Lower limb prosthetic interfaces; Clinical and technological advancement and potential future direction

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Abstract

The human prosthesis interface is one of the most complicated challenges facing the field of prosthetics despite substantive investments in research and development by researchers and clinicians around the world. As the journal of the International Society for Prosthetics and Orthotics, Prosthetics and Orthotics International has contributed substantively to the growing body of knowledge on this topic. In celebrating the 50th anniversary of the International Society Prosthetics and Orthotics, this narrative review aims to explore how human-prosthesis interfaces have changed over the last five decades; how research has contributed to an understanding of interface mechanics; how clinical practice has been informed as a result; and what might be potential future directions. Studies reporting on comparison, design, manufacturing, and evaluation of lower limb prosthetic sockets and osseointegration were considered. This review demonstrates that, over the last 50 years, clinical research has improved our understanding of socket designs and their effects; however, high-quality research is still needed. In particular, there have been advances in the development of volume and thermal control mechanisms with a few designs having the potential for clinical application. Similarly, advances in sensing technology, soft tissue quantification techniques, computing technology and additive manufacturing moving towards enabling automated data-driven manufacturing of sockets. In people who are unable to use a prosthetic socket, osseointegration provides a functional solution not available 50 years ago. Furthermore, osseointegration has the potential to one day provide neuromuscular integration. Despite all of these advances, further improvement in mechanical features of implants and infection control and prevention are needed.

Keywords: Artificial Limbs, Prosthesis Fitting, Lower Extremity, Prosthesis Design, Bone-Anchored Prosthesis

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Introduction

For nearly 50 years, the International Society for Prosthetics and Orthotics has contributed to the knowledge base in the field of prosthetics by sponsoring the journal, Prosthetics and Orthotics International. In a paper published in the first edition of Prosthetics and Orthotics International in 1977, Dr. Sidney Fishman emphasised the need for institutional training and education to ensure that every prosthetist and orthotist demonstrated minimum competencies for the provision of a safe and effective service.[1] One of the competencies Fishman considered necessary was biological sciences. He stated, "The mechanical product (machine) which the prosthetist-orthotist fabricates must be integrated with a biological entity (the human being). It must be fitted and worn in the closest intimacy to the body of the wearer for the purpose of improving the physical resources of that individual." He further pointed out that, "the adequacy of efforts at physical restoration" requires learning new science, such as biomechanics, which can enable understanding of soft tissue mechanics and behaviour under loading.[1] While in the nearly 5 decades since then research has led to a better understanding of tissue mechanics and the human-machine interface, remains one of the most complicated challenges facing the field of prosthetics.

A successful interface must provide a stiff coupling between the user's skeleton and the rest of prosthesis in order to facilitate control without causing pain or discomfort. However, the socket remains the most common mechanism of attaching the prosthesis to the user's skeleton via residual limb soft tissue. Estimates suggest that up to 50% of people with transtibial amputation do not regularly use their prosthesis primarily due to socket problems.[2-4] The disuse rate is even higher in people with transfemoral amputation.[5] The main complaints about prostheses relate to socket discomfort, and problems with socket fit that cause skin problems.[4, 6] These issues may be compounded by short and long term residual limb volume fluctuation,[7] and heat and perspiration caused by the enclosed socket environment.[8] In current clinical practice, the process of prosthetic manufacturing remains empirical rather than data-driven; the process is iterative, labour intensive, wasteful of material, and dependant on the prosthetist's skills and experience with input from the person with amputation. However, a significant advancement of the last few decades is that in selected individuals with amputation who cannot tolerate their prosthetic socket, osseointegration (OI) is available, providing prosthesis users with improved functionality, mobility and quality of life. However, OI remains limited by infection and other major complications, e.g. implant failure or osteomyelitis.[9, 10]

Integrating a prosthesis to the human body poses a great challenge and many studies have been conducted in the last 50 years in an attempt to disentangle its complexities. Accordingly, in celebrating the 50th anniversary of the International Society of Prosthetics and Orthotics, this review aimed to explore how the human-prosthesis interface has changed over the last 5 decades; how research has played a role in shaping our understanding of mechanics of the interfaces; how clinical practice has been informed as a result; and potential future directions.

