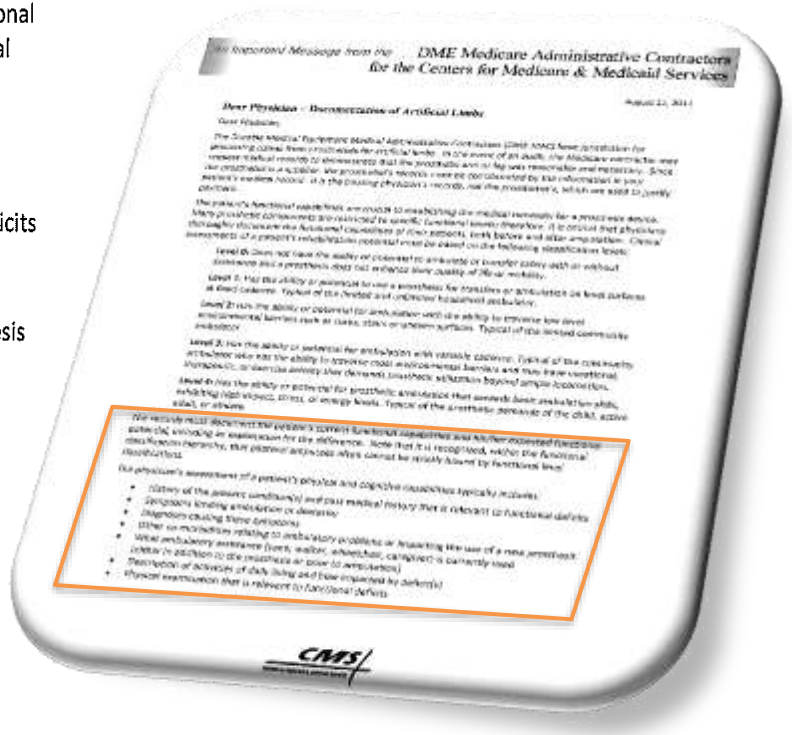
MEDICARE GUIDELINES

The records must document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference. Note that it is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications.

The physician's assessment of a patient's physical and cognitive capabilities typically includes:

- History of the present condition(s) and past medical history that is relevant to functional deficits
- Symptoms limiting ambulation or dexterity
- Diagnoses causing these symptoms
- Other co-morbidities relating to ambulatory problems or impacting the use of a new prosthesis
- What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used (either in addition to the prosthesis or prior to amputation)
- Description of activities of daily living and how impacted by deficit(s)
- Physical examination that is relevant to functional deficits



CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Acknowledgement: CMS - August 2011

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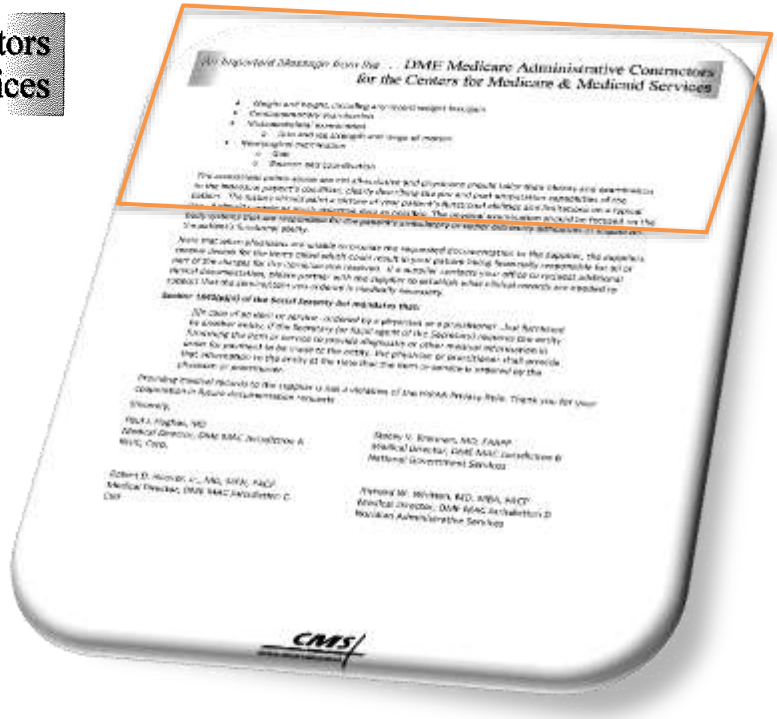
MEDICARE GUIDELINES

An Important Message from the . . . **DME Medicare Administrative Contractors for the Centers for Medicare & Medicaid Services**

- Weight and height, including any recent weight loss/gain
- Cardiopulmonary examination
- Musculoskeletal examination
  - Arm and leg strength and range of motion
- Neurological examination
  - Gait
  - Balance and coordination

The assessment points above are not all-inclusive and physicians should tailor their history and examination to the individual patient's condition, clearly describing the pre and post-amputation capabilities of the patient. The history should paint a picture of your patient's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the patient's ambulatory or upper extremity difficulties or impact on the patient's functional ability.

Note that when physicians are unable to provide the requested documentation to the supplier, the suppliers receive denials for the items billed which could result in your patient being financially responsible for all or part of the charges for the items/service received. If a supplier contacts your office to request additional clinical documentation, please partner with the supplier to establish what clinical records are needed to support that the service/item you ordered is medically necessary.



Acknowledgement: CMS - August 2011

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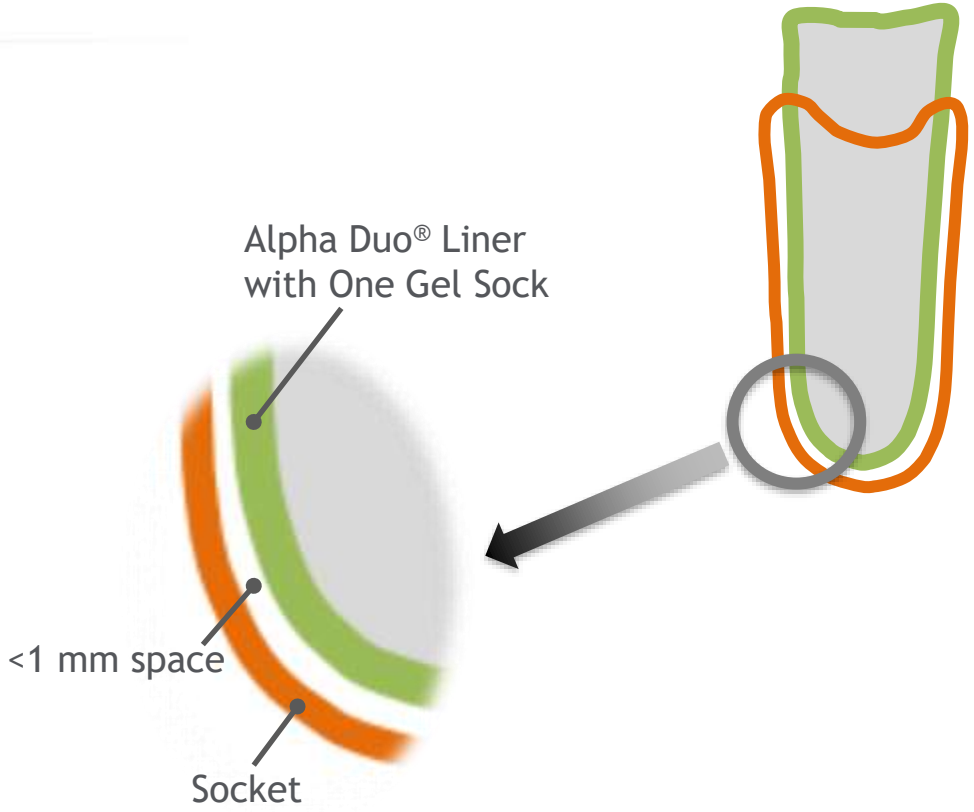
SUCTION/VACUUM

- Air is extracted from the space between the external liner surface and the inner socket wall
- The wicking sock helps the vacuum pressure to build
- Liner movement is initiated by this air removal



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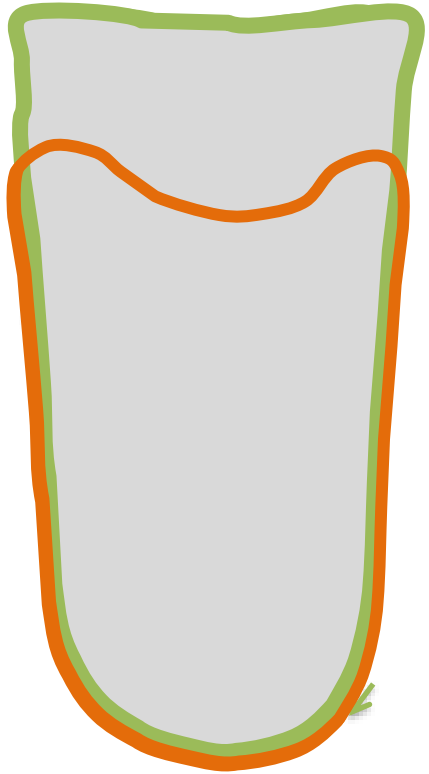
PHASE 1 EFFECT

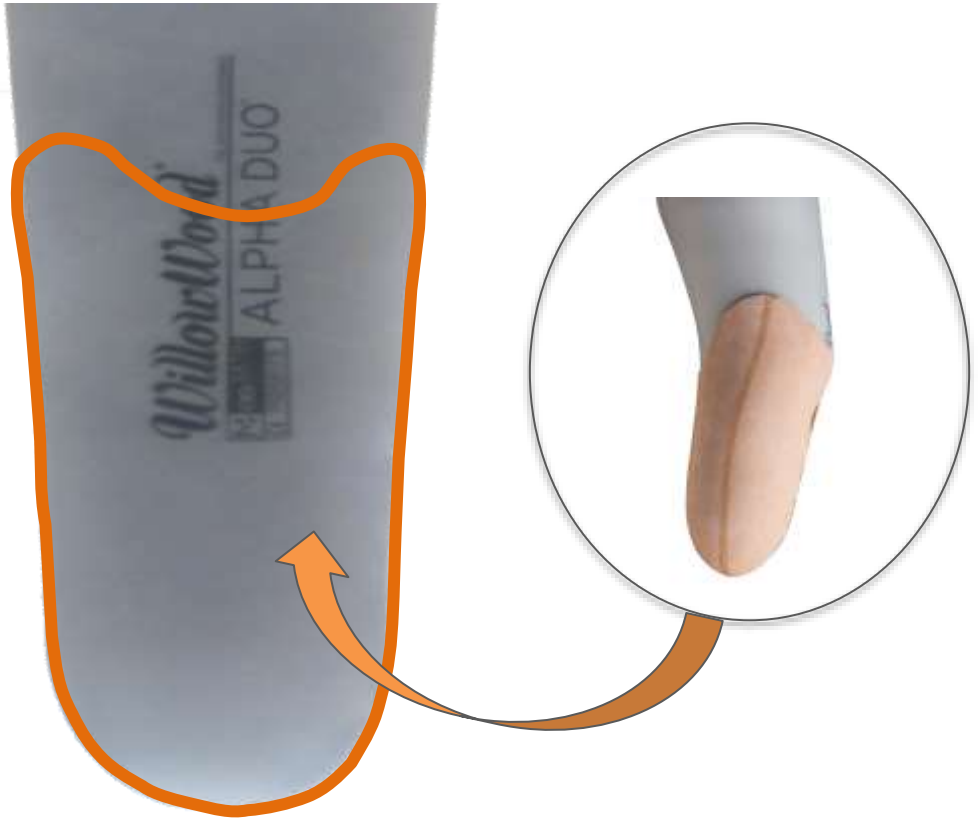
- Under these conditions, the liner is drawn to meet the internal wall of the socket
- This small movement (<1 mm) provides the *element* of suspension
- Adequate vacuum levels keep the status quo



- Reference journal articles and research data

AS VACUUM FORMS

- A *secondary element* is completed when the liner meets the socket wall
- The draw here is on the residual limb tissue surface
- The liner characteristics will determine the amount of draw



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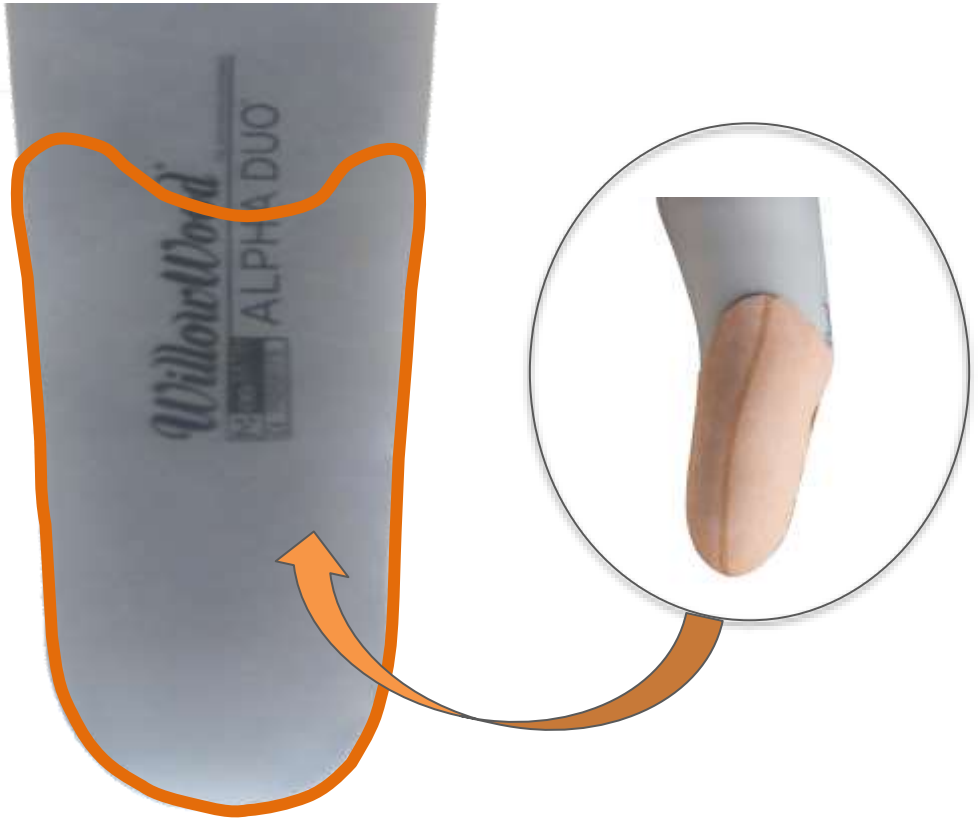
PHASE 2 EFFECT

