The LIM Innovations Infinite Socket: A Needs Finding Assessment Through Early Clinical Results of Patient Use and Satisfaction with a Dynamic Modular Socket System

Prosthetic Access and Acceptability Analysis: White Paper

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ABSTRACT

Introduction: In the United States (US) approximately 2 million people live with limb loss. An estimated 86 percent of these individuals have sustained lower limb loss, and approximately 18.5 percent are transfemoral amputees. In spite of this growing amputee population, there is limited data and analysis in the Orthotics and Prosthetics (O&P) industry, resulting in healthcare service gaps, excess hospital utilization, and increased cost to patients and providers alike. Improving the prosthetic fit for individuals with lower limb amputation is paramount for ensuring timely rehabilitative care and return to independence.

Background: Lower limb prostheses for amputees have significantly advanced in all respects except for the socket. Traditional prosthetic sockets are made using the same manufacturing process as those developed 50 years ago. LIM Innovations™ is a prosthetic research and development and manufacturing company, leading the evolution of prosthetic socket design, offering advanced technology solutions for lower limb amputees.

Methods: This narrative provides a comprehensive overview of the current prosthetic environment as well as the many pitfalls associated with current research and development and manufacturing techniques. Furthermore, a sample of n=35 Infinite Socket™ users ≥ 60 years of age, who had a signed HIPAA release were asked to participate in a survey regarding their novel LIM Innovation Infinite Socket. Subjects were initially contacted via email and/or phone to complete the survey. Thirteen respondents (37%) completed the 37-part questionnaire.

Results: Participants were reflective of the national average for lower limb amputees in the target age group. Seventy-seven percent were between the ages of 65-74; 92% were male; 69% had a BMI corresponding to being overweight or obese and 38% had an amputation due to a dysvascular condition or infection. Individuals were considered proficient users and had owned the Infinite Socket for 1-12 months; 50% acquired their Infinite socket in the past 3 months. More than 50% of the survey sample gave a score of 7 or higher on a scale 1 (low) to 10 (high) when asked to rate their Infinite socket in terms of overall improvement of comfort vs. their prior conventional socket. With the Infinite Socket, 33% of respondents reported discontinuing the use of assistive devices; 16% “wheelchair”, 8% “crutches” and 8% “cane.” Reported falls in the previous year fell 3-fold from 45% to 15% when conventional socket users transitioned to the Infinite Socket; 45% (1-7 times) vs. 15% (1-7 times). Significant improvement in quality of life scores were also reported; 9% with their old conventional socket vs. 83% with Infinite Socket. Almost 70% of respondents wear their Infinite Socket for ≥ 8 hours daily (range 1-2 hours – 17 hours).

Conclusions: In this survey, Infinite Socket users were satisfied with the product and many experienced improvements in comfort scores (higher), need for assistive devices (fewer), number of falls (fewer), quality of life scores (higher) and duration of use (longer).

Next Steps: A larger study examining a broader amputee population using validated survey metrics is needed to generalize these findings. In addition, external clinical review of the Infinite Socket must still be undertaken. Collaborations with academic, military, and rehabilitation institutions for extramural grant funding is currently underway.
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1. INTRODUCTION
In the United States (US) approximately 2 million people live with limb loss.\(^1\) Demographic projections estimate that by the year 2050, nearly 3.6 million Americans will be living with limb loss (1:144 persons).\(^1\) These high estimates have been due to vascular occlusive diseases, which have been known to cause approximately 82 percent of amputation surgeries\(^2\) and account for nearly 30,000 new cases annually.\(^3\) The rising incidence of amputations observed in the US is largely attributable to vascular disease and comorbid diabetes, the latter accounting for more than 60 percent of non-traumatic amputations in the United States today.\(^4\) Across all etiologies, approximately 42 percent of people living with limb loss are 65 years or older (n=665,000).\(^1\) As a result, amputation presents an ever-increasing challenge to our healthcare system.

1.1 Target Population - Lower Limb Amputees
As noted by the National Center for Health Statistics, of the 2 million American amputees, approximately 86 percent are individuals living with lower limb loss,\(^5\) and 18.5 percent are transfemoral amputees.\(^5\) A study by Dillingham et al. titled *Limb Amputation and Limb Deficiency: Epidemiology and Recent Trends in the United States*, corroborate these findings and demonstrated that there were 266,465 transfemoral amputations performed in the United States between 1988 and 1996 (the most recent years available),\(^6\) resulting in an average of 29,607 amputations annually.

In spite of this increasing amputee population, there is limited research and clinical data and subsequent analysis in the Orthotics and Prosthetics (O&P) industry, resulting in healthcare service gaps, excess hospital utilization, and increased cost to patients and payers alike. 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 US hospitals in 2011, with a total cost of more than $5.4 billion.\(^7\) The importance of "disability" in the US healthcare system is gaining attention from policy makers and through the Affordable Care Act (ACA). President Obama is committed “to increasing innovation and access to technology for Americans with disabilities.”\(^8\)
Amputee care is not the only sector of the healthcare industry struggling with limited knowledge and rising costs. Successes in other chronic disease areas (HIV or Parkinson’s), have helped identify potential models to improve the quality, efficiency, or health-related outcomes of care for chronically ill older individuals. These targeted efforts have incorporated integrated care, technology, and clinical best practices. In addition, the rapidly expanding proportion of the US population 65 years and older is anticipated to have a profound affect on healthcare expenditures. To highlight the potential impact of this growing population, Nehler et. al. (2003) conducted a study describing the rehabilitation outcomes of male veterans (median age 62), with amputations due to either critical limb ischemia or diabetes. At 17 months post-amputation, only 42% were using prosthetic limbs, and only 54% were ambulatory. The lack of prosthetic use and ability to ambulate after lower limb amputation may also cause serious implications for other chronic disease conditions that create further financial burdens to the healthcare system. To help address these financial impacts, solutions that prevent disability, or decrease the rates of functional disability, hold promise for reducing this burden.

1.2 Public Health Impact

In the US, access to appropriate rehabilitation and prosthetic care is still significantly limited. Geographical barriers, gender, age, socioeconomic position, race, education, and cost all contribute to healthcare disparities. Fundamental to the rehabilitative care and recovery for those that have lost limbs is the fit of their socket(s) and training to use their prostheses. However, the longevity of a conventional prosthetic socket varies from patient to patient due to its one-off fabricated process and activity of the individual.

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 require additional clinician time, replacement components, and possibly remaking the prosthesis altogether. 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. Successfully fitting the socket reduces this economic burden, and increases prosthetic usage. This increased prosthetic usage correlates with higher levels of employment, increased quality of life, decreased phantom limb pain, and lower levels of general psychiatric symptoms.
1.2.1 Prosthetic Use & Abandonment
Consistent prosthetic use reduces secondary health issues and provides a larger degree of mobility and functional independence for those with amputation. However, although socket fit is the biggest factor in achieving these benefits, the current prosthetic socket technology remains limited. Prosthetic abandonment is especially prevalent among users with an above the knee amputation with a short femur, resulting in psychological problems, reduced quality of life, and lack of community engagement. Chamlian et al. (2014), observed elevated abandonment rates (62.5%) and daily usage decrements (31-85%) following discharge from rehabilitation.