Literature search

For this narrative review, electronic databases such as AMED, MEDLINE, EMBASE, CINAHL, and PsychINFO were searched using a combination of database-specific keywords pertinent to 'lower limb', 'amputation', 'prosthesis', 'socket', 'design', 'biomechanics', 'manufacturing', 'material', 'computer model', Finite Element Analysis', 'human-machine interface', 'osseointegration', 'bone-anchored' and 'soft tissue mechanics'. The databases were searched from their inception to July 2020; however, only studies published in the last five decades that reported on design, manufacturing and evaluation of lower limb prosthetic sockets and osseointegration were considered. Forward and backward searches of citations from included literature reviews was also conducted to identify any potential studies not found by the database searches. Although alignment and other prosthetic components influence interface mechanics, these were not discussed here as the main focus was on the interface itself. The emphasis was on lower limb sockets, upper limb prosthetic sockets were not considered.

Since the first edition of Prosthetics and Orthotics International, there has been a plethora of research on user-prosthesis interfaces. As one of the leading journals in the field of prosthetics and orthotics, Prosthetics and Orthotics International has made a substantial contribution to the growing body of knowledge in human-prosthetic interfaces. The journal is among the top three journals that published top-cited articles in Orthotics and Prosthetics.[11] In the current review, articles published in POI account for the highest number of articles cited from a journal (16.9%, n=37), followed by Journal of Rehabilitation Research Development (10.0%, n=22), the Institute of Electrical and Electronics Engineers (6.4%, n=14), and Journal of Prosthetics and Orthotics (5.9%. n=13), (Figure 1). Journals contributed between 2 and 7 articles to the references accounts for 28.8% (n=63) of the citations, while remaining journals were cited only once (32.0%, n=70). There appears to have been an exponential growth in the body of literature in recent decades. Although commenting on the increase in the number of studies is not practical given the large number of studies retrieved through the database search (~ 3000 records after removal of duplicates), the number of published literature reviews may give an idea; 69.7% (n=46) of the literature reviews identified were published in the 2010s, 19.7% (n=13) in the 2000s and 10.6.0% (n=7) in the 1990s (Figure 2).