- This movement is a direct result of the coefficient of friction between the internal liner surface and the skin tissue
- The flexible properties of the liner material effectively provide this secondary motion
- If vacuum pressure is not high enough, contact on the tissues is insufficient, or the socket is too large, then a disconnect is possible and the vacuum benefits are lost



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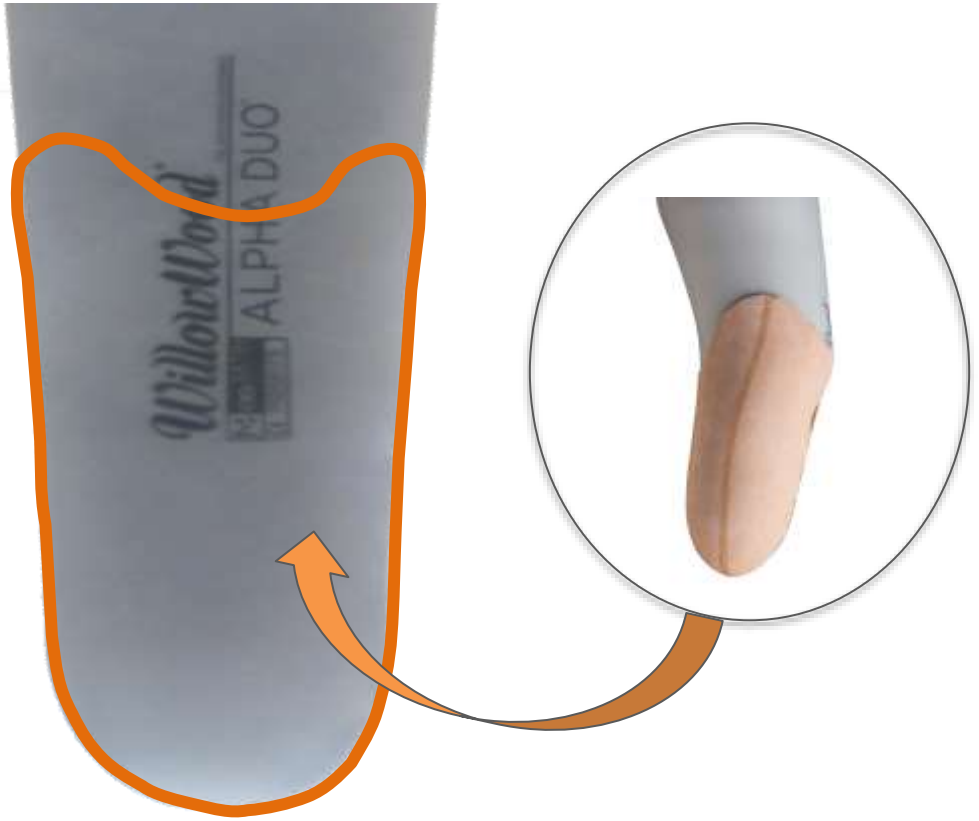
PHASE 2 EFFECT

- The secondary effect is responsible for the physiological well being of the residual limb
- These include:
  - Tissue health
    - Wound healing
    - Preventative tissue breakdown
    - Moisture loss
  - Residual limb stability



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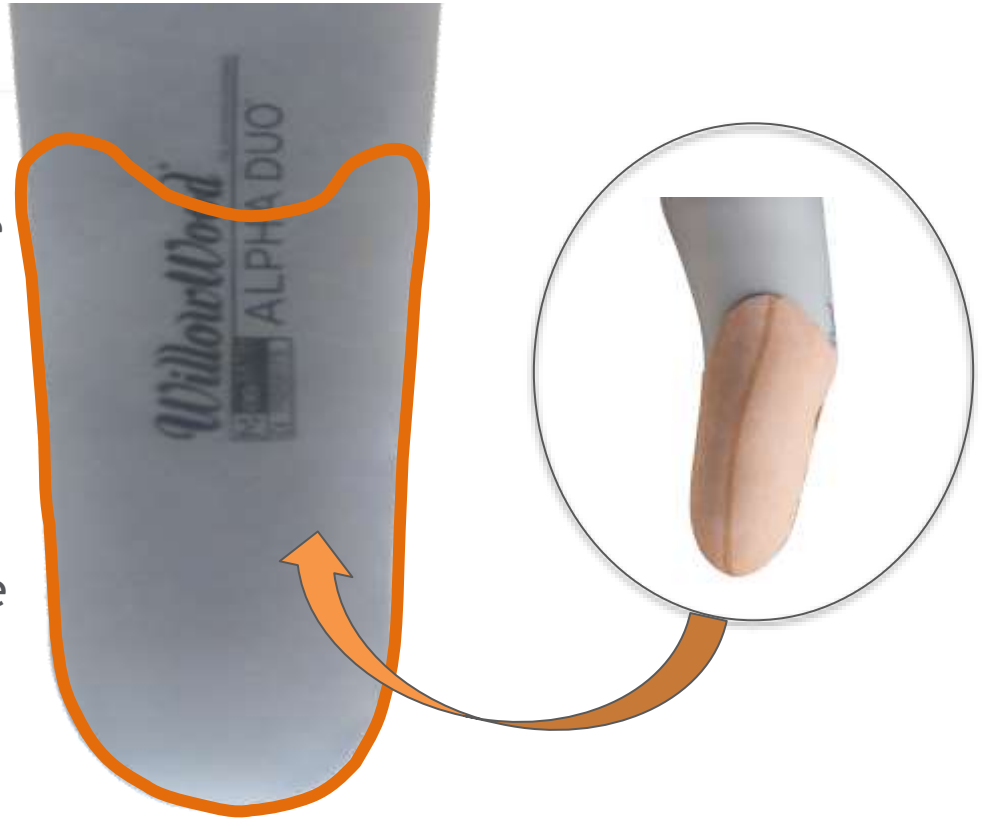
TOTAL EFFECT

- Primary elements (suspension and positive contact within the socket) and secondary elements (limb tissue health and volume stability) provide the positive outcomes that a vacuum socket design provides
- Maintaining the integrity of the vacuum protocols for fitting, delivery, and post delivery are important for successful long-term outcomes



CPO ...

- Elevated vacuum is a prosthetic system linking:
  - Patient
  - Socket
  - Suspension
- Together these factors provide for advanced:
  - Proprioception
  - Gait
  - Prosthesis control

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CPO ...

- There are specific requirements to pay attention to, and a defined process to follow
- It works within much smaller parameters than traditional socket designs and systems
- To be successful, attention to detail is necessary
- Vacuum systems should be carefully prescribed and recorded for future referral and outcome measurements

ELEVATED VACUUM SUSPENSION

Physiological Changes to Limb Health

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PUBLICATION

JRRD Volume 53, Number 6, 2016
Pages ???–???

Elevated vacuum suspension preserves residual-limb skin health in people with lower-limb amputation: Randomized clinical trial

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Abstract—A growing number of clinical trials and case reports support qualitative claims that use of an elevated vacuum suspension (EVS) prosthesis improves residual-limb health on the basis of self-reported questionnaires, clinical outcomes scales, and wound closure studies. Here, we report first efforts to quantitatively assess residual-limb circulation in response to EVS. Residual-limb skin health and perfusion of people with lower-limb amputation ($N = 10$) were assessed during a randomized crossover study comparing EVS with

Key words: amputation, elevated socket suspension, perfusion, prosthesis, residual limb, socket, suspension, transfemoral, transtibial, vacuum.

INTRODUCTION

Shear stress, compression, and moisture exposure associated with prosthesis use cause soft tissue injury to

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EXISTING SUPPORTING LITERATURE

- Our hypothesis is that elevated vacuum allows the beneficial physiological changes as a result of providing a more stable environment
  - Less pistoning (Board 2001, Darter 2016, Gershutz 2010 and 2015)
  - Better volume control (Board 2001, Goswami 2003, Sanders 2011)
  - Reduced contact pressure

JUSTIFICATION

Referencing research journal articles & current outcome studies relating to:

- Optimized prosthetic vacuum system pressures
- Vacuum pressure effects on:
  - Limb tissue
  - Limb volume
  - Socket fit
- Potential outcome measures for patient benefits
- Suction vs. vacuum

And using that information to educate

- Referral sources
- Payer sources

Acknowledgement: Vega Healthcare Consultancy January 2014

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EXISTING SUPPORTING LITERATURE

Author, Year	Subjects	Intervention	Outcome Measured	Findings
Board, 2001	10 - 11 transtibial amputees (outcome dependent)	Socket suspension	Limb volume change, pistoning, gait symmetry	The limb gained or retained volume in an EVS socket, lost volume in suction socket. Pistoning was 4-7 mm less and gait more symmetrical when using the EVS socket.
Beil, 2002	9 transtibial amputees	Socket suspension	Interface Pressures	EVS reduces pressure impulse and peak positive pressures during stance phase, while the impulse, average, and peak negative pressures are increased during swing phase.
Darter, 2015	10 Transtibial amputees	Socket suspension (elevated vacuum vs suction)	Digital video fluoroscopy	Elevated vacuum suspension reduced axial limb-socket motion. Most of this reduction occurred through the reduction of displacement during initial loading 0%-20% body weight.
Goswami, 2003	7 transtibial amputees	Socket volume	Limb volume changes	The residual limb retained or gained volume in excess of the available socket volume without discomfort, pain, or skin reddening.
Traballesi, 2009	Case study	Socket suspension	Wound Healing, prosthesis use, pain	EVS allowed prosthesis fitting and pain-free walking despite open wound with large surface area.

EXISTING SUPPORTING LITERATURE

Author, Year	Subjects	Intervention	Outcome Measured	Findings
Gershutz, 2010	Benchtop tests, 5 transtibial amputees	Negative pressure	Accuracy of function, pressure distribution	The accurary of the Communicator is ±0.5 inHg and the negative pressure is distributed evenly in the socket.
Ferraro, 2011	≤13 amputee subjects (outcome dependent)	Socket suspension	Questionnaire responses	EVS reduced reported pistoning, blisters, falls, and volume change. EVS significantly increased mean ABC score and walking time.
Klute, 2011	5 transtibial amputees	Socket suspension	Pistoning, activity level, limb volume change	EVS reduced pistoning. Activity levels were higher with the pin locking. No differences were found for limb volume. Subjective scores favored the pin system.
Traballesi, 2012	20 dysvascular transtibial amputees	Socket suspension	Prosthesis usage, self-reported responses	EVS facilitated earlier use of a prosthesis and increased activity levels without pain or impact on wound healing.
Kahle, 2013	10 transfemoral amputees	Socket design	Hip kinematics, femur position, contact pressure, preference	The two socket designs were equivalent across outcomes except users favored the brimless design for comfort.

EXISTING SUPPORTING LITERATURE

Author, Year	Subjects	Intervention	Outcome Measured	Findings
Hoskins, 2013	6 transtibial amputees	Socket suspension	Wound healing	All subjects continued to use their prosthesis while the wound healed.
Kahle, 2014	10 transfemoral amputees	Socket design	Kinematics, self-reported responses	The two socket designs were equivalent across most outcomes. PEQ responses found significant improvements with brimless design.
Samitier, 2014	16 transtibial amputees	Socket suspension	Functional outcome measures	EVS significantly improved in balance, gait, and transfers.
Gershutz, 2015	5 transfemoral amputees	Socket suspension	Pistoning	EVS reduced pistoning compared to suction. Vacuum pressure setting can control pistoning.

HOW DOES THIS DATA HELP WITH VACUUM SYSTEMS?

