Published in final edited form as:

Technol Innov. 2016 September ; 18(2-3): 175–183. doi:10.21300/18.2-3.2016.175.

COMPARATIVE EFFECTIVENESS OF AN ADJUSTABLE TRANSFEMORAL PROSTHETIC INTERFACE ACCOMMODATING VOLUME FLUCTUATION: CASE STUDY

Jason T. Kahle^{1,2}, Tyler D. Klenow³, and M. Jason Highsmith^{4,5,6}

¹OP Solutions, Tampa, FL, USA

²Prosthetic Design + Research, Tampa, FL, USA

³Prosthetics and Sensory Aids Service, James A. Haley Veterans' Hospital, Tampa, FL, USA

⁴School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA

⁵Extremity Trauma & Amputation Center of Excellence (EACE), U.S. Department of Veterans Affairs, Tampa, FL, USA

⁶319th Minimal Care Detachment, U.S. Army Reserves, Pinellas Park, FL, USA

Abstract

The socket-limb interface is vital for functionality and provides stability and mobility for the amputee. Volume fluctuation can lead to compromised fit and function. Current socket technology does not accommodate for volume fluctuation. An adjustable interface may improve function and comfort by filling this technology gap. The purpose of this study was to compare the effectiveness of the standard of care (SOC) ischial ramus containment to an adjustable transfemoral prosthetic interface socket in the accommodation of volume fluctuation. A prospective experimental case study using repeated measures of subjective and performance outcome measures between socket conditions was employed. In the baseline volume condition, the adjustable socket improved subjective and performance measures 19% to 37% over SOC, whereas the two-minute walk test demonstrated equivalence. In the volume loss condition, the adjustable socket improved all subjective and performance measures 22% to 93%. All aggregated data improved 16% to 50% compared with the SOC. In simulated volume gain, the SOC socket failed, while the subject was able to complete the protocol using the adjustable socket. In this case study, the SOC socket was inferior to the comparative adjustable transfemoral amputation interface in subjective and performance outcomes. There is a lack of clinical trials and evidence comparing socket functional outcomes related to volume fluctuation.

Keywords

Amputee; Ischial containment; Lower extremity amputee; Limb loss; Rehabilitation; Socket

INTRODUCTION

In the U.S., approximately two million people live with limb loss (1). It is estimated that by 2050, nearly 3.6 million Americans will be living with lower extremity (LE) limb loss (1). Of the two million American amputees, approximately 86% are individuals living with lower limb loss and 18.5% have transfemoral amputation (TFA) (2). In spite of this increasing amputee population, there is limited prosthetic research, resulting in healthcare service gaps, excess hospital utilization, and increased cost to patients and payors (3). Addressing these issues is of critical importance since rehabilitation care, fitting of prostheses, and adjustment of devices alone were the fifteenth most expensive condition treated in U.S. hospitals in 2011, with a total cost of more than \$5.4 billion (4).

The socket-limb interface is vital for functionality and provides stability and mobility for the amputee. An inadequate fit may lead to skin breakdown, thereby limiting mobility and requiring additional clinician time, replacement components, and a possible remaking of the prosthesis altogether (5). As a result, Medicare data shows that 45% of the overall \$750 million in Medicare expenditures on prosthetic technology each year were for socket-related codes. Successful socket fitting reduces this economic burden and increases prosthetic usage. Amputees encounter multiple challenges during their recovery, rehabilitation, and reintegration into their homes and communities. Learning and adopting new strategies for basic mobility, personal hygiene, and activities of daily living with a prosthesis is difficult (6). Complicating this process, the residual limb (RL) naturally goes through a period of volume fluctuation post amputation that impacts fit (7). Newly amputated limbs commonly undergo reduction in size, shape, and volume (7,8). This progression occurs in two phases: 1) rapid, acute shrinkage immediately following amputation and 2) progressive stabilization of volume one year post amputation. These changes are dependent on individual lifestyle, activity level, and weight. Moreover, amputees experience daily volume fluctuations influenced by multiple factors, including diet, environment, and weather conditions. These fluctuations require an iterative process involving numerous trips to the prosthetist for socket adjustments. Poor fit can lead to prosthetic abandonment (9). RL volume management is a common issue for prosthetic users, especially during the intermediate recovery stage of amputee rehabilitation when the most rapid volume fluctuation occurs (7). It has been shown that limb volume decreases 17% to 35% over the first 160 d post amputation, 7% to 10% in the 12-month post-operative period and approximately 2% on a daily basis thereafter, thus requiring patient-provider coordination (7,10). In addition, chronic volume change may continue for up to 12 to 18 months post amputation due to tissue atrophy and indefinite diurnal volume fluctuations. Poor volume management can result in a variety of secondary adverse effects of prosthetic use, including ulcers, verrucous hyperplasia, and osteomyelitis (7). These effects may lead to further amputation and re-hospitalization, which contributes to the annual \$8 billion expenditure on amputee hospital care (11).