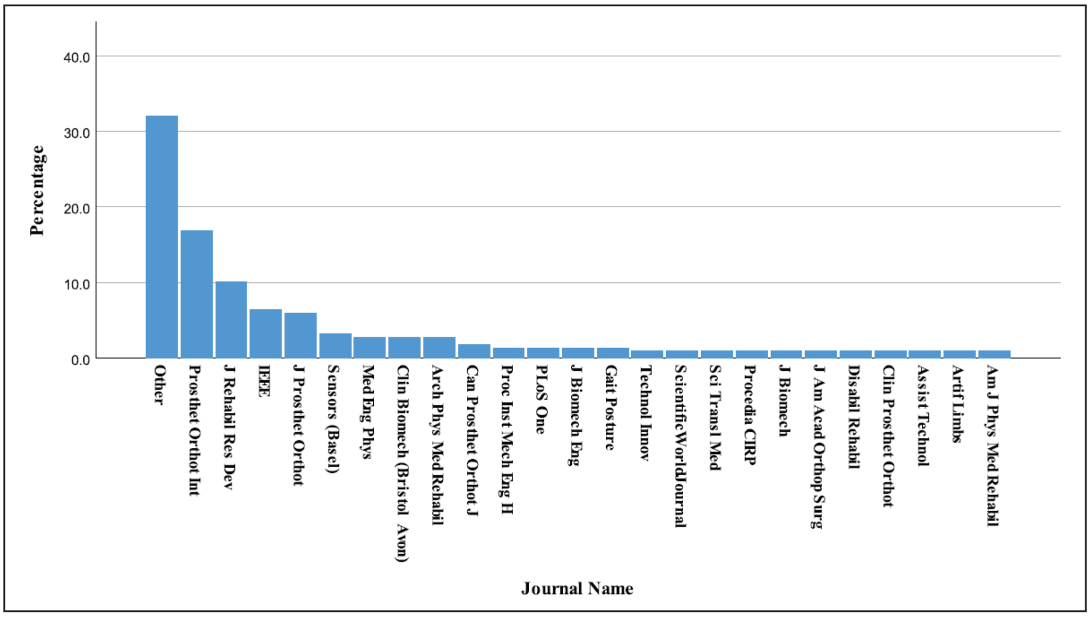

Figure 1: Percentage of articles published in a journal cited in the current review.

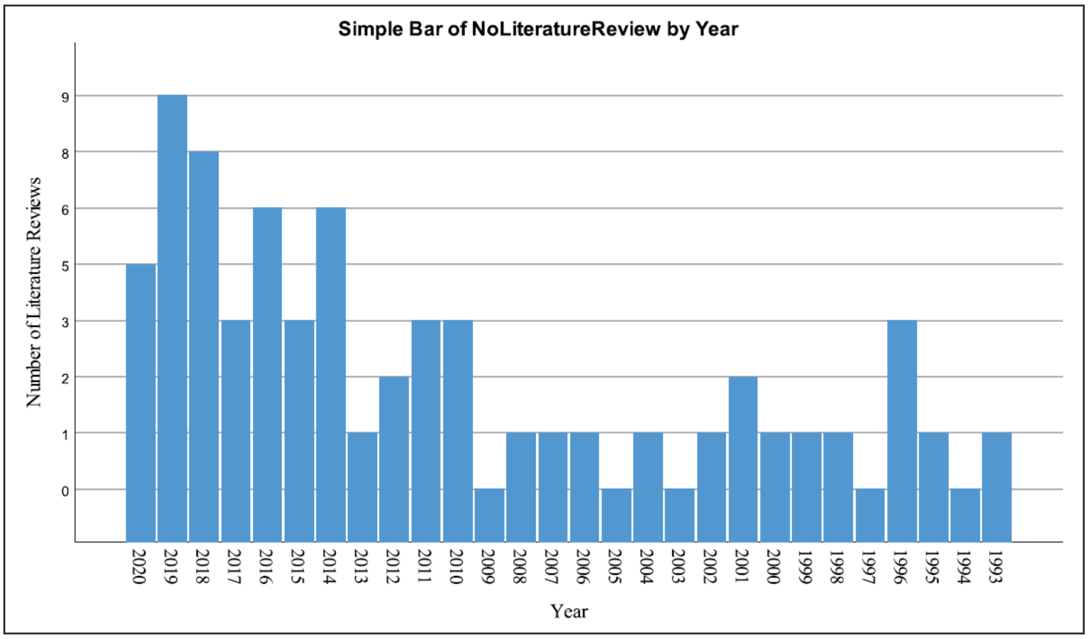

Figure 2: Number of literature reviews published per year on user-prosthesis interface.

Advances in socket design and evaluation

In the last 50 years, owing to advances in technology and material sciences new socket designs have evolved and become clinically available, and clinical studies have improved our understanding of the benefits and the drawbacks of these socket designs. Also, interface pressure and in-socket residual limb displacement studies have examined the effects of different socket designs and suspension systems. Additionally, new methods of residual limb shape capture have been developed and evaluated. Various methods have also been developed for measurement and management of residual limb volume fluctuation, heat and perspiration. Moreover, sensing technologies have been proposed for smart monitoring of residual limb socket mechanics outside of the clinic. In the succeeding sections these advances will be discussed, followed by suggestions for potential future research.