- Increased prosthetic clinical expertise when assessing the amputee and deciding the most appropriate prosthesis to suit their lifestyle
- Improved definition and recording of information that relates to medical necessity and the fitting and delivery of the end product
- Using research information from experiences past, together with new scientific data, in order to expand that prosthetic knowledge for the benefit of the amputee
- Embracing technology as it moves forward to have greater access to more appropriate prostheses that enable the end user to achieve their expectation(s)

CLINICAL APPROACHES

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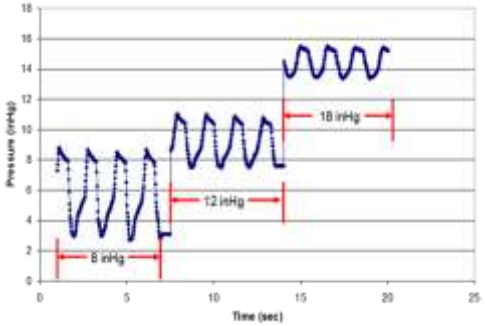
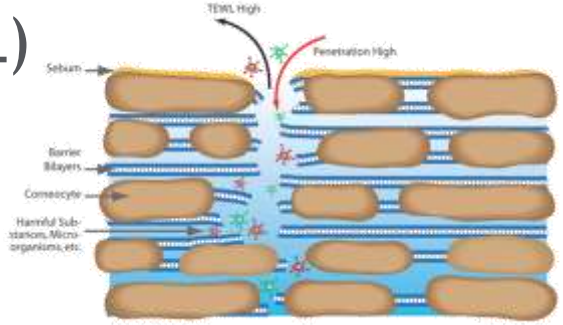
MEASUREMENTS

- Residual limb stability
- Socket fit
- Tissue health
- Limb motion
- Trans Epidermal Water Loss (TEWL)
- Vacuum levels and settings





Acknowledgement: Vega Healthcare Consultancy January 2014

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TISSUE WATER LOSS

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IMPORTANCE OF PROPER SOCKET FIT

- A properly fitting vacuum socket has been shown to enable wound healing

Benefits of a well-fit vacuum socket

Complication of a poorly-fit vacuum socket

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MECHANICAL MECHANISMS LEADING TO ULCER DEVELOPMENT

- Local Ischemia Injury
  - Applied pressure -> restriction of blood flow
- Ischemia/Reperfusion Injury
  - Perfusion restored after injury (REACTIVE HYPEREMIA)
  - Reactive oxygen species in excess
    - Damage endothelium
    - Stimulate tissue necrosis
- Impaired Lymphatic Drainage
  - Pressure collapses lymphatics
  - Obstruct lymph flow
    - Accumulation of waste products
    - Collapse vessel
- Mechanical Trauma

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OBJECTIVE AND APPROACH

- Objective: Quantitatively assess changes to residual limb skin health and circulation in response to elevated vacuum suspension using a non-invasive approach

Out-of-Socket Skin Health and Circulation Imaging

In-Socket Probe Measurement

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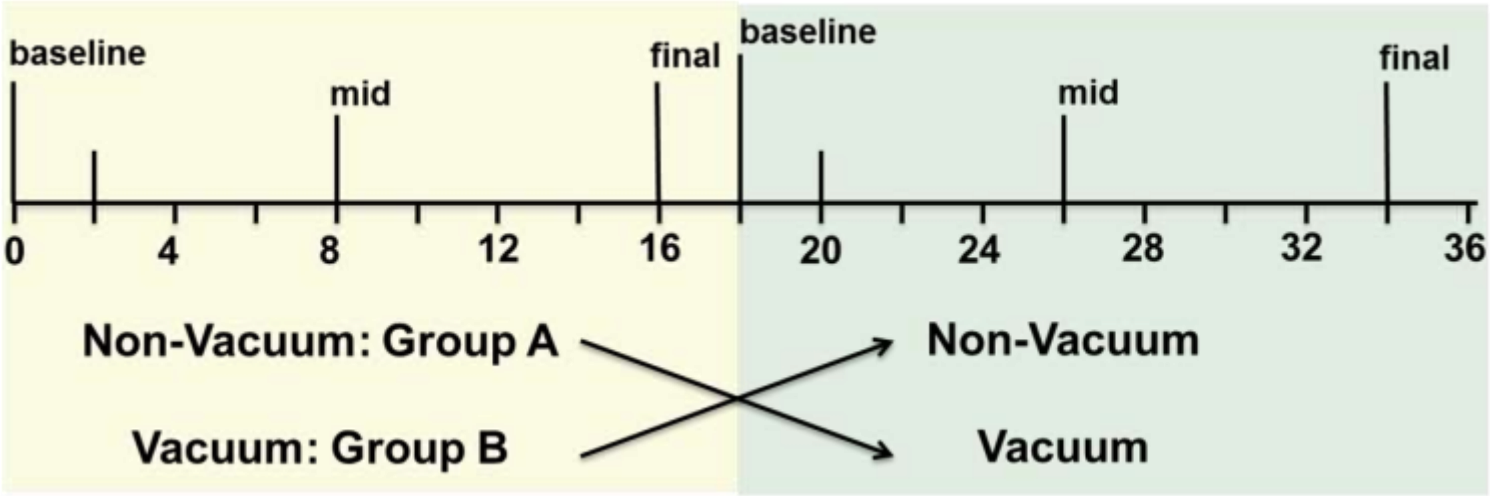
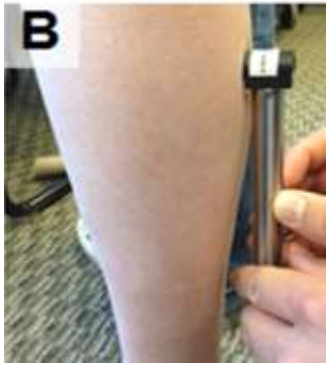
STUDY DESIGN

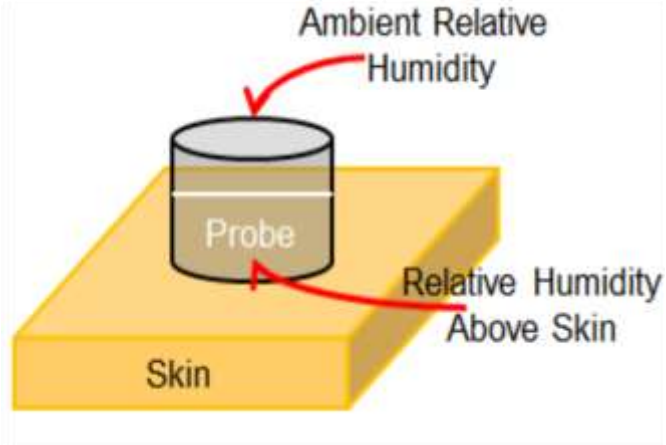


- 10 amputees participated in the RCT with 16-week treatments
- Data collected before, during, and after an activity period
  - Static Poses ⇒ Treadmill Walk ⇒ Static Poses

SKIN HEALTH MEASUREMENTS

- Measures water loss through the epidermis
  - High values indicate **disruption** to skin barrier function
  - Low values indicate **promotion** of skin barrier function





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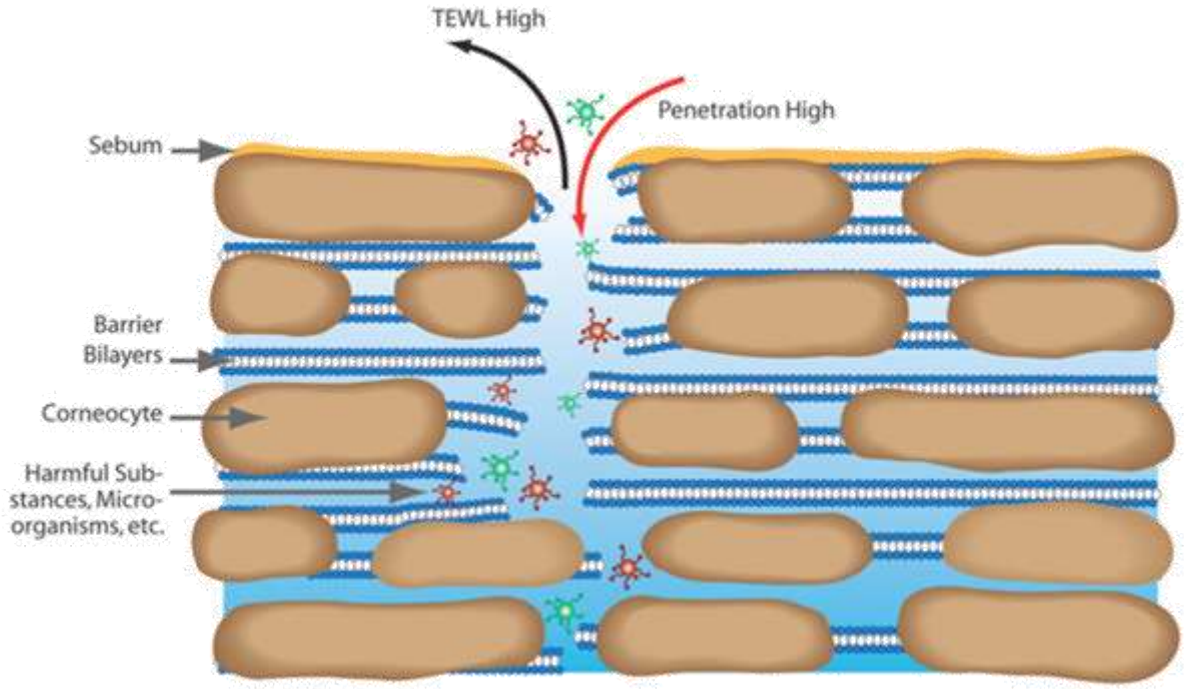
TRANSEPIDERMAL WATER LOSS

- High values indicate **disruption** to skin barrier function
- Low values indicate **promotion** of skin barrier function



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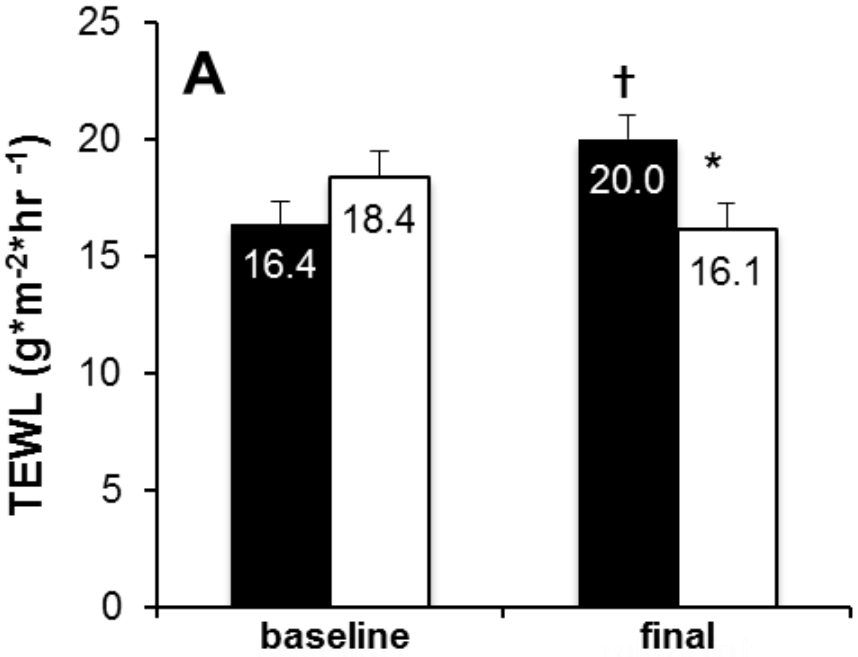
TRANSEPIDERMAL WATER LOSS RESULTS

- Non-vacuum treatment resulted in a significant increase in TEWL over 16-week treatment (disruption of barrier function)
- Vacuum treatment resulted in a decrease in TEWL over 16-week treatment (promotion of barrier function)
- After 16 weeks, EVS resulted in significantly lower TEWL compared to non-EVS



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TISSUE HEALTH

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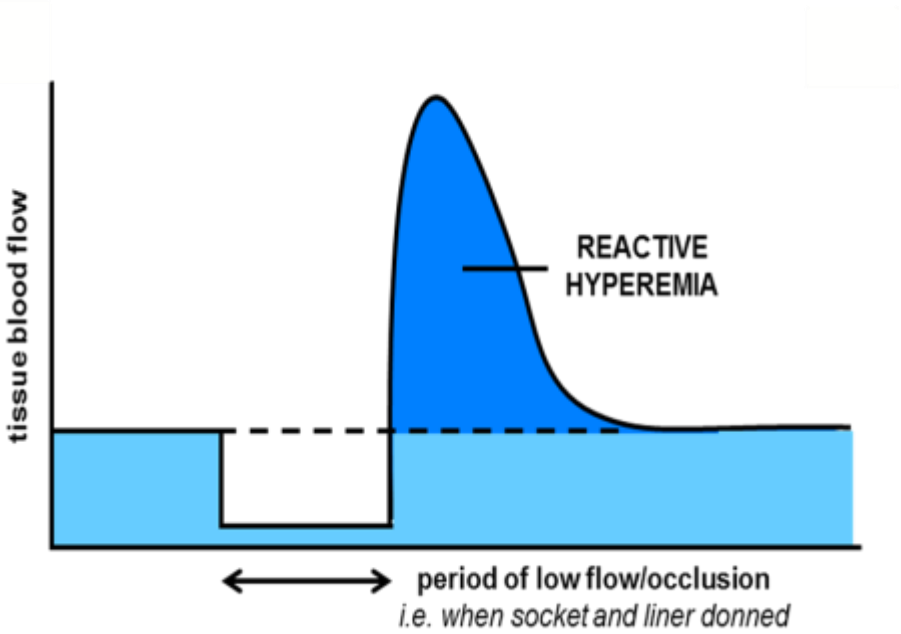
OUT-OF-SOCKET IMAGING

- Hyperspectral Imaging (HI)
  - Two chromophores of physiological relevance:
    - Oxyhemoglobin (OxyHb)
    - Deoxyhemoglobin (DeoxyHb)
  - This data is used to create a map of local oxygen delivery and extraction with the tissue microvasculature

HYPERSPECTRAL IMAGING AND REACTIVE HYPEREMIA

- HI data was collected before and after activity, so we could test for reactive hyperemia
- Reactive hyperemia is the transient increase in blood flow following a period of occlusion
- In this context, we see it as a negative consequence



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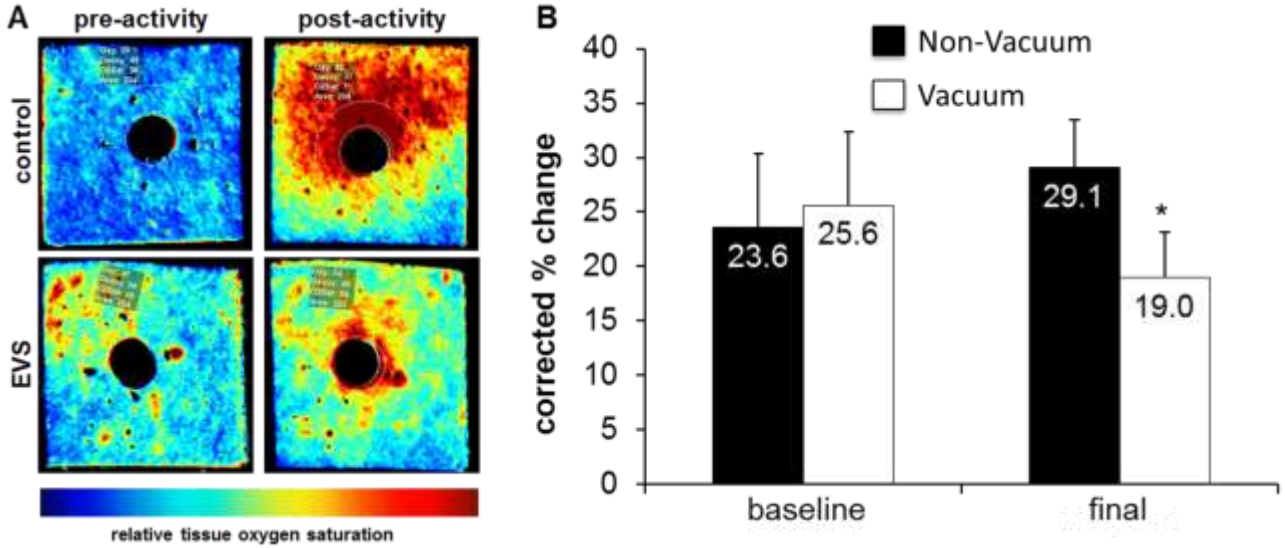
HYPERSPECTRAL IMAGING RESULTS



- The percent change pre-to-post activity (reactive hyperemia) increased over 16 weeks with non-EVS but decreased with EVS. The difference after 16 weeks was significant.