1.2.2 Rehabilitation & Reintegration Challenges
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 prosthesis are difficult. In fact, when creating the prosthesis, multiple attempts are often needed to improve tolerance and comfort. In current practice, traditional prosthetic services and fabrication require multiple office visits, plaster casts and molds, check sockets and final fittings, which means multiple trips to a clinical provider. Further complicating this process, the residual limb naturally goes through a period of volume fluctuation post amputation that impacts fit. These fluctuations require an iterative process involving numerous trips to the prosthetist for adjustments to the socket. Poor fit compounded with a lack of at home options to make adjustments may subsequently lead to abandonment of a prosthesis, or reliance on assistive devices until a person can access their next clinical visit. Missed opportunities for continued prosthetic use directly impacts care, health outcomes and sustained mobility. Long-term medical conditions such as hypertension, diabetes, kidney disease, and weight loss/gain exacerbate this problem as well.

In addition to addressing the clinical challenges regarding prosthetic adjustments, methods for amputee care integration into the healthcare continuum is also garnering attention. As noted by Stanton and Rutherford, 5 percent of the population accounts for almost half (49 percent) of total healthcare expenses. Furthermore, patients with multiple chronic conditions cost up to 7 times as much as patients with only one chronic condition. The prosthetic industry status quo is complicated and difficult to describe given lower limb amputation complexities, the lack of structure paradigms, a historically underserved population, and a long-standing clinical culture of outdated models of care and techniques. In fact, Democratic House member Ed Pastor
recently proclaimed, “access to basic quality healthcare is one of the most important domestic issues facing our nation.” National efforts should be focused on providing more integrated care with improved quality and at lower cost.

1.2.3 Financial Burden of Amputation
Healthcare costs surrounding major surgery and recovery for an amputee have larger financial implications that linger beyond the initial surgical procedure. The costs related to amputation, prosthesis, and rehabilitation can be roughly divided into two categories: (1) those directly associated with the amputation event or surgery (including rehabilitation care, prosthetic fitting, and adjustment of devices) and (2) indirectly associated costs (including those for secondary health complications and their treatment).

- On average, the individual two-year total cost of amputation exceeds $90,000\textsuperscript{25}
- Rehabilitation care, fitting of prostheses, and adjustment of devices alone were the fifteenth most expensive condition treated in US hospitals in 2011, with a total cost of more than $5.4 billion for these services\textsuperscript{7,26}
- Hospital charges for amputation procedures amounted to more than $8.3 billion in 2009, not including prosthetic or rehabilitation costs\textsuperscript{27}
- Based on the statistics available, direct and indirect health costs as a result of amputation could easily exceed $1 million for an individual before accounting for any loss of wages or salary due to an inability to work\textsuperscript{28}

It has been estimated that the total average lifetime expenditures for amputation patients are approximately $509,275.\textsuperscript{29} These costs include rehabilitation, physical therapy and the use of prosthetic devices. Age and the current health status of the amputee may increase these cost impacts as well. For example, a younger more active patient will cost the healthcare system 2 times the amount of an older amputee.\textsuperscript{29}

- $427,457 for an 18-year-old patient
- $350,465 for a 40-year-old patient
- $236,059 for a 63-year-old patient
1.2.4 New Prosthesis and Lifetime Costs

The price of a new prosthetic leg (socket plus distal components) ranges from $15,000 to over $50,000.\textsuperscript{13,29} For patients with health insurance, out-of-pocket costs typically consist of doctor visit copays and coinsurance of 10%-50%.\textsuperscript{30} Many types of prosthetics are typically covered by health insurance, but the particular device depends on the individual patient's amputation level, clinical condition and functional needs. For patients without health insurance, the entire cost of the prosthesis must be paid out of pocket. Traditional custom-molded socket fabrication is a particular challenge because it involves a handcrafted procedure, bearing arbitrary standard of quality and reimbursement.

Lifetime costs for young amputees (assuming 42.8 years of remaining life, and a frequency of prosthetic purchase of every 2.3 years after their first definitive prosthesis) yields an expected purchase of 17.4 complete prosthetic systems (a full leg consisting of socket and distal components) over the course of their lifetime.\textsuperscript{29} Using an average prosthetic socket cost of $10,232, and multiplying it by the expected number of purchases yields an anticipated individual lifetime cost of $178,036 on the healthcare system. This is especially relevant when considering military service members who tend to be younger, require more prosthetic limbs and receive full medical benefits. For civilians, the prosthetic maintenance costs are assumed to be 20% of the prosthetic cost, for an additional $83,490 in expenses.\textsuperscript{29}

Currently there are no set guidelines dictating how to control the quality of custom fabricated devices. This is particularly true for the longevity of the socket; currently a traditional custom-molded rigid device that does not accommodate the dynamic changes of the body over time. Outside of O&P, new reimbursement models already exist in the US healthcare system that cater to large organizations, coordinated and standardized care, and the bundling of payments.\textsuperscript{31} Soon enough, these models will become a significant presence in the O&P sphere as well with the expansion of the ACA. “O&P practice owners need to quickly get their heads out of the sand and realize the whole healthcare world is changing around them,”\textsuperscript{31} stated Mark Ford, Director of Business Development for OPIE Software. The move to coordinated and integrated care models will be a key cost savings component, while rendering care that is appropriate, safe, and timely.
LIM Innovations™ has approached these clinical and reimbursement considerations in a redefining way. We have addressed these ubiquitous healthcare challenges and transformed them into an industry developing opportunity, leveraging our team’s clinical, engineering and public health backgrounds. LIM Innovations has created a custom-molded, dynamic, modular and adjustable prosthetic socket utilizing modern technology, computer-aided manufacturing methods, and image capture software. This is the first commercially available product of its kind. Our overarching goal is to institute more efficient prosthetics services within the integrated care models that focus on a team centered rehabilitation approach to treat an amputee. Each member of the amputee rehabilitation team will play a specific and important role in the care and recovery of the person with limb loss. An adjustable modular socket design is a new tool for the patient, similar to home-based glucose monitoring. This enables patients to adjust their socket and therefore play an equally significant role in the management of their lifelong disability.

2. BACKGROUND
LIM Innovations is a prosthetic research and development and manufacturing company based in San Francisco, CA. Our mission is to lead the evolution of prosthetic socket design, and offer these advanced technology solutions for users and clinical providers. Dr. Andrew Pedtke, MD, and Garrett Hurley, CPO founded LIM Innovations in 2012. These individuals developed a mission statement to empower amputees to achieve a higher quality of life. LIM’s core tenet, “function with purpose,” begins with understanding critical technology gaps for amputees, and addressing them with advanced technical solutions, materials, and design advantages for improved physical function.