Prosthetic socket designs and suspension mechanisms of the last 50 years

In the 1960s, the first theoretical concept for a transtibial socket, the Patellar Tendon Bearing (PTB), was introduced by Radcliff based on the biomechanics of gait and tissue load tolerance.[12] The PTB socket is shaped to load 'pressure tolerant' areas of the residual limb, while providing load relief to more sensitive areas. More than two decades later, Staats and Lundt introduced the Total Surface Bearing (TSB) socket concept, stating that areas previously thought sensitive could be loaded to some extent.[13] With the advent of silicon liners, the modern-day TSB socket and the so-called "Hydrostatic" Socket (HS) provide better load equalising based on the flow properties of the silicon materials.[14, 15] Variations of TSB/Hydrostatic sockets based on method of residual limb shape capture, including air bladder casting, pressurised water casting or vacuum casting, have become available.[16]

The two primary transfemoral sockets designs are the Quadrilateral socket (Quad-S) introduced in the 1950's[17] and the Ischial Containment socket (ICS) introduced in the 1980's.[18-20] The primary difference between them is that the Quad-S has a posterior horizontal brim and a narrow proximal anterior-posterior socket dimension that helps keep the ischial tuberosity on the horizontal brim for weight-bearing; whereas, the ICS encloses the ischial tuberosity and ramus in a curved posterior-medial socket wall for weight-bearing. In the ICS, support is further supplemented by hydrostatic weight-bearing as a result of the relatively smaller socket volume, and a narrow proximal medial-lateral socket dimension improves coronal plane stability. A variant of ICS introduced in early 2000s is the Marlo Anatomical Socket (MAS)[21] which achieves coronal plane stability by containing only the ischial ramus and lowering other trim lines to allow greater range of hip motion. Another design, introduced in the last decade, is the High Fidelity (Hi-Fi) socket[22] which has struts that compress the soft tissues of the thigh to achieve femur stabilisation, allowing excess tissue to flow through openings between the struts.[22] Also in the past decade, sub-ischial sockets have been introduced based on the TSB/Hydrostatic weight-bearing concept that eliminate all contact with the pelvis to improve user comfort without loss of function.[23-25]

The use of gel liners led to improvements in suspension. Of particular note is the advent of suction suspension, pin-lock suspension, and vacuum assisted socket suspension (VASS). Early suction suspension was introduced in 1970s.[23, 26] and in current clinical practice, an airtight environment between the liner and the socket is generated by expelling air via a distal one-way valve. Air infiltration is prevented by either a few gaskets at the outer surface of a liner that conforms to the internal socket walls (e.g. Iceross Seal-In®, Össur, Sweden) or a sleeve worn at the proximal end of the socket (e.g. Alps EasySleeve™, Blatchford, UK). With pin-lock suspension, introduced in late 1980s[14] a pin attached to the distal end of the liner engages with a locking mechanism fitted into the socket. The VASS, introduced in the 1990s, uses a pump to apply active suction between the liner and socket.[27] While initially used for persons with transtibial amputation, VASS has more recently been successfully used in persons with transfemoral amputation and sub-ischial sockets.[25, 28, 29] Although, VASS was originally developed to improve suspension, it has since demonstrated other advantages in terms of more even socket pressure distribution, control of residual limb volume fluctuation, and improved residual limb health.[30-34] These will be discussed further in the following sections.

Clinical research of effectiveness

There have been many studies in the last 50 years evaluating the effects of transtibial socket designs and materials on various functional, biomechanical and patient-reported outcomes aimed at developing a better understanding of socket design. This body of evidence has spurred a number of recent reviews that help identify benefits, drawbacks and limitations of available prosthetic socket designs, socket materials and suspension techniques.[30-39] The findings of these reviews have been summarised in clinical guidelines[40, 41] and are highlighted below.

Overall, studies indicate that TSB sockets incorporating elastomeric liners may lead to improved satisfaction and greater activity among active and younger people with amputation with a comparable manufacturing and fitting cost to PTB sockets.[32, 35] Compared to PTB, TSB sockets with viscoelastic liners may decrease dependence on walking aids, improve suspension and load distribution, decrease pain, and improve comfort.[30, 32, 33] A TSB socket with VASS provides the least pistoning, followed by a TSB suction socket (Seal-In), a TSB socket with sleeve suspension, and a TSB socket with a pin-lock liner.[33] The least suspension is provided by a PTB socket with sleeve suspension or a PTB socket with supracondylar suspension.[33, 34] A TSB socket with VASS may also decrease residual limb volume loss, improve balance, increase physical function, and help with skin health compared to non-vacuum suspension systems.[30-34] Despite these advantages, VASS requires more maintenance, user cognitive ability, and compliance; therefore, it is not recommended for all adults with amputation.[31]