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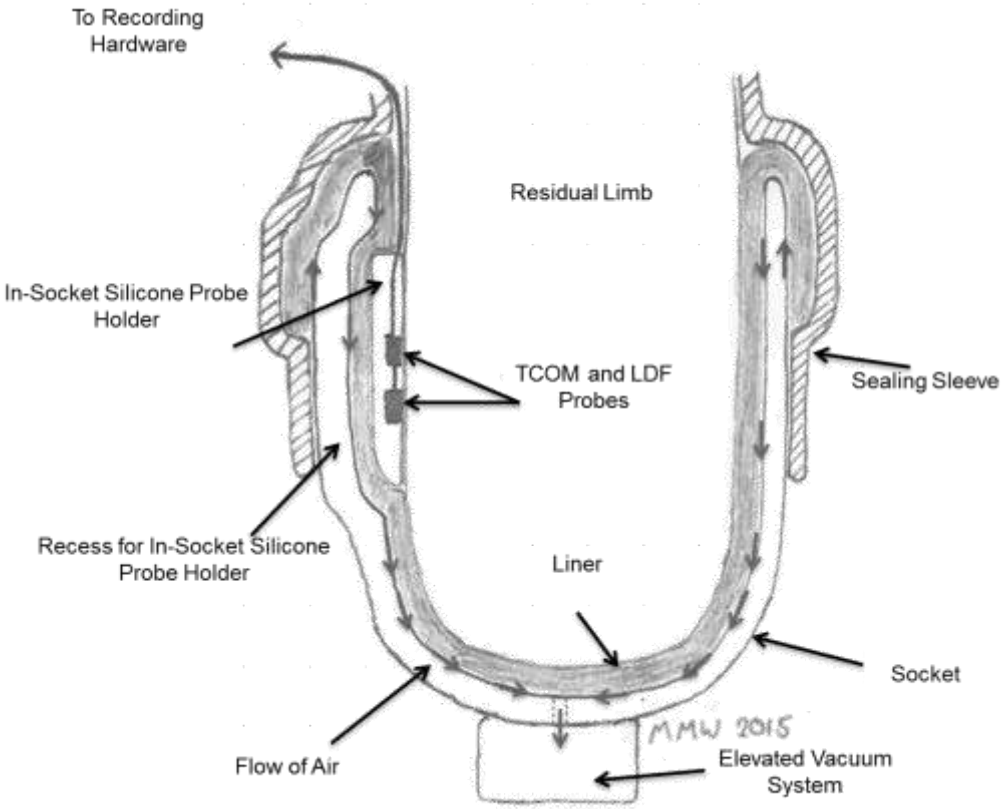
IN-SOCKET PROBES

- Laser Doppler Flowmetry
  - Blood perfusion
- Transcutaneous Oxygen Measurement
  - Tissue oxygenation

IMPORTANCE OF PROPER SOCKET FIT



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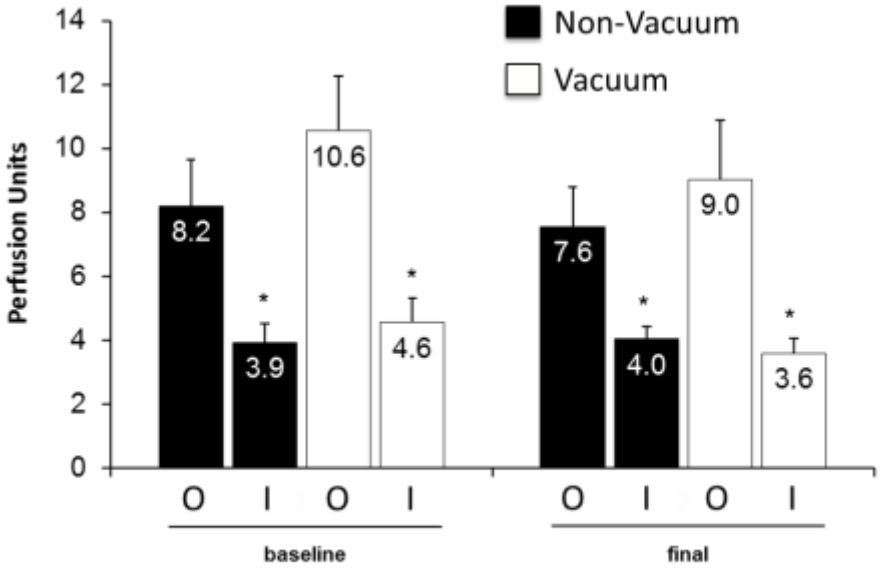
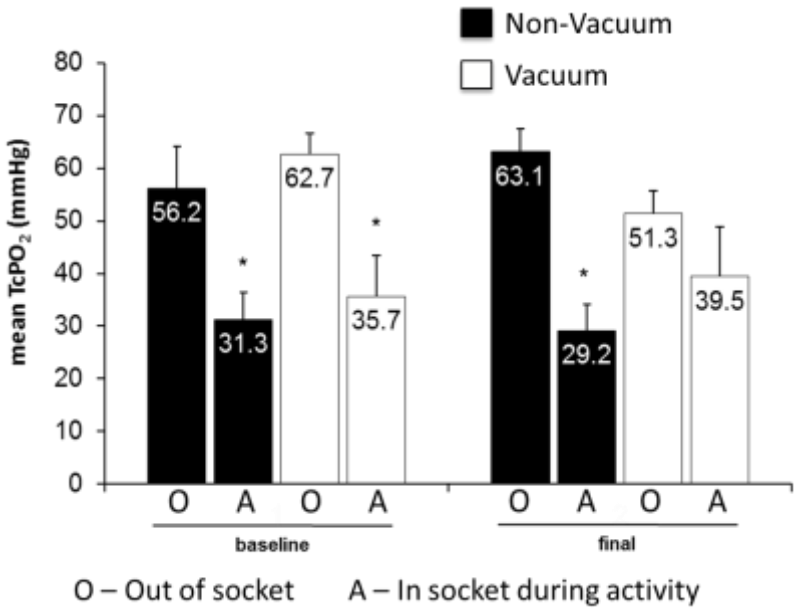
LASER DOPPLER FLOWMETRY RESULTS

- Note: sensor sensitive to movement, so data only collected during quiet standing
- Data showed donning a socket is occlusive and significantly lowered in socket blood perfusion from out of socket levels across all suspension systems and time points
  - Not surprising since sockets are made to have a reduction in volume compared to the unconstrained limb



TRANSCUTANEOUS OXYGEN MEASUREMENT RESULTS

- Significant decrease in tissue oxygenation was found for non-EVS and EVS at baseline and for non-EVS at final during activity compared to out of socket
- EVS had a decrease in tissue oxygenation, although not significant, after 16 weeks of use, suggesting better blood perfusion during activity
  - 40 mmHg is a critical point below which tissue hypoxia occurs. With EVS we approach this critical point.



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SUMMARY AND CONCLUSIONS

- EVS lowers transepidermal water loss (TEWL) after 16 weeks of use
- Prosthesis donning lowers residual limb perfusion at rest
- EVS improves tissue oxygenation during activity after 16 weeks
- EVS attenuates reactive hyperemia

- Taken together, the results suggest that EVS-dependent differences in the prosthetic socket residual limb interface account for residual limb health improvement in part by beneficial changes in residual limb perfusion and stresses applied to the soft tissues of the residual limb

RESIDUAL LIMB STABILITY

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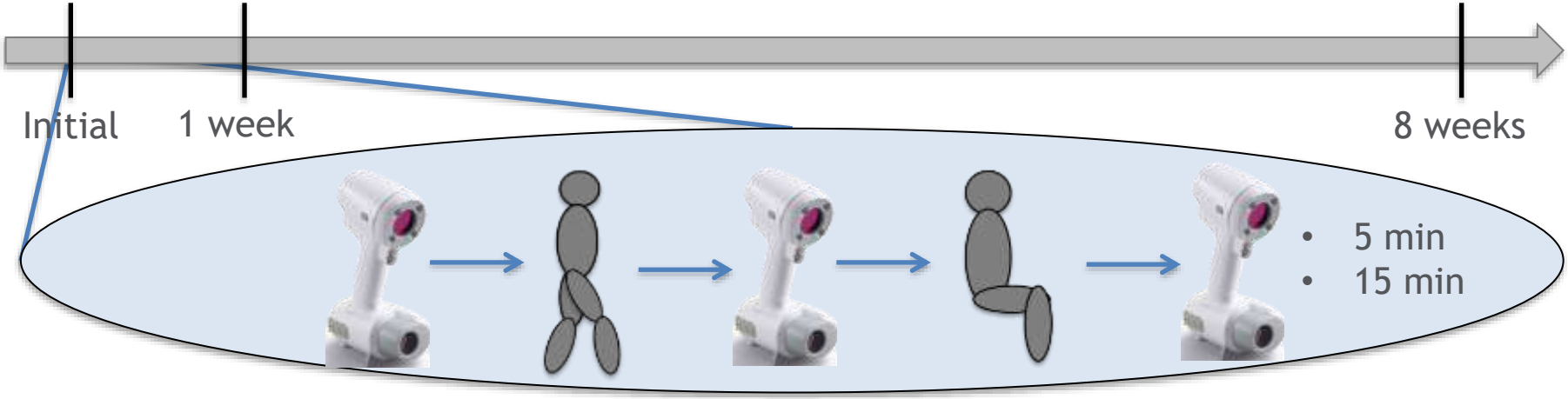
EXISTING SUPPORTING LITERATURE

- Our hypothesis is that elevated vacuum allows the beneficial physiological changes as a result of providing a more stable environment
  - Less pistoning (Board 2001, Darter 2016, Gershutz 2010 and 2015)
  - Better volume control (Board 2001, Goswami 2003, Sanders 2011)
  - Reduced contact pressure

STUDY MOTIVATION AND DESIGN

- To further evaluate this hypothesis, we designed a study to measure limb volume and socket motion and repeated these measures
  - 15 total participants (9 vacuum, 6 suction)
  - Measured limb motion, limb volume, vacuum usage



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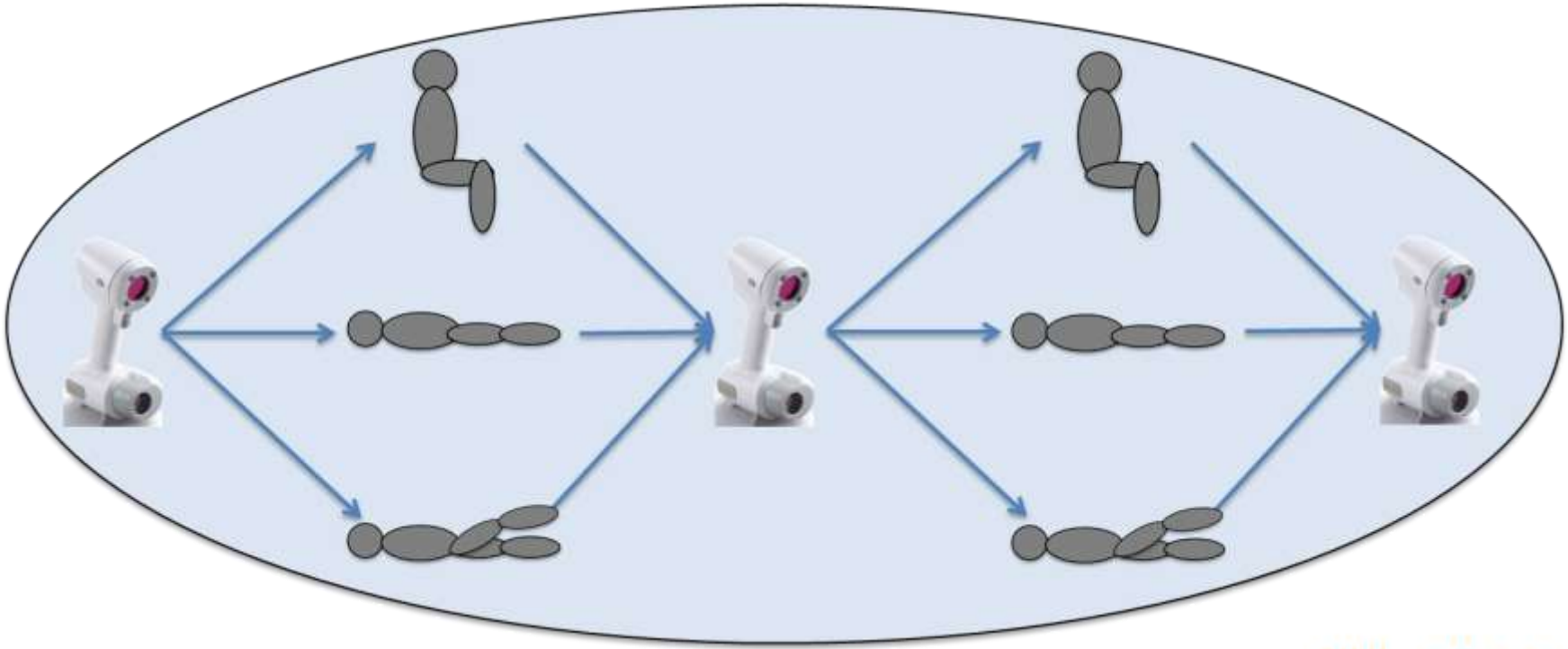
REST PERIOD DEFINED