Traditional rigid sockets do not accommodate volume fluctuations. Poor fit can cause skin ulcerations and infection and may lead to revision amputation (12). Furthermore, socket discomfort is common among LE amputees and may delay prosthetic use, prevent return to normal function, compromise patient outcomes, and increase healthcare costs. The primary cause for failure of amputee prostheses is user dissatisfaction associated with poor socket fit

and comfort (9,12–14). In addition to the unmet need in addressing comfort, there is a considerable technology gap in the area of socket fabrication and access. Therefore, the objective of this prospective experimental clinical case study is to compare the effectiveness of the standard of care (SOC) ischial ramus containment (IRC) to an adjustable transfemoral prosthetic interface socket in the accommodation of volume fluctuation by observing both functional and subjective outcomes.

METHODS

Methods were in accordance with the Declaration of Helsinki, and the subjects provided informed consent.

Subject

Subject inclusion was unilateral TFA, either gender, any ethnicity, between 18 and 65 years of age, and <113.4 kg. Exclusion criteria included non-TFA level, <18 and >65 years of age, and >113.4 kg. The subject identified had the following characteristics: male, 24 years old, right unilateral TFA, 1.7 m, 70.3 kg, and a BMI of 24 kg/m². The subject elected for limb amputation at age 19, secondary to osteosarcoma. His activity level was K4 per his medical record. No other known injuries were present. Subject exhibited upper and LE active range of motion within normal limits. His current prosthesis included a pin-lock gel liner, Infinite Socket™ (LIM Innovations, San Francisco, CA, USA), Genium knee, and Triton foot (Otto Bock Healthcare, Duderstadt, Germany). The subject was physically capable of completing the functional testing protocol. The subject had normal cognitive ability and was able to provide informed consent and socket fitting feedback to investigators.

Interventions Tested

1. IRC—This design is characterized by a high (proximal) brim that medially contains the ischio-pubic ramus and is the SOC. The socket consisted of a rigid thermoplastic material. This was suspended with a gel pin-locking liner. The subject was casted and fit into a custom SOC socket over the same liner he had been using to eliminate confounding and the potential introduction of dermatologic issues.

2. Adjustable TFA Interface—The Infinite Socket™ is a custom-molded four-strut design combined with a textile brim and tensioner to contain and control the pelvis and femur and soft tissues across a varying volume. Adjustments can be made by both clinicians and patients to manage long-term and daily fluctuations. The pivoting and sliding connection between the struts and base provides additional flexibility in adjustability as well as shock absorption and energy response. The dynamic frame of the Infinite socket™ has a textile interface that is reportedly low in friction, anti-microbial, durable, and washable. The Infinite Socket™ achieves control and pressure distribution through multiple custom components, which include an ischial seat, proximal brim, four struts, and a flexible inner distal cup.

Study Design

To simulate the same volume fluctuations an amputee would experience, three conditions were tested. First, to establish a baseline (BASE), the subject was casted over his Otto Bock 6Y87 3D TF pin-locking liner (Otto Bock Healthcare, Duderstadt, Germany) and a five-ply sock. Both the SOC and Infinite™ sockets were fabricated from this cast. The sockets were then fit and adjusted to this configuration to ensure an equal baseline. Second, to simulate volume loss (VLOSS), the five-ply sock was removed from the RL and liner, and then the subject was tested in this condition. This constituted a 2 cm circumferential volume change (VLOSS) less than the BASE circumference. Third, to simulate volume gain (VGAIN), the five-ply sock plus an eight-ply sock was added to the RL and liner for a total of 13-ply. This constituted a 2 cm circumferential volume change (VGAIN) more than the BASE circumference.