LIM’s vision is to advance outcome-based measures, prosthetic socket standards, and amputee care models through improved technology solutions and efficient access to care. LIM’s approach has been to understand the foundational landscape in prosthetics, evaluate the unmet needs, and provide technology solutions with new care models. The foundation for LIM began with a realization that current prosthetic socket designs restrict amputees from living a more functional and liberated life.
2.1 The Unmet Need in Prosthetics

Lower limb prostheses for amputees have significantly advanced in all respects except for the socket. Traditional prosthetic socket technology and methods have seen little advancement in the past 50 years, while distal components have developed rapidly. In fact, less than 50% of amputees wear their prosthesis regularly, and the primary cause of prosthetic abandonment is due to socket discomfort. The inability for conventional sockets to respond to the daily needs of amputees leads to short-term and long-term consequences. The majority of users require multiple replacement sockets per year, costing upwards of $30,000. In severe cases, users are forced to undergo revisions of their amputation. This cyclic process creates not only financial burdens to amputees and the healthcare system, but also reflects the fragmentation of the care continuum and the lack of coordinated efforts to ensure appropriate access to medical care.

2.1.1 Access to Care

Following amputation, definitive treatment and rehabilitation requires a large, multidisciplinary team to provide comprehensive medical and supportive care. Associated injuries are frequent, thereby complicating treatment plans and delaying rehabilitation outcomes research. Patient and family psychosocial issues must also be evaluated and addressed.

Currently, individualized prosthetic rehabilitation initiates shortly after the amputation, with the treating physician and prosthetist evaluating the patient's medical history and expectations during surgical recovery. The immediate prosthesis phase, or the time required to heal a wound and attain readiness for a preparatory prosthesis, varies dramatically, from as short as 3 weeks to as long as 4 months. The associated delays of multiple appointments with numerous specialists, coupled with inherent latency in the transfer of medical information, such as chart notes and evaluations, delay the receipt of a prosthesis.

2.1.2 Fragmented Continuum of Care

Anyone seeking post-surgical services understands the frustrations of dealing with a fragmented healthcare system. The coordination of physical therapy, prosthetics, insurance, and other in and outpatient medical appointments often overwhelm and isolate new amputees. Interventions to address these secondary conditions and improve the health and outcomes of people with disability should focus on the integration of standard medical treatments, such as medication or physical rehabilitation therapies. In fact, Stineman et al. compared outcomes between lower-
extremity amputees who received and did not receive acute postoperative inpatient rehabilitation within a large integrated healthcare delivery system. After reducing selection bias, the investigators found that patients who received acute postoperative inpatient rehabilitation compared to those with no evidence of inpatient rehabilitation had an increased 1-year survival. These results illustrate that an integrated model of care may positively impact amputee care.

Following lower limb amputation many patients are unaware of the treatment options and prosthetic alternatives available to them. Through conversations with LIM Innovations clients, our team discovered that many patients were not adequately informed by their healthcare providers about the rehabilitation and prosthetics process. In fact, several indicated that their prosthetist was the one choosing their socket and components for them, at times with little or no discussion. Individuals expected to return to a “normal” life following their amputation, wherein this goal serves as a primary rehabilitative motivator. It has become evident that patient information and discussions should be an important part of the rehabilitation process before, as well as during rehabilitation, to help shape realistic expectations.

2.1.3 Poor Functional Outcomes
Long-term functional use of a prosthesis following discharge from the hospital is important for ensuring high quality of life for lower limb amputees. Limited research exists on long-term outcomes in relation to prostheses following discharge from rehabilitation. In particular, there is a lack of objective evidence to guide clinical decisions and many individuals with limb loss have noted that it takes far longer to adjust to a new prosthesis than they had expected. At this time, there is no standard accommodation time for sockets, liners, knees, or feet.

2.1.4 Lack of Standardized Metrics & Evidence-based Medicine
Over the past 20 years, more than 25 different healthcare indicators have been used as primary outcome measures, however, no single set of measures has emerged as being universally appropriate for prosthetic care. This lack of a standardized set of metrics has not allowed the O&P industry to optimize decision-making by emphasizing the use of evidence from well-designed and conducted research. While prosthetic technology advances, if the provision of care remains as isolated silos, gaps in communication will continue to exist. One solution to address the lack of communication is to explore the use of integrated care models. Furthermore,
many physicians currently responsible for overall patient care and conducting clinical research are not fully integrated into an amputee’s prosthetic care and decision-making. To truly drive evidence-based medical decision-making, a standardized set of universally accepted outcome metrics will need to be created, evaluated and accepted.

Prosthetic prescription for patients with lower-limb amputation is primarily based on empirical knowledge and experience from the physicians, therapists, and prosthetists.\(^\text{38}\) To our knowledge, no scientifically based guidelines for lower-limb prosthetic prescription exist. In depth conversations between the physiatrist, amputee and prosthetist provide a great opportunity for the patient to request access to new technology and to discuss treatment plan options. Furthermore, it would also establish a precedent with the payer for standardizing coordinated and medically justified prosthetic care.\(^\text{38}\)

2.1.5 Critical Need: Volume Management
Residual limb (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.\(^\text{19}\) With respect to amputees, it has been shown that limb volume decreases by 17-35% over the first 160 days post-amputation, 7-10% in the 12 month postoperative period and approximately 2% on a daily basis thereafter.\(^\text{19,21}\) In addition, chronic volume change may continue for up to 12-18 months post-amputation due to tissue atrophy and indefinite diurnal volume fluctuations occur. Poor volume management can result in a variety of secondary adverse effects of prosthetic use including ulcers, verrucous hyperplasia, and osteomyelitis.\(^\text{19}\) These effects may lead to further amputation and re-hospitalization, which contributes to the annual $8 billion expenditure on amputee hospital care.\(^\text{27}\)

Traditional rigid sockets do not accommodate volume fluctuations, and poor fit can cause skin ulcerations, infection, and may potentially lead to revision amputation.\(^\text{14,39}\) Furthermore, socket discomfort is common among lower-limb amputees and may delay prosthetic use, prevent return to normal function, compromise patient outcomes and increase healthcare costs. Medical literature cites that the primary cause for failure of amputee prostheses is user dissatisfaction associated with poor socket fit and comfort.\(^\text{3,20,23,32}\) In addition to the unmet need in addressing comfort, there is a significant technology gap in the area of socket fabrication and access.
2.2 Lack of Existing Clinical Data

An important basis for optimal acute and long-term management of amputees is an in-depth understanding of the patient and the functional consequences of the amputation. A systemic and detailed consideration of the patient and their environment, as well as sound objectives and functional outcome measures are important to obtain. Establishing prosthetic socket effectiveness guidelines will provide a much needed tool to deliver the best prosthetic care to individuals who have sustained lower limb extremity loss.

Two surveys conducted in 1991 and 2009 polled amputees on the information and education they received prior to their amputations. In 1991, 53% of respondents said that they received little to no prosthetic information, and in 2009, 59% of respondents answered ‘no prior information’. Despite the passage of nearly two decades, these sample populations indicate that patient education has not improved enough to address the well-being of 185,000 new amputees each year in the US. Informed patients understand expectations regarding their surgery, recovery, prosthesis fitting, and rehabilitation process. Implementing a continuum of care model for amputees would promote a consolidated system for patients and providers alike.