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VOLUME MEASUREMENT

- The OMEGA® Scanner was used to capture limb shape with the socket off and then calculate limb volume
- Markers were added to the limb so a repeatable process could be used to orient the limb and size the limb shape

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VOLUME MEASUREMENT

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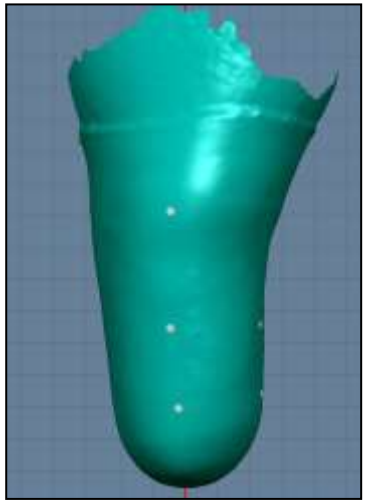

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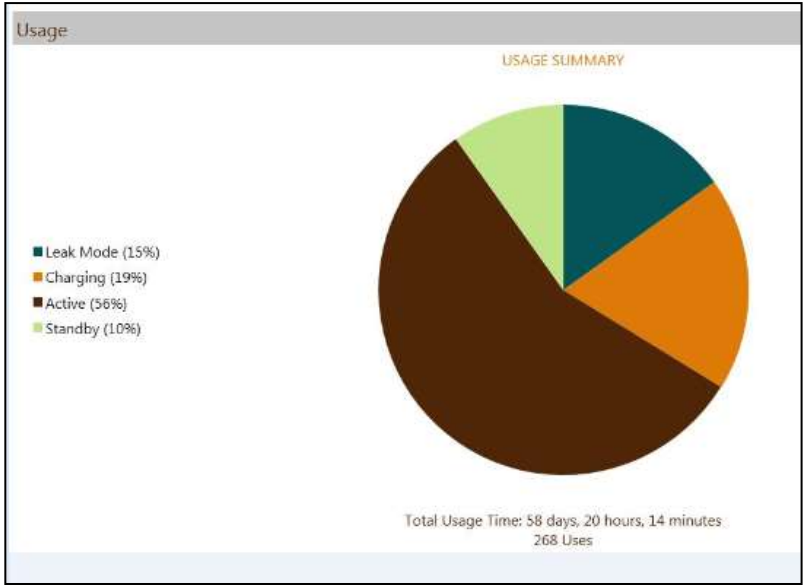
EXCLUSION CRITERIA FOR VACUUM GROUP

- 9 vacuum users and 6 suction users
- LimbLogic Communicator was used to quantify compliance
- Socket volume was compared to limb volume to rank socket fit

1. Use
2. Lowest socket-limb volume difference
3. Highest socket-limb volume difference



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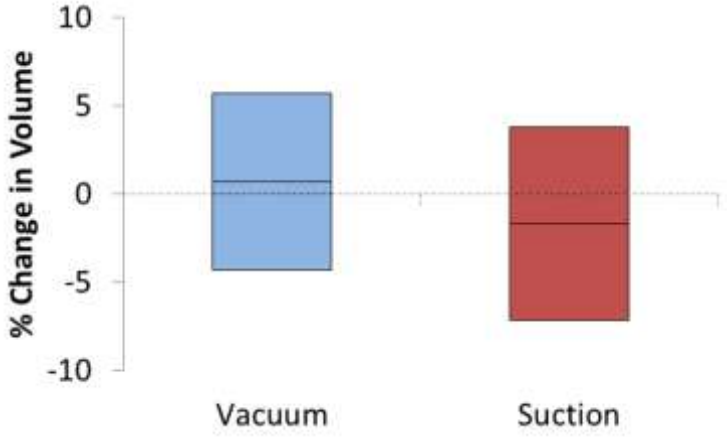
VOLUME CHANGE AFTER ACTIVITY



- For users with socket volumes less than the average initial limb volume, the limb still tended to gain or maintain volume
- This is consistent with data reported by Goswami 2003

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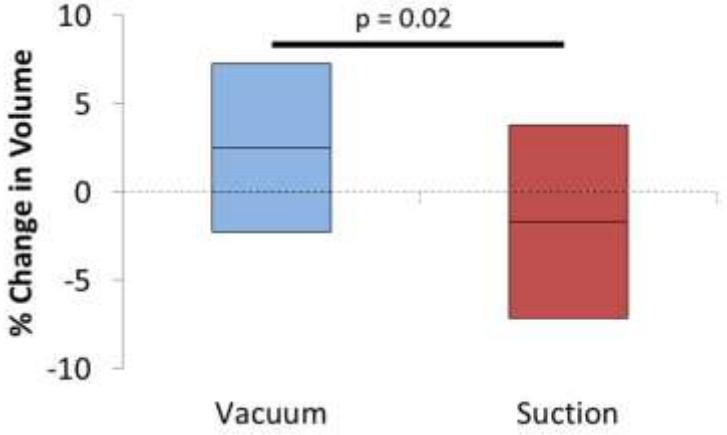
VOLUME CHANGE AFTER ACTIVITY



- For users with socket volumes greater than the average initial limb volume, the limb tended to gain more volume
- This is consistent with data reported by Goswami 2003

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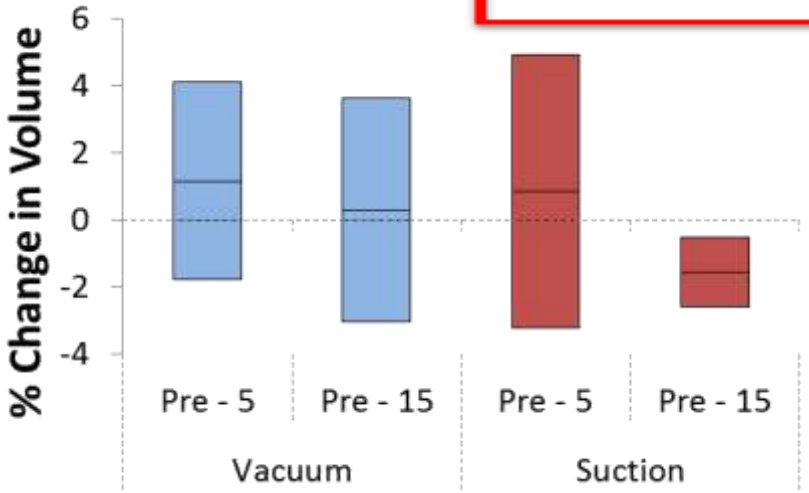
VOLUME CHANGE AFTER REST



- Limb volume was more stable with EVS compared to suction suspension

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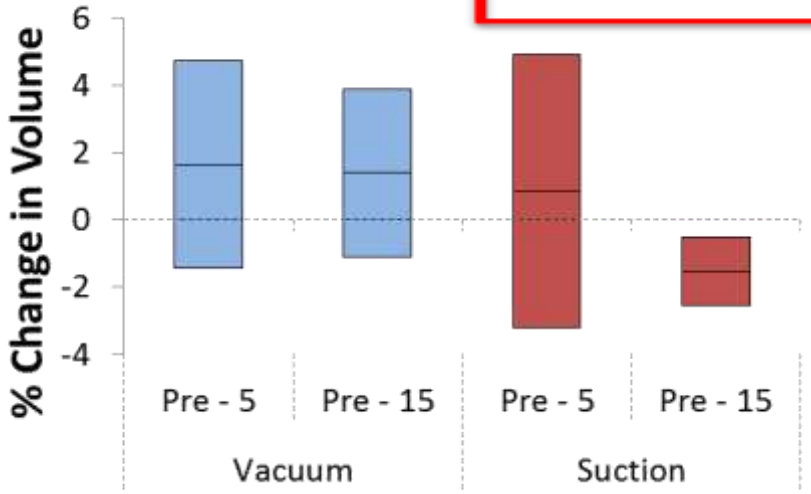
VOLUME CHANGE AFTER REST



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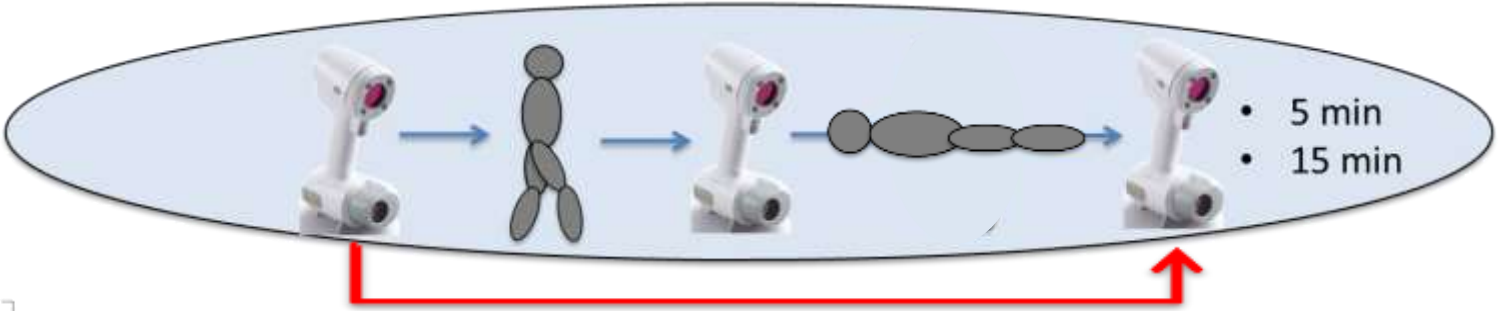

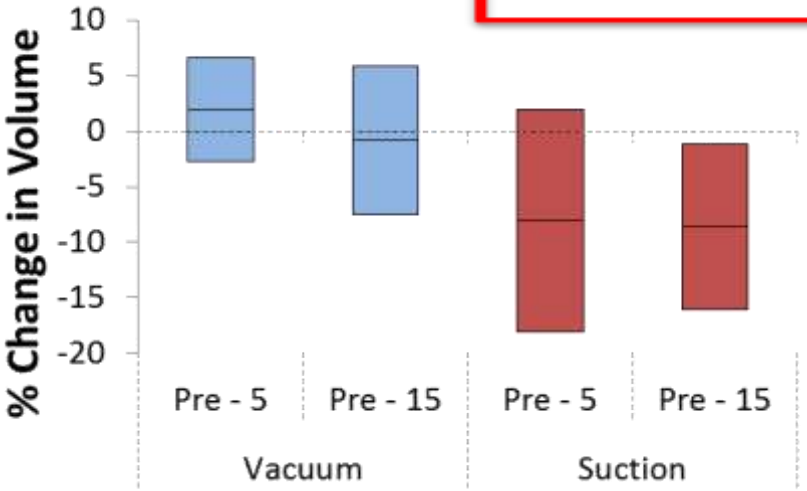

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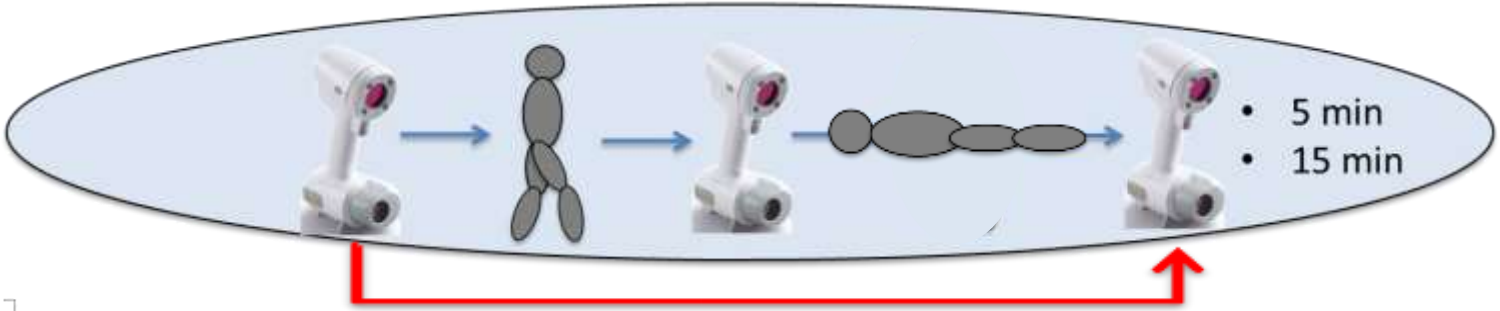