An experimental case study design was utilized for this project. An independent researcher randomized six study conditions across three repeated independent utilization periods, each followed by an outcome assessment. The study design controlled for all prosthetic variables (Table 1), as the subject utilized his usual prosthetic components with only the exception of the socket (independent variable) throughout the study. The order of testing was randomized using an offsite computer randomized number generator to improve methodological quality and minimize bias risk. Further, raters and the study statistician were blinded to the independent variables. Data collection was completed over three sequential days. Each data collection period began at the same time of day. The subject was instructed to maintain fluid, salt intake, and diet over the study period. Weight was recorded each day, in addition to RL circumference measurements, to help ensure volume consistency. A ten-minute rest period between conditions was provided between tests to mitigate confounding from fatigue. Blood pressure and heart rate were monitored before each test to ensure normalization prior to re-testing.

Outcome Measures

Physical performance measures were selected to assess functional capability and safety differences between the two socket conditions. For instance, speed of movement and walking are valuable clinical tests of functionality and provide good identification of multiple-falls risk (15–17). Slower gait has also been shown to be an indication of fall risk (18). Thus, the following tests were selected:

- a. *L-Test*: a short walking test with transitional movements and multiple turns
- b. *Four Square Step Test (4SST)*: a brief assessment of multi-directional stepping (15)
- c. *Two-Minute Walk Test (2MWT)*: a test to provide insight into cardiorespiratory and functional capacity and determine walking speed
- d. *The Amputee Mobility Predictor (AMP)*: an instrument used to determine mobility and ambulatory status for amputees

- e. *Socket Comfort Score (SCS)*: a valid, reliable, and sensitive assessment between practitioner and patient that indicates comfort and the need for interface adjustments (19)
- f. *Pain Scale*: a valid and reliable tool for determining the severity of specific types of pain

Data Analyses

Data were entered into a database and analyzed for normality and completeness. Central tendency, variance, and percent differences were calculated where possible. The analysis included a two-part approach. Repeated measures assessment was selected to determine differences across assessment sessions and between conditions. Additionally, differences were assessed at individual volume points (i.e., dependent, between-group comparison tests) as well as cumulatively across conditions. Parametric tests were used when possible (i.e., normal distribution); otherwise, non-parametric equivalent tests were selected. Statistical significance was set *a priori* at $p = 0.05$. It must be noted that the use of statistical analysis with case studies is not novel, but it is also not a commonly accepted practice. However, at times, data generation from case studies may be mathematically conducive to analyses that may provide insight into a magnitude of effect that could be useful for power and sample estimates for future expanded research with the intervention (20).

RESULTS

In the BASE condition, SCS in the Infinite socket improved 37% over SOC, L-Test improved 21%, FSST improved 19%, whereas 2MWT demonstrated equivalence. In the VLOSS condition, SCS improved 93%, L-Test improved 22%, FSST improved 25%, and 2MWT improved 26% with the Infinite socket compared with the SOC. The VGAIN condition could not be analyzed across all three data collections, as the patient was unable to don the prosthesis on the second and third collection due to pain and the inability to don the SOC prosthesis. All aggregated data (BASE, VLOSS, VGAIN), SCS improved 50%, L-Test improved 18%, 2MWT improved 21%, and 4SST improved 16% using the Infinite socket compared with SOC (Figure 2).

DISCUSSION

In this study, we simulated minimum volume fluctuations that have been reported to occur commonly among amputees during the acute and intermediate stage of rehabilitation. Generally, improvements with the Infinite socket were shown in the outcomes of SCS, mobility, and gait speed. These functional outcomes are predictive of falling. SCS, mobility, and gait speed should be a focus of interventions used in rehabilitation of the amputee. Preventing falls during the acute and intermediate stages of amputation rehabilitation should be a priority in minimizing adverse effects. Curtze et al. reported the annual fall incidence in lower limb amputees as approximately 50% (21,22). Injuries are sustained in 61% of falls, necessitating fall prevention strategies, such as improved socket interfaces, for the LE amputee (23). Falls in amputees can be mitigated with strength and gait training programs. However, to begin a strength and walking program, the use of an effective well-fit socket