Condie et. al. conducted a systematic review of outcome measures used for lower limb prosthetics between 1995 and 2005. Their results showed a multitude of measures; however, there was no agreement on a gold standard. In fact, their review of 28 articles demonstrated 25 primary outcome measures, with none emerging as universally appropriate. In addition, the authors themselves noted that there was little agreement regarding when to capture and use this information.

2.2.1 Challenges in Conducting Outcomes Studies

The majority of prosthetic outcome trials attempt to standardize socket fit by using the phrase "socket fit and alignment were verified by a certified prosthetist." While this has become the common solution to this difficult problem, it does not address the underlying issue. Currently, there is no validated comprehensive measurement tool to assess the fit and comfort of an individual’s prosthetic socket.

In a 2006 publication, Douglas Smith identified six issues that highlight the challenges in conducting outcome studies in amputee populations. These six complications preclude the
isolation and measurement of specific study variables and prohibit the definitive conclusions that can be drawn from the collected data.\textsuperscript{36}

1. Lack of a valid and reliable tool(s) to document socket fit and comfort
2. Variability in day-to-day activity level in lower limb amputees using prosthetic devices
3. No set standard for defining and measuring accommodation time to new prosthesis
4. Impact of co-morbidities on outcomes of interest
5. Question fatigue for research participants
6. Small research populations and duration of study designs

To date, the most widely used outcome metric related to prosthetic sockets is Hanspal’s Socket Comfort Score (SCS).\textsuperscript{42} The challenge is that it only provides general information on a patient’s socket comfort and does not provide specific indications regarding effectiveness. This tool cannot accurately assess the day-to-day variation in functional activity, walking ability, walking symmetry and forces, which are difficult to measure.\textsuperscript{36} The wide range of functional impairment may impact prosthetic and orthotic intervention, and affect the integrity of clinical research.

\textit{2.2.2 Mitigating Selection Bias}

It remains unlikely that a large prosthetic socket randomized clinical trial will be conducted due to the custom nature of the devices, and the associated costs and time commitments required. Due to the small number of research eligible amputees, selection bias and hidden motives (i.e. some study subjects may only seek to participate in research as a mechanism to obtain technology driven prosthetic devices that are unattainable to them through their current health insurance) are unavoidable problems. Furthermore, to maintain adequate sample numbers, subject selection by the research team may lead to selecting subjects who are not likely to get sick, move, or have dramatic changes in their health or social situations. This may cause researchers to create a study sample that may not be reflective of the larger lower limb amputee population.

\textit{2.3 The Bigger Picture}

Over the past several decades, the US government has funded the development of model systems of care for complex debilitating disorders, such as spinal cord injury, traumatic brain injury, and post-traumatic stress disorder, that have demonstrated encouraging results in their
ability to influence and improve care.\textsuperscript{27} It is apparent that the development, implementation and evaluation of such a framework would have substantial benefits post-amputation. Consider how this could have benefited traumatic amputee veterans who are transitioning from the military to civilian life after injuries sustained in the Iraq and Afghanistan conflicts.

There remains a large discrepancy between people who have functional prosthetics and mobility, and those who abandon or do not have access to prosthetic limbs. This is especially concerning because amputees experience significant emotional ramifications following limb loss and require support from one part of the continuum to the next. In addition, healthcare is characterized as multiple practitioners, specialists and complex organizational structures, created around the needs of professional groups and insurance companies, rather than the needs of patients.\textsuperscript{43} The consequence is consumer frustration, escalating costs, and recognition by many providers that there has to be a better way of organizing care.

Formal clinical knowledge has considerable gaps concerning the effects of different prosthetic components and their mechanical characteristics on human functioning with lower limb prostheses. The lack of standardization and inconsistent data collection procedures limit precise market data for prosthetics. A number of studies\textsuperscript{3,12,13,14,17,20,23} have attempted to identify variables that explain inconsistent use rates and identify persons less likely to wear and benefit from prosthesis, however information remains limited. Therefore, with regard to prosthetic guideline development, the O&P industry must still largely rely on clinical consensus among experts until a gold standard of specific metrics is defined and universally accepted.

LIM Innovations is attempting to bridge the prosthetic socket technology, research and integrated comprehensive amputee care gap by providing novel technology with metric-based outcome measures. Our approach to product development focuses on the human to technology interface, residual limb volume change, usability, and early return to function. We leverage our team’s knowledge base to create and redefine the model of integrated amputee care. Most importantly, LIM Innovations is emphasizing the critical need of “volume management.” We accomplish this by deconstructing the prosthetic socket into its functional components to address this unmet issue in modern prosthetic designs.
3. TECHNOLOGY

The Infinite Socket™ is the first custom-molded, dynamic, and modular prosthetic socket. It is engineered to maintain an optimal fit for the user by accommodating volume and shape change of the residual limb. LIM Innovations has set out to improve amputee satisfaction and the standard of care by providing a socket that can adjust in size, shape, alignment, suspension system and tension. Digital software allows for a custom molded carbon fiber frame, and advanced textiles to create a socket that can be adjusted by users. Clinician’s benefit by using a custom fabricated device for each patient and having the ability to make large-scale volume and shape changes to the prosthetic socket in response to the changes to the user’s residual limb. In fact, the Infinite Socket decreases clinical time by an estimated 75% compared to conventional sockets using modern methods of manufacturing.44 Users can acquire a socket three times faster, thereby improving their quality of life and reducing the potential for comorbidities. An optimal fit can be achieved during the first appointment thereby reducing the number of sockets needed in the postoperative phase.

3.1 LIM Innovations Infinite Socket

The LIM Innovations Infinite Socket was created to address fundamental unmet needs of the prosthetics health care community that LIM identified through in-depth conversations with patients, O&P clinicians, and other amputee care stakeholders. The five major identified needs were: (1) addressing dynamic physical changes, (2) improving satisfaction, (3) streamlining access to care, (4) comfort/wearability focused design and materials, and (5) the ability for the clinician to maximize patient care time. The lack of validated tools for collecting and measuring data also proved to be a challenge when attempting to translate R&D into reliable data sets.

In addition to tacking the needs identified above, there are several definitive functions that a socket needs to accomplish in order to provide adequate ambulatory support: pressure distribution, biomechanical control, suspension, and alignment.45 The Infinite Socket achieves all of these by ensuring appropriate pressure distribution through multiple components, which include an ischial seat, proximal brim, four struts, and a custom-formed flexible inner cup.

These components can be configured in a way to produce different load distributions based on a patient’s needs. For example, some patients need significant ischial load bearing while others bear more on the struts and brim. Biomechanical control, or proper containment, is achieved
using the brim, struts, flexible inner, and ischial seat. Suspension is achieved using roll on gel liners (pin lock, seal-in suction, and elevated vacuum). Alignment modifications can be incorporated into the positive impression or adjusted via the base plate and pyramid adapters. The socket integrates with distal hardware with the standard 36mm threaded adaptor or the M6 four-hole configuration.