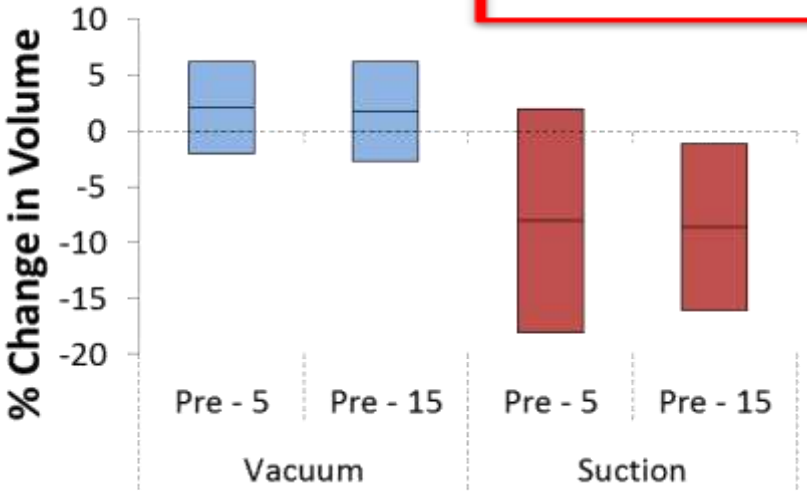

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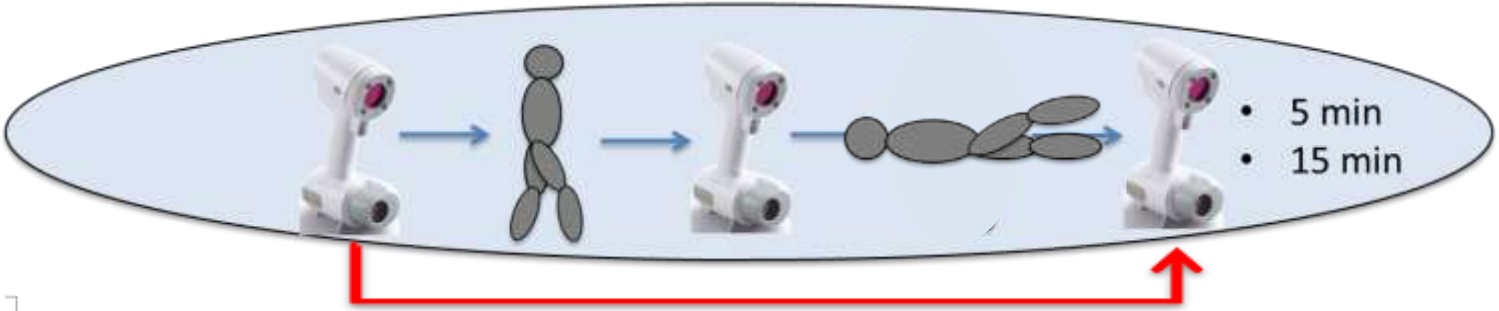

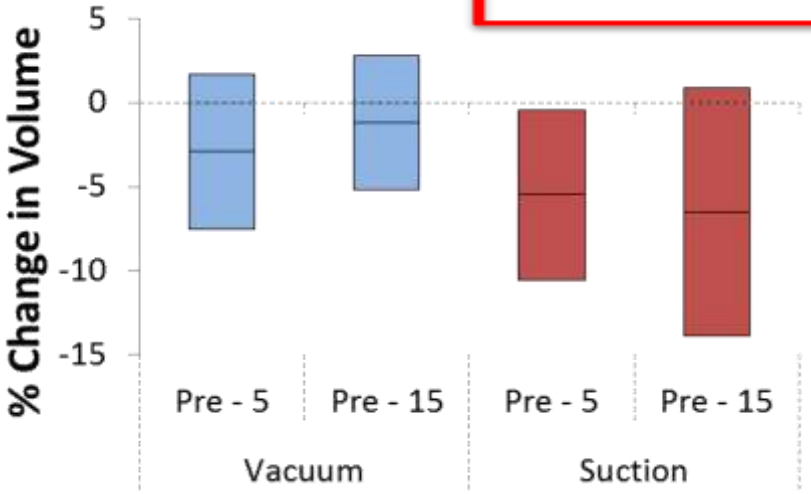

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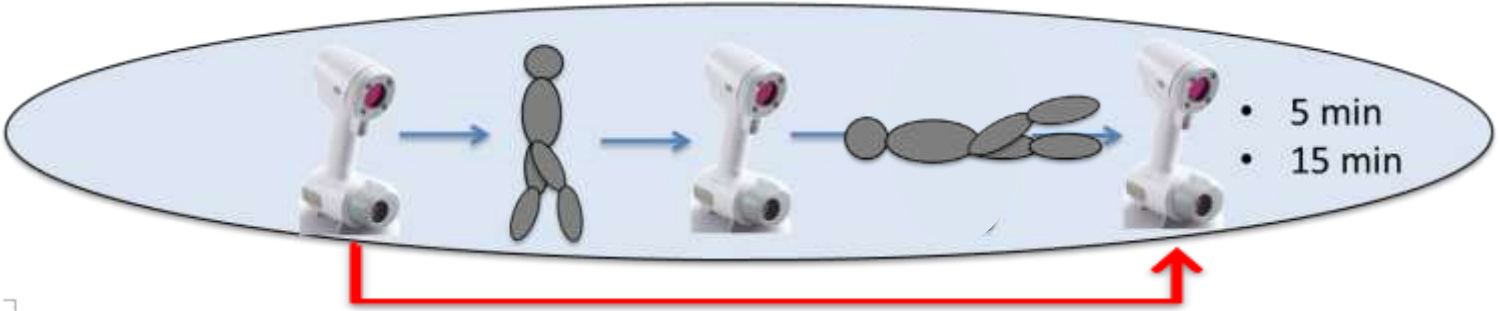

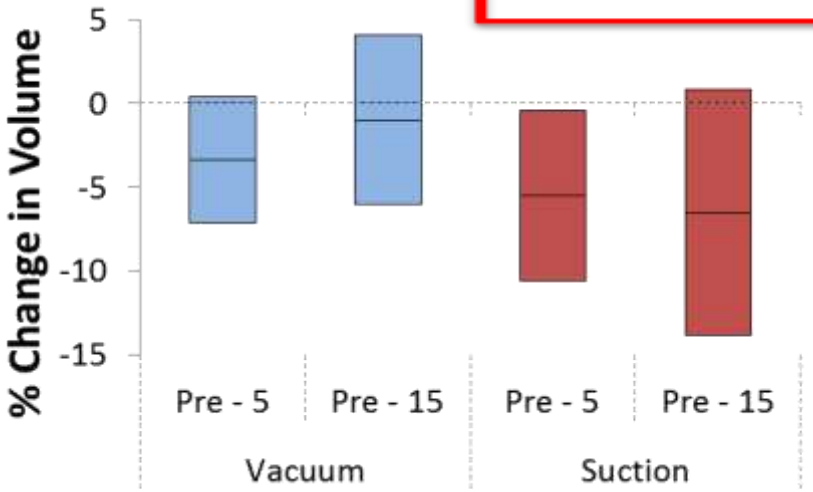

- Limb volume was more stable with EVS compared to suction suspension

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LIMB MOTION

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PROSTHETIC SOCKET FITTING

- Fitting procedures lack direct measures
  - Experience dominates
  - Feedback from patients is helpful
  - No quantitative documentation
- The process would greatly benefit from a method to quantify socket suspension and fit
  - Prevent and/or eliminate soft tissue injury
  - Optimize socket performance
  - Provide documentation for why a socket revision or replacement is needed

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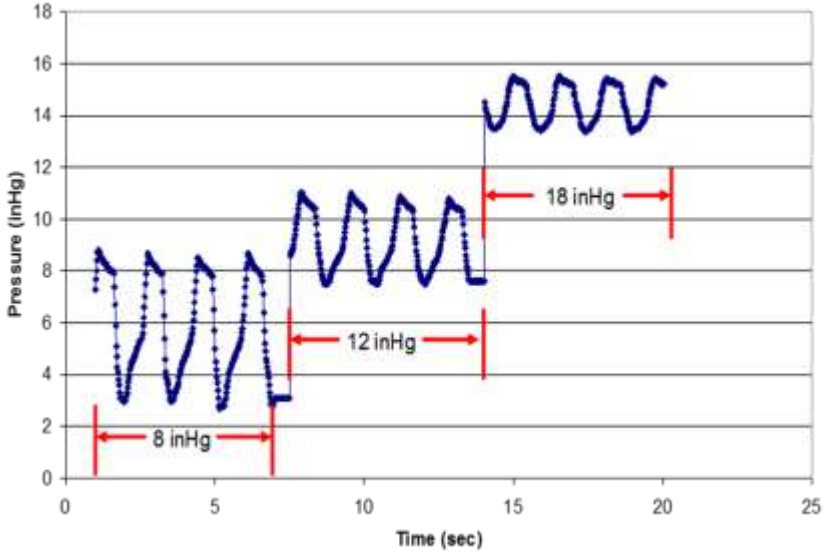
LIMB MOTION MEASUREMENT

- Negative pressure generated by elevated vacuum suspension fluctuates during gait.*



*Key Assumption: A step is a constant loading condition. Not necessarily true for a single step. However, is reasonable for trends of a collection of steps.

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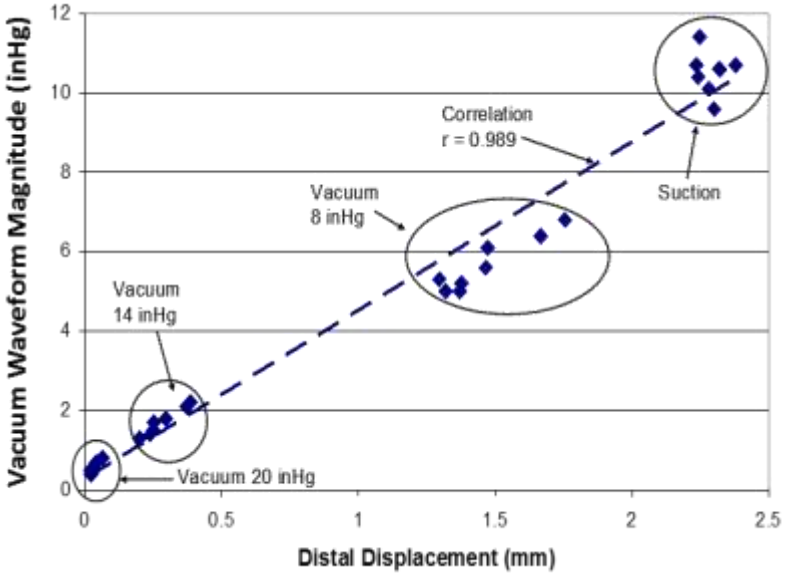
INDUCTIVE SENSOR TEST

- Direct correlation between vacuum pressure and distal displacement (Gershutz, JPO, 2015)