interface is imperative. A prosthetic socket interface that accommodates an amputee's volume fluctuation, known to occur in the acute and intermediate stage of rehabilitation, could improve clinical outcomes and function. For instance, Schon et al. reported on the use of an ambulatory immediate post-operative prosthesis (IPOP) and found that none of the 19 patients had falls while wearing the IPOP. However, in the non-IPOP group, 12 of 23 patients had a total of 34 falls. Further, there were no revisions in the IPOP group, but eight patients in the non-IPOP group required 10 revisions to a higher amputation level, four of which were related to falls (24). Others have noted that interventions that could prevent secondary effects of falling in amputee rehabilitation would be beneficial, including prosthetic devices that better accommodate the acute phase when volume fluctuation is most prevalent (25–27). Evidence is not available comparing the efficacy of interventions addressing issues related to poor socket fit during the intermediate stage of rehabilitation in TFA patients. An adjustable TFA socket interface that better addresses the known problems of the SOC IRC socket interface could improve functional outcomes. Additional research is required to develop appropriate intervention strategies to ameliorate the risk of falling during amputee rehabilitation (28–31).

This case study compared the efficacy of an alternative TFA intervention for volume fluctuation. The socket is the most important element of the prosthesis. However, prosthetic fit in the TFA during volume fluctuations is problematic using the current SOC prosthetic socket interface. As the socket loses its fit quality, the user loses control and comfort, which eventually leads to pain, compromised function, reduction in use, and potentially prosthetic abandonment. The current SOC clinical procedure for volume management is the addition and subtraction of prosthetic socks of various ply to fill the void between RL and socket. Although common, this method is sub-optimal. An adjustable prosthetic socket is advantageous in assisting prosthetic users in managing common volume fluctuations. A socket with instant adjustability could be a valuable alternative to common volume management strategies and may help reduce adverse effects of prosthetic use due to poor volume management and socket fit (7,32–36).

Limitations

Case studies could provide insight into important variables that should be considered in a larger clinical trial, and their conclusions merit consideration in the development of future clinical trials. The outcome measures selected in this case showed a difference between the socket conditions. However, the strategy for simulating volume change and then comparing the different sockets may require reconsideration. In this case, the VLOSS condition was designed to simulate a situation where an amputee may not know, or have the option, to add a sock in a SOC socket. In the VGAIN condition, the subject was unable to don the SOC socket. The absence of these data points did not allow for comparison between sockets under this condition. In a larger funded clinical trial, using liners of different thickness to simulate volume gain and loss should be considered. Finally, as previously mentioned, the use of statistical analysis in case studies, while not novel, is also not widely accepted. Statistical significance in case reports should be interpreted with caution, as the findings of case reports are commonly regarded as non-generalizable.

CONCLUSION

A well-fit prosthetic socket interface is the most important aspect of a prosthesis. Volume fluctuation is a pervasive problem in a lower extremity amputee. This fluctuation can contribute to socket fitting issues and compromised function. The standard of care socket interface does not offer inherent adjustability. In this case study, the standard of care socket was inferior to the comparative adjustable TFA interface in subjective and performance outcomes. This case study demonstrates the need for a well-designed clinical trial using outcome measures comparing the efficacy of an adjustable prosthetic socket interface to the standard of care. There is a lack of clinical trials and evidence comparing socket functional outcomes related to volume fluctuation.

Acknowledgments

Contents of this manuscript represent the opinions of the authors and not necessarily those of the U.S. Department of Defense, U.S. Department of the Army, U.S. Department of Veterans Affairs, or any academic or health care institution. This project was partially funded by National Institutes of Health Scholars in Patient Oriented Research (SPOR) grant (1K30RR22270). Authors declare no conflicts of interest.