Comparative study of transfemoral sockets has drawn less attention from researchers than transtibial sockets. Compared to the Quad-S, the ICS results in a lower energy cost of walking,[42] increased walking speed and stride length,[43] more even interface pressure distribution,[44] improved comfort [45] and less restriction of the hip motion.[46] Sub-ischial sockets appear to be comparable to ICS in coronal plane stability and vertical movement, but with lower peak pressure at the proximal-medial brim during gait.[24, 47, 48] Greater socket comfort and a narrower base-of-support during gait were reported for the sub-ischial socket compared to ICS due to its lower proximal trim line.[24, 47] A literature review of transfemoral socket suspension systems concluded that aside from suspension enhancement, the use of liners and inner flexible socket walls improves function, and comfort, and may reduce the rate of skin problems.[49]

The main concern with the available evidence is the low methodological quality of clinical studies; there is a lack of sufficiently powered randomised controlled trials assessing the benefits and harms of available socket designs. Heterogeneity of intervention, study population and outcome measures makes meta-analysis impossible. Additionally, the inter-related and aggregate performance of factors such as socket design, liner properties, suspension system, prosthetic alignment and components other than the socket preclude measurement of the isolated effect of these factors on fit, comfort and function. Questionnaires assessing patient-reported outcomes use different operationalize constructs differently, adding to the complexity of comparison of the effects of the various prosthetic sockets.[38] Further, long term cost-effectiveness study of these sockets, in particular VASS, is needed.[41]

Vacuum level in VASS

As noted earlier, previous studies highlight potential benefits of VASS, for which understanding of the vacuum level is needed to achieve favourable results. Studies indicate that there is a correlation between the amount of vacuum and prosthetic socket fit, residual limb volume fluctuation, and distal displacement; moreover, this relationship is affected by the type of tissue, size and shape of the residual limb, and the swing and stance phases of gait.[50-52] Residual limbs with firmer tissues exhibit higher pressure fluctuations compared with limbs with medium firm tissues for a given magnitude of pistoning.[51] The effect of muscle contraction on pressure is larger in residual limbs with firmer soft tissues than those with medium firm tissues.[51] For a given vacuum level, firmer tissues result in less pistoning than medium firm tissues.[51]

Pressures created by electrical elevated vacuum pumps are reported to range between -27 to -85 kPa.[50, 52-59] A few studies have evaluated the performance of different VASS pumps, highlighting differences in maximum pressure and time to achieve a desired vacuum level.[31, 58-60] Variability of mechanical vacuum pump in transtibial VASS socket was tested by logging socket air pressure over time during functional tasks.[61] The socket showed a decrease in socket air pressure by -34.6 ± 7.7 kPa during a 2-minute walk-test over 10 gait cycles but no significant difference in task performance was observed between vacuum and suction conditions perhaps due to the short duration of the test.[61] A study by Xu et al. revealed that higher vacuum level in transtibial VASS socket (50 - 67 KPa) appeared to be more comfortable and improved loading of the intact limb but increases hip and knee external adduction moments, potentially increasing the risk of knee osteoarthritis on the amputated side; whilst, lower vacuum levels adversely affected gait symmetry.[62] Whether vacuum was active or inactive in VASS sockets was shown to have a small but significant effect on a few gait parameters; in particular, gait was affected when the vacuum pumps were off for an extended period of time possibly due to increased residual limb volume fluctuation and poor socket fit.[63]

While much has been learned about vacuum over the last two decades, future studies are needed to systematically evaluate and compare different vacuum systems, to study use of vacuum over longer periods of time, to explore the effect of different activity levels and functional tasks, and to explore the effect of varying patient characteristics, e.g. residual limb geometry and tissue type.