3.1.1 Framing the Infinite Socket: Base Plate & Struts

The base plate of the Infinite Socket is the foundation of the prosthesis, and is machined from 7075-t6-aluminum alloy, often referred to as military grade aluminum. This material is optimal for prosthetic application given its strength to weight ratio, which reduces the amount of effort needed for ambulation.

The struts, suspension unit, and distal componentry of the Infinite Socket are all tied together using the base plate (Figure 1). The components also slide in and out radially, and pivot circumferentially to address differences in patient anatomy at the time of fitting and over the course of use.

The radial slots of the base plate are positioned so that the strut placement is functional and comfortable for the amputee. The components were designed using anatomic assessment, foundational understanding of prosthetic socket contact weight bearing, and empirical user testing. Strut locations are posterior-medial, anterior-medial, anterior-lateral, and posterior-lateral to match spaces between the adductor, quadriceps and hamstrings muscle groups.
The respective angles between these struts are 110, 90, 70, and 90 degrees with the largest separation located between the posterior medial and anterior medial struts and the smallest spacing on the lateral aspect. Base plates are left and right specific and sized. They also have built in flexion and positional offset for the distal componentry. The options for flexion angles are 0, 5, 10, and 15 degrees (Figure 2). The amount of built-in offset is specific to each flexion angle, and is designed to ensure loading is underneath the patient’s body.

3.1.2. Use of Carbon Fiber & Thermoplastic Acrylic

The carbon fiber used in the Infinite Socket is 0-90 twill weave carbon in a thermoplastic acrylic (PMMA) matrix. Traditional carbon fibers are made with a thermoset resin or a thermoset acrylic. The key distinction between these acrylics is that the thermoset cannot be heated and reformed while the thermoplastic can be remodeled. Specific stiffness can also be achieved by using 7 ply carbon fiber sheets in the layup. Since the struts can be reformed when using the Infinite Socket, it gives the prosthetist the option to make some onsite modifications to the shape of the struts. Lastly, the struts are subject to a large bending moment at the distal end where they are fastened to the base plate. At this location they are reinforced with fully hardened 301 stainless steel metal cladding on the inside and outside of the strut. To ensure maximum reinforcement, the metal cladding is riveted and bonded together using an industrial strength adhesive, Loctite H8000.

3.1.3 Ischial Ramus Containment

The ischial seat is affixed to the top of the posterior-medial strut, which is positioned to fall underneath the ischium. A toothed mechanism between the seat and locking mechanism has been designed to allow for telescoping of up to 25 mm (Figures 1 & 2). This also gives the prosthetist the option of onsite adjustment to the socket and affords more flexibility than conventional prosthetic limbs. The ischial strut is formed purposefully in a way that angles the seat toward the body, and helps engage under the patient ischium.
True ischial containment is one of the most subjective components of an above the knee socket design. A conservative text book description includes: (1) maintenance of normal femoral adduction and narrow based gait, (2) enclosure of ischial tuberosity and ramus in the socket creating a “bony lock”, (3) maximal effort to distribute forces along the femur shaft, and (4) use of suction suspension whenever possible. However, our review of the clinical literature and empirical testing has discovered significant inconsistencies in the language of ischial containment which led us to conclude that this applies to design theory rather than any biomechanical standardization.

3.1.4 Biomechanical Control

Traditional interface designs have largely focused on tissue containment of the encapsulated limb and establishing stability via anatomical contouring in the areas of the interface closest to the proximal joint of the affected limb. Firm control of the shaft of the underlying bone of the encapsulated limb has either been wholly ignored or given only a cursory examination at best. Indeed, for many socket designs, there still remains a question whether the skeletal structure can be controlled at all. At this time, there is no true understanding of the clinical benefit of skeletal control for various patient indications.

The base plate, carbon fiber struts and ischial seat of the Infinite Socket are fastened together to form the frame and capture the shape of a patient’s limb. This is the basis for biomechanical control. Affixed to the frame are the brim, strut sleeves, and flexible inner. A unique feature of the Infinite Socket is that it uses a tensioning system to dynamically vary the pressure applied by the brim and struts, and increase the seat engagement to better account for limb volume fluctuations (Figure 3). By utilizing the tensioning system, the patient can dynamically vary the...

Figure 3: Infinite Socket Soft Goods
pressure applied by the brim and struts, and increase the seat engagement. Subsequently, as the compressed tissue’s density increases, so too does its ability—when trapped between the target bone and the interface wall—to provide a counterforce to unwanted skeletal motion.\textsuperscript{49,50} This reduces skin breakdown, risk for infection and ensures that the amputee is ambulatory.

Our theory around biomechanical control is that it may fluctuate in micro and macro circumstances. Currently, limited biomechanical knowledge, as well as the associated technology to assess the socket environment in a comprehensive fashion, has inhibited rapid interface advancement.\textsuperscript{47} As a result, our socket was designed to allow the socket user to dictate the required amount of biomechanical control (Figure 3).

The brim and struts are composed of layered internal structural plastic, intermediate foam, and outer layer of textiles (Figure 3). The inner layer of plastic provides rigidity to these components, the foam creates comfort, and the outer textile layer has a low coefficient of friction and is antimicrobial and anti-fungal.

3.1.5 Suspension & Proprioception
Control is a critical requirement for individuals with limb loss and the prosthetic limb requires a robust suspension system. Improper suspension results in poor gait, decreased safety and increased chance of skin irritation and other complications.\textsuperscript{45} Secure and dependable suspension enhances proprioception (awareness of the movement and position of the body and its parts), and is the system that gives a patient an optimal connection between the socket and limb.\textsuperscript{45} In the Infinite Socket, the suspension unit is attached to the base plate and inside of the struts (Figures 1 & 3). Both mechanical locking and suction are offered. The latter offers the greatest socket strength against compressive forces during gait. To form the suction suspension, an air valve is embedded into the flexible inner. The chosen suspension system is based primarily on patient preference given prior experience and/or discussion with one’s clinician on potential optimal suspension indications.

Excessive translation, rotation, and vertical movements between the residual limb and socket should be prevented through the suspension system.\textsuperscript{51,52,53} A number of prosthetic suspension systems are available for lower or upper limb amputees.\textsuperscript{51,54} Suspension systems mostly have two parts; namely, soft liner and lock system, which link them to the rest of the prosthetic
components. Objective and subjective studies have shown improved suspension with the use of silicone liners, most probably due to the firm union between the socket and the residual limb that is created by the liner. However, based on the literature, no standard suspension system exists that satisfy the needs of all amputees.

### 3.1.6 Fabrication & Customization

When a healthcare provider orders an Infinite Socket, it is assembled and made to specific specifications on-site at the LIM Innovations headquarters. The process starts by analyzing patient data submitted by the clinician in the form of cast wraps, measurements, and/or images. A positive mold is created with the appropriate clinical modifications. Thermoplastic carbon fiber struts are formed to the modified positive and struts are cut to length specific to the user’s needs and assembled to the base appropriate for the user. The flexible inner is formed over a positive; accounting for the thickness variation caused by the flexible inner. The strut sleeves are cut to a specified length, donned on the struts, which are bolted to the base plate. The specific brim is modified as needed. Lastly, the seat is installed. The socket is inspected for quality, the dimensions are verified to match the strut height, inter-strut distance, and seat height.