References

1. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch phys med Rehabil.* 2008; 89(3): 422–9. [PubMed: 18295618]
2. Limb Loss Statistics. Manassas (VA): Amputee Coalition; http://www.amputee-coalition.org/fact_sheets/amp_stats_cause.pdf [accessed 8 Aug 2016]
3. Highsmith MJ, Kahle JT, Miro R, Orendurff MS, Lewandowski A, Oriolla JJ, Sutton B, Ertl JP. Prosthetic interventions for transtibial amputees: a systematic review and meta-analysis of high quality, prospective literature and systematic reviews. *J Rehabil Res Dev.* 2016; 53(2):157–184. [PubMed: 27149143]
4. Torio, CM.; Andrews, RM. Statistical Brief #160. Rockville (MD): Healthcare Cost and Utilization Project; 2013. National inpatient hospital costs: the most expensive conditions by payer, 2011. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf> [accessed 8 Aug 2016]
5. Raichle KA, Hanley MA, Molton I, Kadel NJ, Campbell K, Phelps E, Ehde D, Smith DG. Prosthesis use in persons with lower- and upper-limb amputation. *J Rehabil Res Dev.* 2008; 45(7):961–72. [PubMed: 19165686]
6. Pasquina CP, Carvalho AJ, Sheehan TP. Ethics in rehabilitation: access to prosthetics and quality care following amputation. *AMA J Ethics.* 2015; 17(6):535–46. [PubMed: 26075981]
7. Sanders JE, Fatone S. Residual limb volume change: systematic review of measurement and management. *J Rehabil Res Dev.* 2011; 48(8):949–86. [PubMed: 22068373]
8. Fernie GR, Holliday PJ. Volume fluctuations in the residual limbs of lower limb amputees. *Arch Phys Med Rehabil.* 1982; 63(4):162–5. [PubMed: 7082139]
9. Roffman CE, Buchanan J, Allison GT. Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. *J Physiother.* 2014; 60(4):224–31. [PubMed: 25450484]
10. Mosadeghrad AM. Factors influencing healthcare service quality. *Int J Health Policy Manag.* 2014; 3(2):77–89. [PubMed: 25114946]
11. Limb Loss Task Force/Amputee Coalition. Roadmap for preventing limb loss in America: recommendations from the 2012 Limb Loss Task Force. Knoxville (TN): Amputee Coalition; 2012. http://www.amputee-coalition.org/wp-content/uploads/2014/09/Isp_Roadmap-for-limb-loss-Prevention-and-Amputee-Care-Improvement_241014-092312.pdf [accessed 8 Aug 2016]

12. Reiber GE, McFarland LV, Hubbard S, Maynard C, Blough DK, Gambel JM, Smith DG. Servicemembers and veterans with major traumatic limb loss from Vietnam war and OIF/OEF conflicts: survey methods, participants, and summary findings. *J Rehabil Res Dev.* 2010; 47(4): 275–97. [PubMed: 20803399]
13. Moore TJ, Barron J, Hutchinson F 3rd, Golden C, Ellis C, Humphries D. Prosthetic usage following major lower extremity amputation. *Clin Orthop Relat Res.* 1989; (238):219–24.
14. Gailey RS, McFarland LV, Cooper RA, Czerniecki J, Gambel JM, Hubbard S, Maynard C, Smith DG, Raya M, Reiber GE. Unilateral lower-limb loss: prosthetic device use and functional outcomes in servicemembers from Vietnam war and OIF/OEF conflicts. *J Rehabil Res Dev.* 2010; 47(4):317–31. [PubMed: 20803401]
15. Whitney SL, Marchetti GF, Morris LO, Sparto PJ. The reliability and validity of the Four Square Step Test for people with balance deficits secondary to a vestibular disorder. *Arch Phys Med Rehab.* 2007; 88(1):99–104.
16. Dite W, Connor HJ, Curtis HC. Clinical identification of multiple fall risk early after unilateral transtibial amputation. *Arch Phys Med Rehabil.* 2007; 88(1):109–14. [PubMed: 17207685]
17. Dite W, Temple VA. Development of a clinical measure of turning for older adults. *Am J Phys Med Rehabil.* 2002; 81(11):857–66. quiz 67–8. [PubMed: 12394998]
18. Montero-Odasso M, Schapira M, Soriano ER, Varela M, Kaplan R, Camera LA, Mayorga LM. Gait velocity as a single predictor of adverse events in healthy seniors aged 75 years and older. *J Gerontol A Biol Sci Med Sci.* 2005; 60(10):1304–9. [PubMed: 16282564]
19. Hanspal RS, Fisher K, Nieveen R. Prosthetic socket fit comfort score. *Disabil Rehabil.* 2003; 25(22):1278–80. [PubMed: 14617445]
20. Carson R, Stevens PM, Webster JB, Foreman KB. Using clinically relevant outcome measures to assess the ambulatory efficiency, balance confidence, and overall function associated with “stubby” prostheses and C-Leg prostheses for a patient with bilateral transfemoral prostheses. *J Prosthet Orthot.* 2010; 22:140–144.
21. Curtze C, Hof AL, Otten B, Postema K. Balance recovery after an evoked forward fall in unilateral transtibial amputees. *Gait Posture.* 2010; 32(3):336–41. [PubMed: 20609587]
22. Curtze C, Hof AL, Postema K, Otten B. The relative contributions of the prosthetic and sound limb to balance control in unilateral transtibial amputees. *Gait Posture.* 2012; 36(2):276–81. [PubMed: 22525420]
23. Yu WY, Hwang HF, Hu MH, Chen CY, Lin MR. Effects of fall injury type and discharge placement on mortality, hospitalization, falls, and ADL changes among older people in Taiwan. *Accid Anal Prev.* 2013; 50:887–94. [PubMed: 22878142]
24. Schon LC, Short KW, Soupiou O, Noll K, Rheinstein J. Benefits of early prosthetic management of transtibial amputees: a prospective clinical study of a prefabricated prosthesis. *Foot Ankle Int.* 2002; 23(6):509–14.
25. Gardner LA, Bray PJ, Finley E, Sterner C, Ignudo TL 3rd, Stauffer CL, Kincaid SA, Marella WM. Standardizing falls reporting: using data from adverse event reporting to drive quality improvement. *J Patient Saf.* 2015
26. Gardner MM, Buchner DM, Robertson MC, Campbell AJ. Practical implementation of an exercise-based falls prevention programme. *Age Ageing.* 2001; 30(1):77–83. [PubMed: 11322678]
27. Gardner MM, Robertson MC, Campbell AJ. Exercise in preventing falls and fall related injuries in older people: a review of randomised controlled trials. *Br J Sports Med.* 2000; 34(1):7–17. [PubMed: 10690444]
28. Pauley T, Devlin M, Heslin K. Falls sustained during inpatient rehabilitation after lower limb amputation: prevalence and predictors. *Am J Phys Med Rehabil.* 2006; 85(6):521–32. [PubMed: 16715022]
29. Vrieling AH, van Keeken HG, Schoppen T, Postema K. Gait adjustments in obstacle crossing, gait initiation and gait termination after a recent lower limb amputation. *Clinical Rehabil.* 2009; 23(7): 659–71.
30. Vanicek N, Strike S, McNaughton L, Polman R. Postural responses to dynamic perturbations in amputee fallers versus nonfallers: a comparative study with able-bodied subjects. *Arch Phys Med Rehabil.* 2009; 90(6):1018–25. [PubMed: 19480879]