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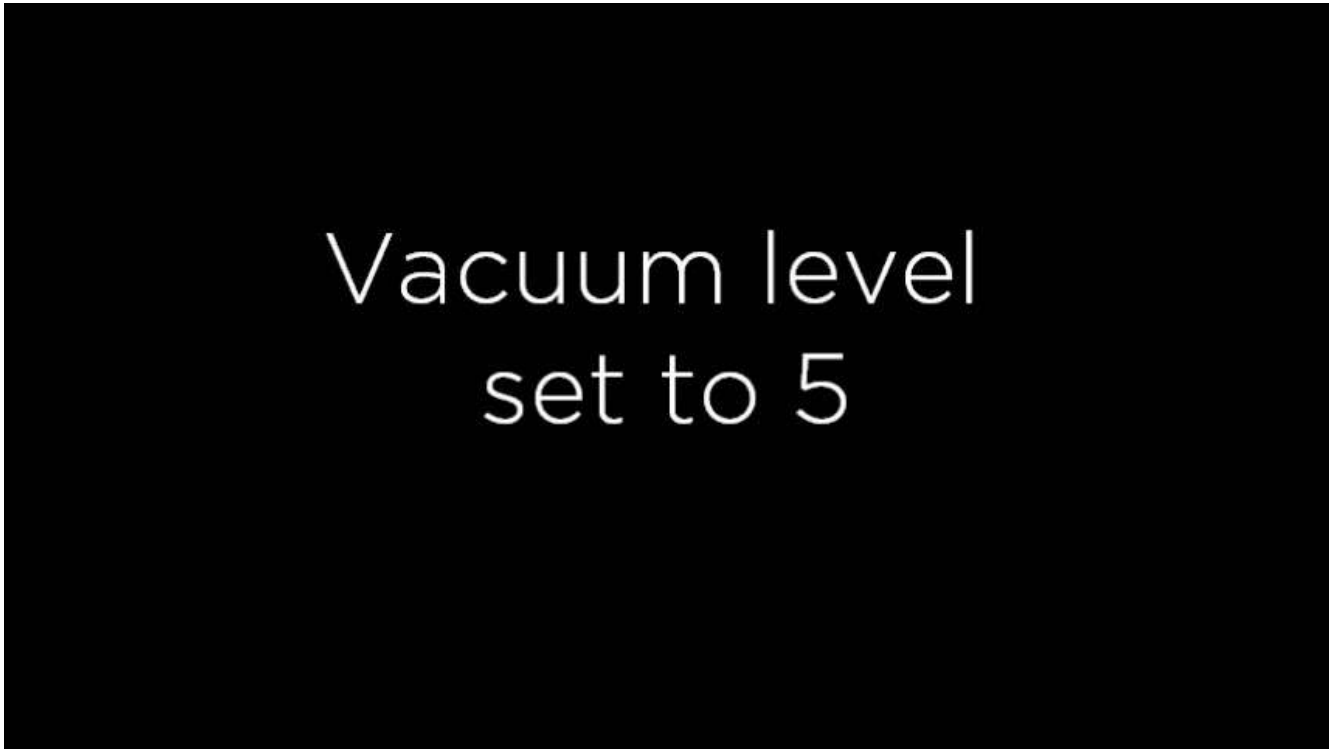
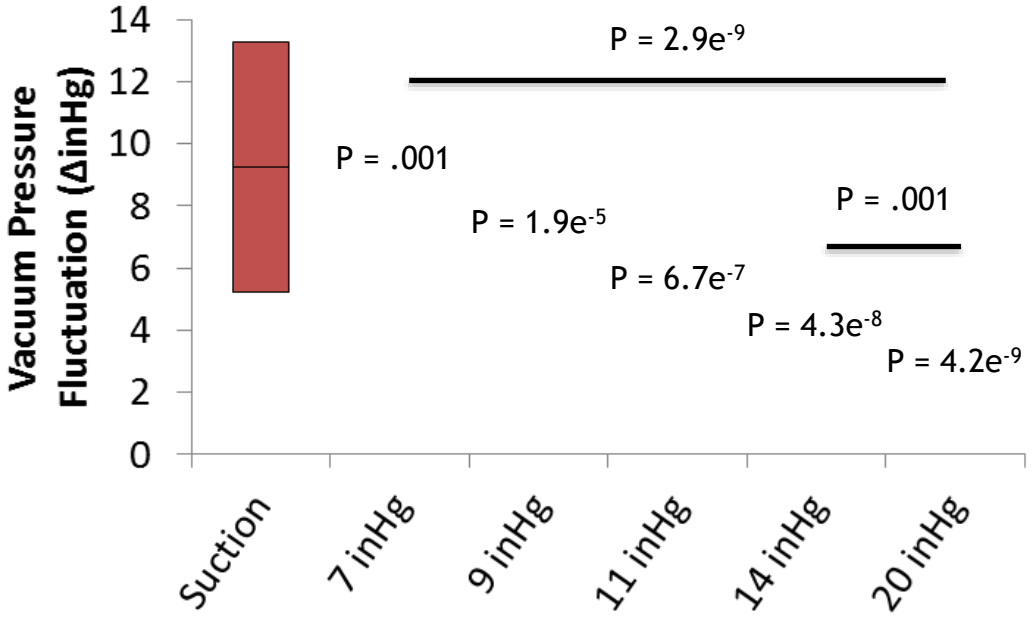

Vacuum level
set to 5

IMPORTANCE OF PROPER SOCKET FIT

- Measured ΔinHg during walking activity
  - Suction suspension allowed significantly more movement
  - High levels of vacuum allowed significantly less movement than lower levels of vacuum



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CONTROLLED BENCHTOP TEST

- Test configuration allowed researchers to control alignment, frequency of force application, magnitude of force, and amount of limb under vacuum

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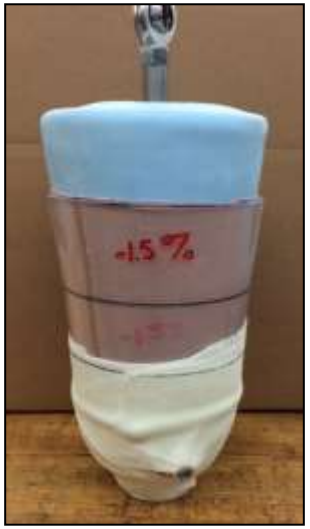
CONTROLLED BENCHTOP TEST

- Three sockets of different volumes relative to the limb model were fabricated to facilitate the test procedures



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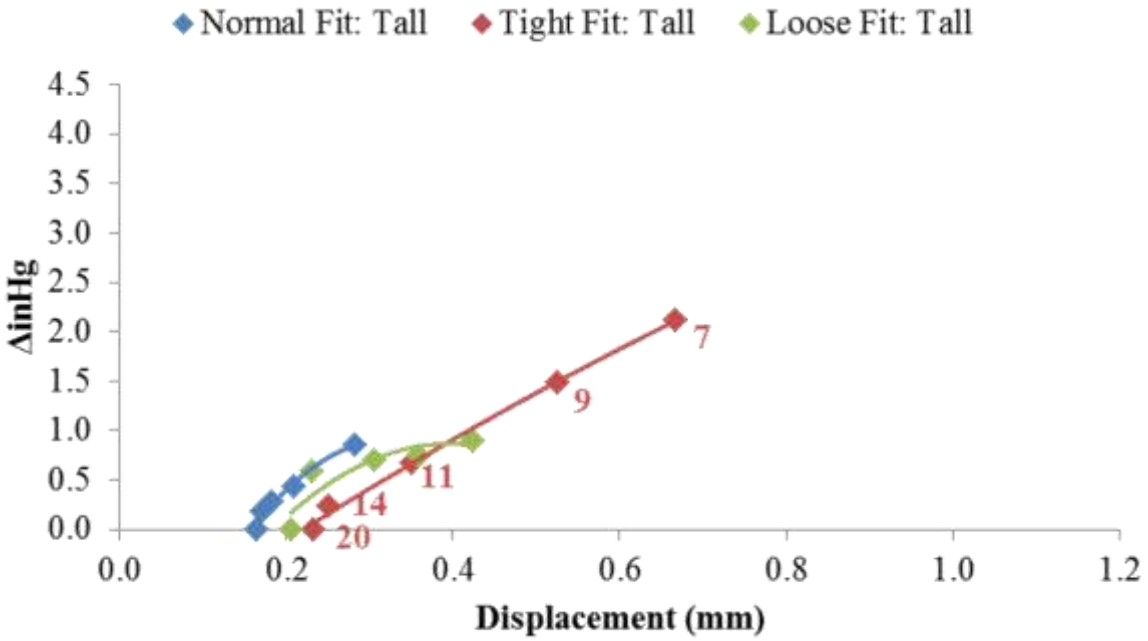
RESULTS

- Trends in the data are indicative of the type of fit



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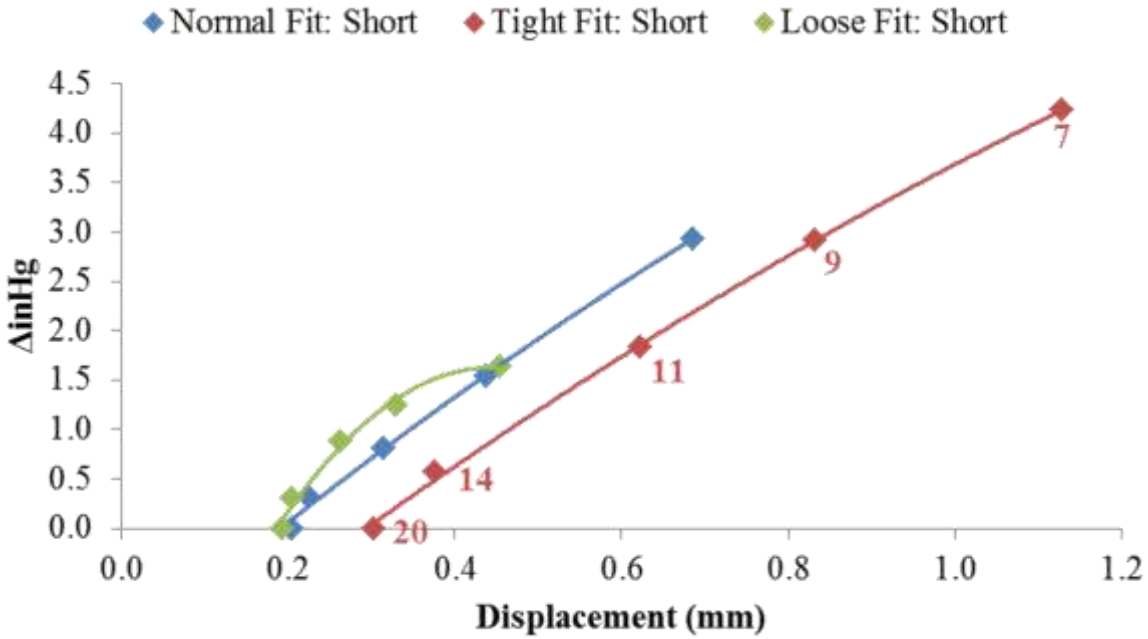

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LIMB MOTION SUMMARY

- Results support hypothesis of a more stable socket environment with the use of vacuum suspension

- Future work should explore the relationship between in-socket motion, vacuum pressure setting, and limb health and the ability to optimize these factors so as to provide suspension that:
  - Promotes optimal limb health
  - Promotes the highest level of function possible for a given patient
  - Awarded DoD funding (W81XWH-16-2-0059)

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SOCKET FIT PARAMETERS

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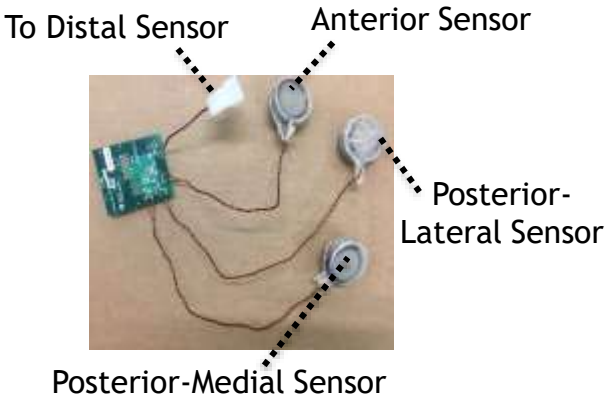
HUMAN TRIALS TO UNDERSTAND SOCKET FIT/LIMB MOVEMENT

- 20 participants completed 50 trials
  - Global and local socket fit conditions
  - 5 vacuum pressure settings
  - 2 walking speed



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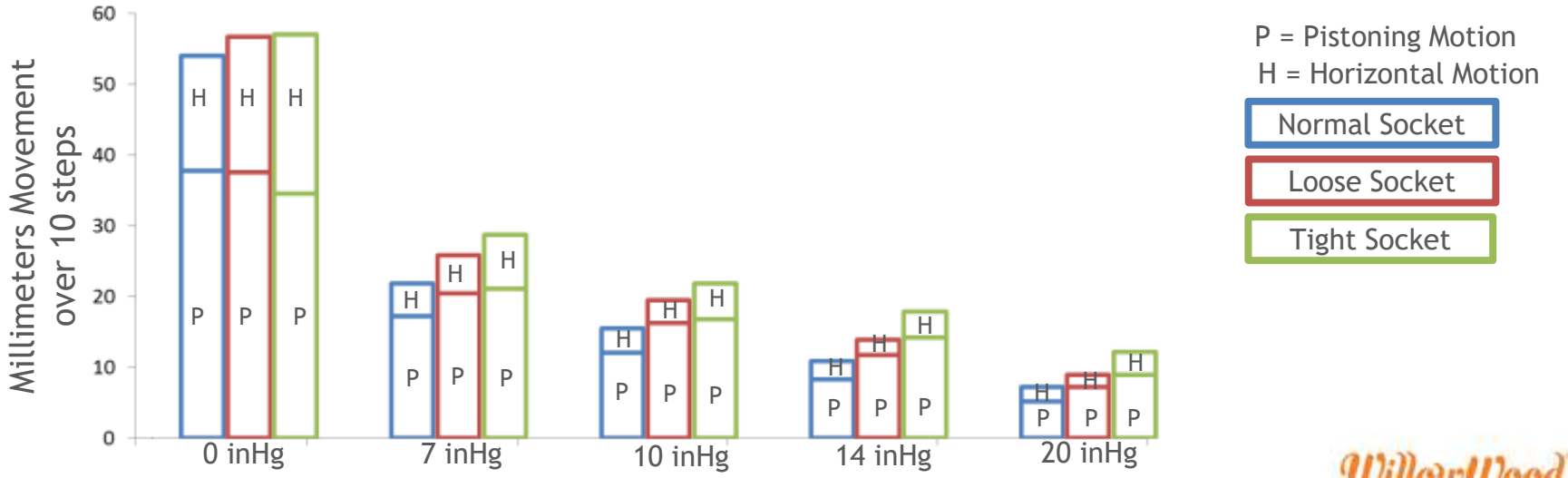
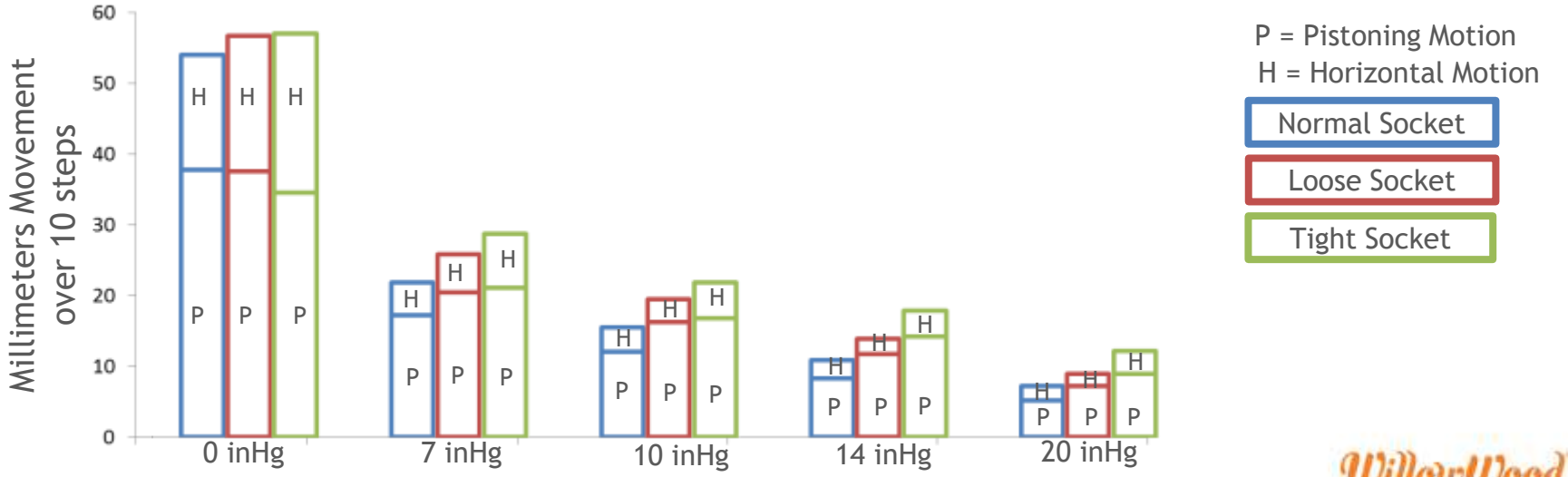
GLOBAL FIT CHANGES: INDUCTIVE SENSOR RESULTS