### 3.2 Pre-commercialization Process

Most prosthetic sockets are fabricated and custom-made in-house at the prosthetist's office. Due to the boutique craftsman-like model of this industry, devices are not subjected to any set of standards or external testing. LIM Innovations has sought to introduce standardization to the prosthetic socket industry with the launch of the Infinite Socket. Preliminary steps are outlined below.

#### 3.2.1 FDA Class I Device Registration

Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the Food & Drug Administration (FDA). LIM Innovations submitted paperwork to the FDA for the Infinite Socket on May 16, 2014 as a Class I Medical device. Registration information is reviewed and updated annually. To the best of our knowledge we are one of the few (if not the only) prosthetic socket manufacturer registered with the FDA.

Registration # 3010900475; Registration Description: External limb prosthetic component; Submission Type: 510(K) Exempt
3.2.2 ISO 10328 Testing

The integrity of the Infinite Socket was verified using biomechanical testing to ensure ISO10328 testing standards were achieved. This required maintaining a 2240N static load and ultimate strength of 4480N. The Infinite Socket was also subjected to compression testing using a servo-hydraulic testing machine for adult users in categories: P3 (< 60 kg/132 lb.), P4 (< 80 kg/176 lb.), and P5 (over 100 kg/200 lb.). BAE Systems, Santa Clara, California, conducted all testing in March of 2014.

Test results shown below illustrate that the Infinite Socket exceeds the standard for both proof strength P5(I) (2240N) and ultimate strength P5(I) (4480N) (Figure 4).

Figure 4: Infinite Socket ISO Testing Results

3.2.3 Conformite Europeenne (CE) European Conformity Mark

In addition to completing the US based approvals above, LIM Innovations was approved on June 19, 2015 to distribute the Infinite Socket in international and European markets. The CE marking indicates our compliance with EU legislation for prosthetic products, wherever in the world manufactured, and enables its free movement within the European market. By affixing the CE marking on our product, LIM Innovations declares conformity with all of the legal requirements and affirms that the product conforms with all EU directives or EU regulations that apply to it.

Reg# NL-CA002-2015-33482; Article 14 of the Medical Devices Directive, 93/42/EEC
3.2.4 Patient Profile Testing (Internal)

Preliminary prototypes of the transfemoral (TF) and knee disarticulation (KD) Infinite Socket were tested by the LIM Innovations team (Table 1). Five male subjects were selected with a median age of 34 years (23-52). They were approximately 5’10” (5’8” – 6’1”) tall, and tested the device up to a weight of 250 pounds. They were all very active with a K-level of 4. The reasons for amputation included traumatic event, cancer, and infection (no dysvascular complication or congenital amputees worked for LIM at this time). Residual limb length, shape and size varied and allowed LIM to test the device under different conditions.

<table>
<thead>
<tr>
<th>Table 1: Internal Tester Profiles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Height</td>
</tr>
<tr>
<td>Weight</td>
</tr>
<tr>
<td>BMI</td>
</tr>
<tr>
<td>Activity K Level</td>
</tr>
<tr>
<td>Amputation</td>
</tr>
<tr>
<td>Socket Type</td>
</tr>
</tbody>
</table>

Internal test users were evaluated and fit for their Infinite Socket by a certified prosthetist specifically trained on how to fit and adjust this device. Once securely fit in their socket, each individual was asked to complete the following set of tasks. Testers only progress to the next task if they successfully complete the prior task.

- **Task 1: Parallel Bars**
  In the clinician’s office, walk down and back 10 times in between a standard set of parallel bar (18 feet one way, 36 feet each set).
- **Task 2: Hallway**
  In the clinician’s office, walk down and back 10 times on a flat, carpeted surface, such as an open hallway or room (47 feet one way, 94 feet each set)
• Task 3: Uneven Surfaces & Outdoors
  Under clinician observation, walk outdoors on a variety of surfaces (pavement, gravel, grass etc.) under different terrains.

• Task 4: Daily Activities
  Amputee wears the socket and records any issues while wearing it during the course of their daily activities. Since all 5 of our users were highly active, these activities could range from walking long distances (>15min) to hiking, bike riding etc.

Qualitative data in the form of user feedback was collected in the weeks following their Infinite Socket use. Each user subjected their socket to real life, high impact, daily use. No catastrophic failures or major falls were reported. Overall, internal testers were highly satisfied with their Infinite Socket and all 5 continue to wear their socket as their prime prosthetic interface for daily activities.

3.3 Commercialization & Clinician Training
To successfully launch the Infinite Socket, LIM Innovations has incorporated education and hands on technical training with physicians and patients. LIM Innovations holds strict safety standards, and a clinician must complete the corporate clinical training process in order to offer the Infinite Socket to users. This training is composed of: (1) a 2-4 hour didactic training session in which the clinician must successfully pass the LIM Clinical Training Exam, a 23 question exam composed of both multiple choice and true/false questions, (2) the clinician receives in-person fitting assistance on their first two candidates provided by the LIM Innovations Clinical Team.

Our Clinical Specialist (CS) team is composed of American Board of Certification (ABC) certified prosthetists that cover designated regions across the country. CSs are critical for ensuring that users and clinicians receive the best fit and experience. Furthermore, the first two client fittings are used as the basis for the hands on in-person LIM Training. These two fittings typically require 4 hours to complete. In addition, ABC provides 8 Continuing Education Units (CEU) to clinicians that complete the LIM Clinical Training Process.
4. METHODS
The O&P industry has undergone drastic changes and experienced exponential growth in the quality of prosthetics on the market due to advancements in technology. Novel materials and design principles make prosthetic devices lighter, stronger, cheaper, and customizable to the user. LIM Innovations has taken advantage of these technology advancements and established common product definitions with comparable outcome measures in order to rebalance the cost – quality equation. To evaluate clinical indicators through patient use of the Infinite Socket, we have conducted a survey via follow-up phone calls with Infinite Socket users ≥ 60 years of age in September of 2015.