31. Vanicek N, Strike S, McNaughton L, Polman R. Gait patterns in transtibial amputee fallers vs. non-fallers: biomechanical differences during level walking. *Gait Posture*. 2009; 29(3):415–20. [PubMed: 19071021]
32. Sanders JE, Rogers EL, Abrahamson DC. Assessment of residual-limb volume change using bioimpedence. *J Rehabil Res Dev*. 2007; 44(4):525–35. [PubMed: 18247249]
33. Sanders JE, Severance MR. Assessment technique for computer-aided manufactured sockets. *J Rehabil Res Dev*. 2011; 48(7):763–74. [PubMed: 21938663]
34. Kahle JT, Orriola JJ, Johnston WJ, Highsmith MJ. The effects of vacuum assisted suspension on residual limb physiology, wound healing, and function: a systematic review. *Technol Innov*. 2014; 15:331–41.
35. Kahle JT, Highsmith MJ. Transfemoral interfaces with vacuum assisted suspension comparison of skeletal kinematics, pressure and preference: ischial containment versus brimless. *J Rehabil Res Dev*. 2013; 50(9):1241–1252. [PubMed: 24458964]
36. Kahle JT. A case study using x-ray and fluoroscope to determine the vital elements of transfemoral interface design. *J Prosthet Orthot*. 2002; 14(3):121–6.

Figure 1. Interventions tested. Pictured left is the standard of care socket with the 5-ply sock and the pin system. Pictured right is the Infinite adjustable socket.

Figure 2.

Results for: Socket Comfort Score (SCS), 2-Minute Walk Test (2MWT), 4 Square Step Test (4SST), and L Test.

*Statistical significance $p < 0.05$, NT = not tested due to missing data.

Table 1

Table of Variables

Independent		Dependent		Controlled	
•	SOC- IRC TFA Interface	•	Subjective Response (i.e., Comfort, Pain)	•	Accommodation
•	LIM -Adjustable TFA Interface	•	Mobility, i.e., 4SST	•	Clinical Schedule
		•	Function, i.e., AMP	•	Environment
		•	Gait Speed, L-Test, 2MWT	•	Knee, Foot, Liner, Suspension