- Pistoning motion accounted for 61% - 82% of the overall motion
- Horizontal motion accounted for 18% - 39% of the overall motion
- EVS significantly reduced both motions ($p=3.8e^{-7}$ and $p=2.9e^{-7}$ respectively)



GLOBAL FIT CHANGES: INDUCTIVE SENSOR RESULTS

- Socket fit significantly impacted the amount of total motion ($p=5.3e^{-7}$)
  - Near significant for pistoning motion ($p=0.06$)
  - Significant for horizontal motion ($p=0.01$)



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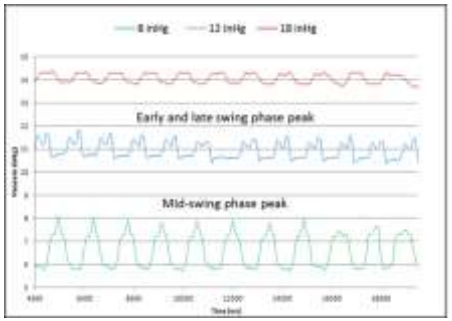
CURRENT RESEARCH FOCUS

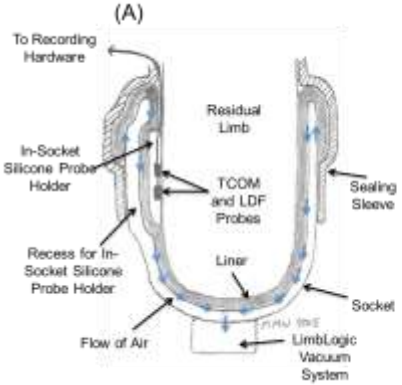
- Now we need to link health and movement!

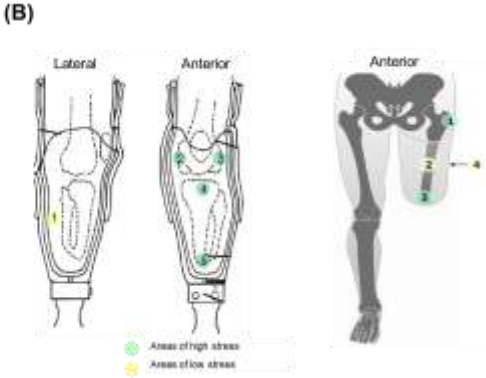
- Ongoing work (DoD contract W81XWH-16-2-0059) is exploring the relationship between in-socket motion, vacuum pressure setting, and limb health and the ability to optimize these factors so as to provide suspension that:
  - Promotes optimal limb health
  - Promotes the highest level of function possible for a given patient

MEASURING LIMB HEALTH IN RESPONSE TO LIMB MOVEMENT

- Using the Limblogic® and Limblogic® Communicator, we are controlling the level of vacuum, thereby controlling the level of limb movement







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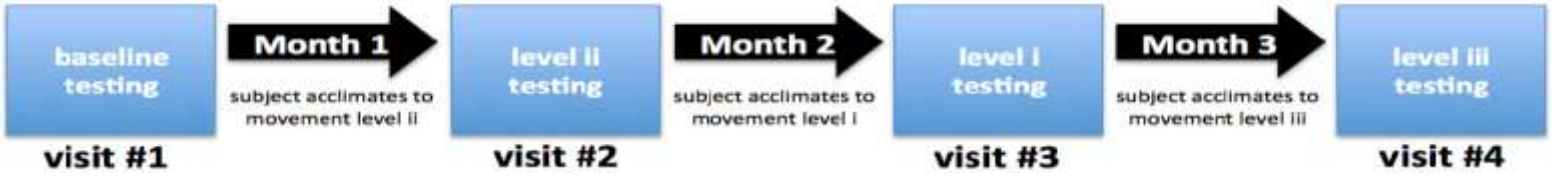
PRELIMINARY DATA

- Data collection completed for 15 subjects
  - 8 Transfemoral
  - 7 Transtibial
- Vacuum levels controlled movement in the socket
  - Low = 10 inHg with a range of 4 inHg
  - Med = 15 inHg with a range of 4 inHg
  - High = 20 inHg with a range of 4 inHg



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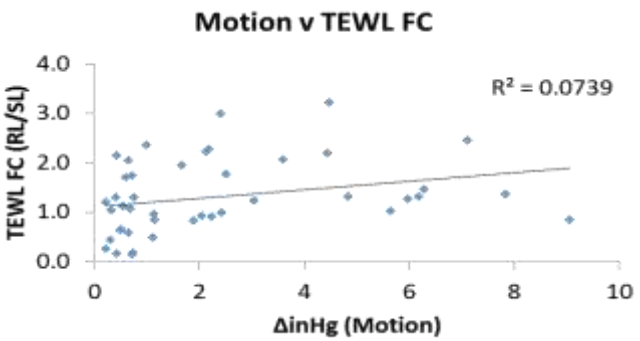
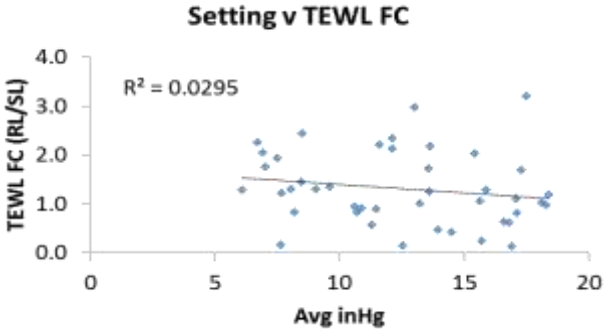
PRELIMINARY DATA: TEWL



- In-socket motion **correlates** with TEWL
  - p=0.07 (Near Significant)

- Vacuum setting **does not correlate** with TEWL
  - p=0.27 (Not Significant)



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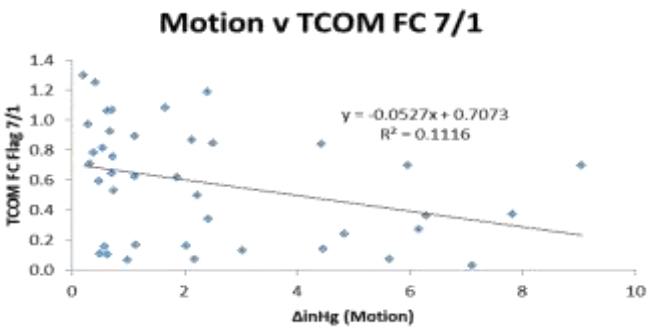
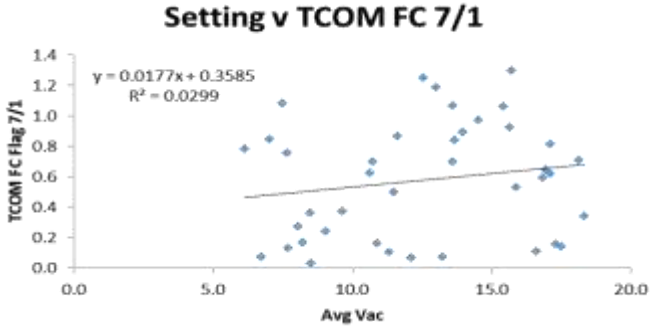
PRELIMINARY DATA: TCOM



- In-socket motion **correlates** with TCOM
  - p=0.03 (Significant)

- Vacuum setting **does not correlate** with TCOM
  - p=0.28 (Not Significant)



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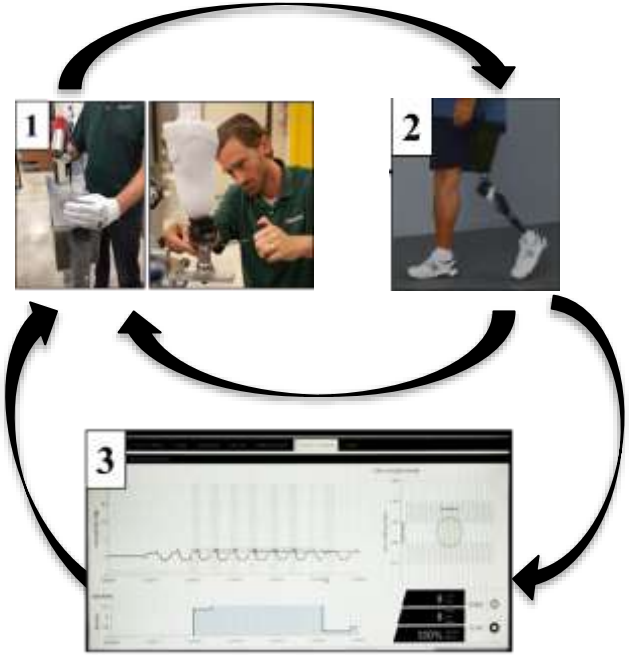
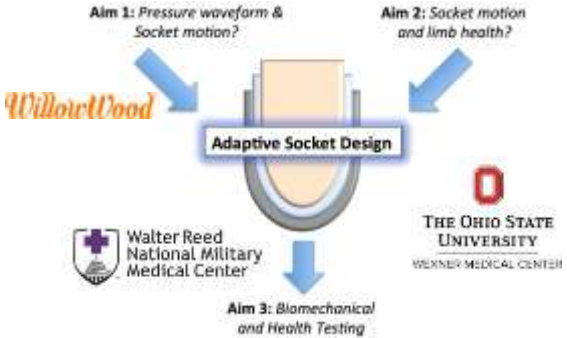
DISCUSSION

- Vacuum suspension has been shown to improve health measurements after long term-use
- This suggests adaptation over a period of time, possibly through a reduction in socket movement
- Movement is found to be correlated with the health of the limb, where reducing/controlling movement improves health scores
- This data can ultimately lead to new suspension technologies and socket fitting parameters





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HOW TO BE SUCCESSFUL

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INVOLVING THE RIGHT PERSONNEL

- Amputee
  - Cognitive ability is good
  - Realistic expectations are evident
  - Family are supportive
  - Prosthetic system criteria is met
- Referral Source
  - Physician is familiar with prosthetic vacuum systems and their potential
- Practitioner
  - Knowledge and understanding of utilizing vacuum technologies in prosthetics
- Paying source
  - Reimbursement requirements
  - Administration detail

ASSESSMENT OF PATIENT

- Potential patient benefits (above present abilities of mobility and cognitively)
- Initial patient mobility scores — baseline data
- Treatment plan — brief summary
- Potential mobility score and outcomes expected within the plan's progress
- Detailed prescription returned to prescriber with complementary medical notes

Acknowledgement: Vega Healthcare Consultancy January 2014

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INSURANCE AND REIMBURSEMENT

- Medical notes providing necessity of provision that covers:
  - Vacuum Suspension
  - Residual Limb Benefits
  - Research Data and Published Literature
- L-Code and descriptor relating to current assessment:
  - **L5781** Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system (Lower limb pros vacuum pump)

Acknowledgement: Vega Healthcare Consultancy January 2014

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WILLOWWOOD ONE® TRANSTIBIAL SYSTEM

- Vacuum/suction components
- Donning review
- Activating vacuum/suction in the socket
- Effects of vacuum/suction
  - Phase 1
  - Phase 2
  - Long-term benefits

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DONNING REVIEW

- Fit the liner (Alpha Duo) to residual limb
- Fit wicking sheath (One Gel Sock) over the liner to create an air wicking surface and some shape stabilization
- Fit diagnostic socket (socket should be precise and close fitting)
- Assess liner/socket contact (air chamber size)

SEALING THE SYSTEM

- Assess liner/socket contact (air chamber size)
- Apply sealing sleeve and componentry
- Begin creating vacuum in the socket environment

MAINTAINING THE SYSTEM

- Consistent vacuum levels
  - Keeping the negative pressure elevated
- Control of limb volume
  - Allowing the limb to stabilize during use
- Control of motion
  - Keeping a positive suspension throughout daily living
- Maintaining airtight qualities
  - Maintaining the sealing properties intact
- Clinical and end user knowledge
  - Systematic diagnostics post delivery

TIMELINE

- Initial shape capture and fittings (Phase 1)
- Extended trial with restricted activity or under supervision
- Review of socket fit (Phase 2 development)
- Definitive socket delivery
- 4 - 6 week follow up (Physiological development)
- 6 month follow up (Physiological development)

- Refit socket in 8-12 months post delivery

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RESEARCH OUTCOMES

Clinical Essentials for Vacuum Prostheses

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