4.1 Participants
A sample of n=35 Infinite Socket users ≥ 60 years of age, who had signed a HIPAA release allowing members from LIM Innovations to contact them, were identified as eligible for contact for this survey. Study participants were contacted via email and the survey administered over the phone. Thirteen subjects (37%) completed the 37-part questionnaire. Our survey response rate is in line with results from other email-based survey response rates.57

4.2 Data Acquisition
Outcome indicators of interest and user satisfaction questions were assessed using the LIM Innovations Marketing Research Survey (Appendix A). Data was collected with quantitative and qualitative questions designed by the LIM Innovations Research and Marketing Departments, and many questions were based on ones from validated survey tools. Simple frequencies and descriptive statistics are reported below. The information collected in this survey will be used to make targeted marketing materials and product improvement decisions. A larger sampling of all LIM Innovations Infinite Socket users will be conducted in the fourth quarter of 2015.
5. RESULTS

5.1 Demographics

Table 2: Eligible Amputees & Survey Respondents

<table>
<thead>
<tr>
<th>Eligible (N = 35)</th>
<th>Participant (N = 13)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>#</td>
</tr>
<tr>
<td>60-64</td>
<td>9</td>
</tr>
<tr>
<td>65-69</td>
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<tr>
<td>85-90</td>
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<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>31</td>
<td>89%</td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
<td>11%</td>
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</table>

<table>
<thead>
<tr>
<th>BMI</th>
<th>&lt; 18.5</th>
<th>0</th>
<th>0%</th>
<th>&lt; 18.5</th>
<th>0</th>
<th>0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.5-24.9</td>
<td>8</td>
<td>23%</td>
<td>18.5-24.9</td>
<td>4</td>
<td>31%</td>
<td></td>
</tr>
<tr>
<td>25-29.9</td>
<td>16</td>
<td>46%</td>
<td>25-29.9</td>
<td>8</td>
<td>61%</td>
<td></td>
</tr>
<tr>
<td>&gt; 30</td>
<td>11</td>
<td>31%</td>
<td>&gt; 30</td>
<td>1</td>
<td>8%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Amputation Cause</th>
<th>D/I</th>
<th>Trauma</th>
<th>Other/Cancer</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>D/I</td>
<td>14</td>
<td>40%</td>
<td>D/I</td>
<td>5</td>
</tr>
<tr>
<td>Trauma</td>
<td>14</td>
<td>40%</td>
<td>Trauma</td>
<td>3</td>
</tr>
<tr>
<td>Other/Cancer</td>
<td>5</td>
<td>14%</td>
<td>Other/Cancer</td>
<td>3</td>
</tr>
<tr>
<td>Missing</td>
<td>2</td>
<td>6%</td>
<td>Missing</td>
<td>2</td>
</tr>
</tbody>
</table>

5.2 Comfort & Function

More than 50% of the survey sample gave a score of 7 or higher (scale 1-10) when asked to rate their Infinite socket in terms of overall improvement in comfort vs. their prior conventional socket (Figures 5 & 6). Almost 70% of respondents wear their Infinite Socket for ≥8 hours daily (range 1-2 hours – 17 hours). Quality of life scores for respondents increased dramatically when they transitioned to the Infinite Socket. Only 9% reported a score of ≥8 with their conventional socket, while 83% of Infinite Socket users reported a score of ≥8.
5.3 Wearability & Blistering

When asked if they “take their Infinite Socket off less than their prior conventional socket during a normal day”, 27% of respondents replied that they never take off their socket, and 36% indicated that they take it off less. Almost 75% of respondents experienced more blistering with their conventional socket versus their Infinite Socket (figure 7). Only 1 patient experienced increased blistering with their Infinite Socket, and this was due to the increased amount of time that they were able to wear the Infinite Socket vs. their previous conventional socket.
5.4 Falls & Resource Utilization

When asked about falls in the previous year, 27% of respondents reported that they fell 1-3 times, and 18% reported that they fell 4-7 times when using their conventional socket, as compared to 15% reporting that they fell 1-3 times while wearing their Infinite Socket (Figures 8 & 9). None of the Infinite Socket users reported falling more than three times in the previous year.

5.5 Clinical Impact

Since receiving their Infinite Socket, 33% of respondents reported discontinuing the use of assistive devices with 16% reporting discontinuing the use of a wheelchair, 8% discontinuing the use of crutches and 8% discontinuing the use of a cane.
5.6 Socket Replacement
Sixty-four percent of survey respondents who had used both a conventional and Infinite socket (n = 11) indicated that they replaced their conventional socket annually (7/11). Of these 7 respondents, 5 reported replacement in less than 1 year. The reason reported for replacement by all of these respondents was “poor fit – volume.”

<table>
<thead>
<tr>
<th>Reason for Replacement</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Fit</td>
<td>58.3%</td>
</tr>
<tr>
<td>Wear &amp; Tear</td>
<td>25%</td>
</tr>
<tr>
<td>New Technology</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

6. DISCUSSION
In this survey we retrospectively followed up with eligible Infinite Socket users over the age of 60 years to determine their satisfaction with the product and the Infinite Socket’s potential to impact the current state of the O&P industry. Overall, Infinite Socket users are satisfied with the product. They indicate that they wear it just as long, or in a few cases longer than their prior conventional socket. Several survey respondents ended their survey with statements focusing on improved comfort, specifically the ability to sit comfortably while wearing their prosthesis for longer periods of time (car/plane). Another point worth emphasizing was that Infinite Socket users experienced decreased blistering and skin complications as compared to conventional sockets. Wounds and wound care are of great concern to amputees and may often become a barrier to successful mobility. The fact that Infinite Socket users saw less skin-related issues, even with 8-17 hours of daily use, is a testament to the product’s ability to better manage daily volume fluctuations.

The impact on clinical care and socket replacement should not be overlooked in these results. More than 50% of subjects reported replacing their conventional socket in one year or less, with
the main reason being poor fit. The biggest takeaway from the survey was the dramatic improvement in reported quality of life scores for respondents when they transitioned to the Infinite Socket. After receiving their Infinite Socket, an almost 10-fold positive response was reported. This preliminary work suggests that overall quality of life in older individuals with lower-limb amputations can be achieved with the use of the Infinite Socket.

With such a strong response from an older population and the positive outlook they have now been given, it will be interesting to see how it translates to younger amputees who have a longer period of prosthetic use ahead of them.

6.1 Study Limitations

There are a few drawbacks to this pilot study worth noting. First and foremost, the initial contact by the CS was via email. While our response rate of 35% is typical of survey methods that use email as the primary point of contact,\textsuperscript{57} we would have anticipated a higher response rate if we had the ability to make the primary contact by text or phone. Secondly, a larger study sample spanning a greater range of Infinite Socket users is needed. While the purpose of this pilot was to evaluate users over the age of 60 years, greater generalizability of these findings will be needed. A sample of our entire Infinite Socket population will need to be conducted. Third, while many of the concepts and some of the questions came from validated survey tools, a formal validated questionnaire should be used for the larger study. Finally, many of the Infinite Socket users surveyed have only had their device for a short period of time (<3 months). One of the main purposes of having a dynamic module socket is its ability to be used over a long period of time.

7. CHALLENGES & FUTURE STUDIES

One of the biggest challenges facing the O&P industry is the lack of structured research studies and focused outcome metrics and scoring systems to better understand the success, limitations or impact of new prosthetic technology. As we continue to discover and define gaps in the industry, solutions to address them will be found. The team at LIM Innovations believes strongly in laying the groundwork to create a sustainable research infrastructure, complete with well defined outcome metrics to better inform clinicians, improve data collection and drive evidenced based practice to improve amputee care.

7.1 LIM Innovations User Registry
Our company places emphasis on user-generated data. One method for collecting this information is to follow-up with Infinite Socket users to collect periodic feedback. In Q4 2015 we plan to build and launch a user-based registry. All current and new Infinite Socket users will be invited to participate. The registry will contain contact information (name, phone number, email, address) as well as the responses to a limited set of questions. Users will have this data collected at the time of their LIM CS supported fitting. Follow-up intervals have initially been proposed for 3 months, 6 months, 1 year and annually thereafter. The questions included are:

- Currently wearing Infinite Socket (Y/N)
- Comfort Score (Scale 1-10)
- Current functional capacity (Scale 1-10)
- Quality of Life (Scale 1-10)
- Duration of use (Average hours/day)
- Falls per month (average over last reporting period)
- Use of assistive devices (Discontinued use of cane, crutches, wheelchair etc.)
- Independent living (Y/N)
- Visits to Hospital/Nursing home/Rehabilitation center (0, 1, 1-3, >3)
- Overall satisfaction with Infinite Socket (Scale 1-10)

### 7.2 Outcomes Consortia Proposal

To facilitate research and delivery of this care, we have proposed mobilizing a consortia of industry, academic and military prosthetic leaders to develop an appropriate suite of clinical and economic outcomes measures and a mechanism for collecting, analyzing and longitudinally evaluating this data. The Department of Defense (DOD), through a Congressionally Directed Medical Research Program's (CDMRP) recent Orthotics and Prosthetics Outcome call for proposals, invited this project for submission.

In this proposal, we will attempt to conduct a comprehensive review and evaluation of the outcomes of prosthetic socket effectiveness and services to provide a much needed tool to help plan and deliver the best prosthetic options and care to individuals who have sustained lower limb loss. Furthermore, the consortia will establish a universally accepted set of patient-centric outcomes metrics with algorithms to calculate and interpret the collected data, which will impact how amputees receive clinical care (Table 3).
Table 3. Examples of Potential Outcome Metrics and Tools for Assessment

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Description</th>
<th>Foundational Metric</th>
<th>Examples of Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort</td>
<td>Subjective measurement describing the patient’s sense of how the socket feels</td>
<td>Patient satisfaction</td>
<td>10 point Hanspal SCS PEQ-A</td>
</tr>
<tr>
<td>Daily usage/Mobility</td>
<td>Quantitative measurement describing duration of use</td>
<td>Steps taken Hours worn</td>
<td>Accelerometer Pedometer</td>
</tr>
<tr>
<td>Functionality</td>
<td>Quantitative tests used to evaluate the patients ability to use prosthesis</td>
<td>Time to compete test</td>
<td>AMP L-Test 2 Minute Walk Test FSST</td>
</tr>
<tr>
<td>Efficiency/Efficacy of Care</td>
<td>Quantitative measure that defines the how a socket meets the users need as a function of time</td>
<td>Number of days between evaluation and delivery Number of follow-up visits/period of time</td>
<td>Medical record data Billing data</td>
</tr>
</tbody>
</table>

8. CONCLUSION

Amputee care remains complex and challenging. Recent medical, surgical, rehabilitative, and prosthetic advancements have raised both patient and caregiver expectations for outcomes. Because amputation is not an isolated event, associated injuries and social issues should be addressed simultaneously to maximize the rehabilitation process. This requires a multidisciplinary approach to patient evaluation and treatment, with further contributions from other supporting organizations. It is our contention that creating a comprehensive, flexible Amputee Patient Care Program will adapt to the dynamic needs of our patients and help them achieve the maximum functional and social outcomes possible.

The cost of providing evidence can be prohibitive for a manufacturer, inventor or entrepreneur. Although great ideas often are generated by these entities generally, experienced research teams are associated with universities and independent institutions. Evidence Based Practice (EBP) as mandated by DHHS, CMS, VA, DOD, and the ACA are driving healthcare. Without
supplemental information, practitioners and payers are skeptical of new interventions, and may not support new strategies for reimbursement and care.

9. NEXT STEPS
The need for critical external clinical review of the Infinite Socket has been in LIM Innovations plans since June of 2015. In March, a research epidemiologist was hired, and this addition has allowed the team added expertise in grant writing and data collection methodologies. We continue to seek NIH, DOD, NSF and private foundation funding and have partnered with several well-respected clinical prosthetic and orthotic researchers. LIM Innovations is exploring externally funded projects to collect data on the Infinite Socket with the Rehabilitation Institute of Chicago, Prosthetic Amputee Rehab and Research Foundation, and TIRR Memorial Herman Rehabilitation and Research. We plan to launch a prospective cohort study in early to mid 2016.
REFERENCES

8. https://www.whitehouse.gov/issues/disabilities


44. Internal LIM Innovations operations report – data available upon request


APPENDIX A: SURVEY QUESTIONS

1. On a scale from 1 to 10, how would you describe your quality of life with your conventional socket?
2. On a scale from 1 to 10, how would you describe your quality of life after receiving your Infinite Socket?
3. On scale from 1 to 10, how would you rate your Infinite Socket in terms of overall improvement of comfort vs. your conventional socket?
4. How many hours each day do you wear your Infinite Socket?
5. Prior to receiving your Infinite Socket, how many hours per day did you wear your conventional socket?
6. Do you take off your Infinite socket less than your conventional socket during a normal day?
7. How often did you replace your conventional socket?
8. What were the reasons for replacing your conventional socket?
9. How frequently did you visit your prosthetist with your conventional socket?
10. What were the reasons for visiting your prosthetist for your conventional socket?
11. Do you experience blistering more or less with the Infinite Socket versus your conventional socket?
12. How often have you fallen with your conventional socket (number of times/year)?
13. How often have you fallen with your Infinite Socket (number of times/year)?
14. Since receiving your Infinite Socket, have you discontinued the use of any assistive devices?
15. Have you attended an amputee support group in the past 12 months? Ever?
16. How would you describe your activity level BEFORE your amputation?
17. How would you describe your activity level AFTER your amputation with your conventional socket?
18. How would you describe your activity level AFTER to your amputation with your Infinite Socket?
19. On what side of your body is your amputation located?
20. When was your amputation?
21. What was the cause of your amputation?
22. When you received your most recent prosthesis - were given the choice to select your own components? If no, who made the choice for you?
23. Do you currently suffer from any other health conditions?
24. Do you currently live independently?
25. Have you experienced any revision surgery since your initial amputation? If yes, was this a single event or have you had multiple revisions.
26. Did you experience any skin ulcerations/complications with your conventional socket? If yes, please describe.
27. Have you experienced any skin ulcerations/complications with your Infinite Socket? If yes, please describe.
28. Have you visited the Emergency Department for any reason in the past 12 months? If yes, please describe.
29. Are you currently employed? If yes, are you employed in the same or a similar job to the one you had PRIOR to your amputation?
30. User Name
31. User Age
32. User Gender
33. How long has this user had an Infinite Socket
34. User Weight on Infinite Socket order form.
35. Current user weight WITH prosthesis
36. What state do you currently reside in?
37. Is there anything else that you would like to share with us today?