Residual limb geometry quantification

Accurate and reliable quantification of residual limb geometry is a fundamental step in socket manufacturing and long-term evaluation of shape and volume is needed for continuous clinical decision making. Numerous measurement techniques have been developed for shape and volume measurements including the water displacement method (i.e. submerging the residual limb in water and measuring the volume of displaced liquid), anthropometric measurement, contact methods (casting or probes), optical or laser scanning, ultrasound (US), Computerised Tomography (CT), Magnetic Resonance Imaging (MRI) and bioimpedance.[7, 64-66] Although US, CT and MRI provide useful internal and external structural data, their clinical application has not proved feasible for routine residual limb imaging due to high cost, potential hazards (e.g. ionising radiation in CT and risk of projectile in MRI), and long scanning time. Shape capture in current clinical practice mainly involves plaster casting, surface scanning, and anthropometric measurement.

Load distribution in the Hydrostatic socket is a result of the synergistic effect of casting method and flow properties of liner material. To evaluate the isolated effect of hand casting and pressurised water casting methods on the outcome. the PTB and the Hydrocast sockets, were compared using pelite liner.[67] Participants reported lower socket comfort score after one month of Hydrocast socket use compared to the PTB socket.[67] However, in another study, where the sockets were used for a longer period (5 months), the Hydrocast socket resulted in improved temporal gait parameters; hence, increased loading of the prosthetic limb.[68] Nevertheless, no significant differences were found in functional capacity, mobility or satisfaction between sockets.[68]

Studies have shown that the pressure-casting approach results in greater repeatability than hand-casting method.[69, 70] However, the overall inter-cast volume difference was not considered clinically meaningful (i.e. smaller than the volume of a sock over the residual limb).[70] Both casting methods showed inconsistency regarding the shape of the cast. Interfacial pressure measurements highlight that the Hydrostatic socket does not result in uniform pressure distribution, contrary to the claimed hydrostatic theory, however, it produces a pressure distribution with less variation, potentially resulting in less pressure gradient and hence lower shear stress.[71] Socket interface pressure distributions in PTB and TSB/hydrostatic sockets during gait do not fully comply with the biomechanical assumptions proposed by Radcliffe.[71, 72]

The structured light surface scanner, Omega Tracer (Ohio Willow Wood, USA), was evaluated on residual limb models showing a reliable method for measuring residual limb volume.[73, 74] Using residual limb models, the photometric scanner TT Design (Otto Bock, Germany), Omega Scanner, the laser line scanner Bioscanner (BioSculptor, USA), and the infrared scanner Rodin4D (Rodin4D, France) were reported reliable (error variance of 3%) and repeatable in volume measurement.[75] Comparing across structured light scanners such as Go!SCAN (Creaform, Canada), the 2nd generation Sense and the iSense / Structure Sensor (3DSystems, USA) with the hand-cast method on residual limbs, Dickinson et al. concluded that the Go!Scan (similar to Omega scanner) was more reliable than hand-casting in volume and perimeter measures, and the iSense and Sense scanners both had larger deviations than hand-casting.[76]

Despite the successful application of commercial scanners in capturing a 3D model of the residual limb for socket manufacturing, they have seen limited use in inter- and intra-session geometric evaluations because they do not provide internal structure data. Their application for out of socket volume/shape measurements are also limited due to relatively long scanning time that make them ill-suited to quantifying volume changes that occur within minutes after socket removal. Bioimpedance analysis has been developed as a method for in- and out of-socket residual limb volume measurement for inter- and intra-session volume change measurement during static and dynamic situations.[77] However, bioimpedance is limited to measurement of residual limb fluid content and has been employed for research purposes only. More recently, a high-resolution multi-camera system (up to 40 cameras) has been developed for instantaneous in-vivo measurement of residual limb shape, volume and strain.[78] Also, a mechanised water tank with an ultrasound transducer, in combination with a structured light-based 3D camera for motion compensation, was developed and tested on a residual limb model.[79] The system generated a safe and adequately accurate 3D image of the residual limb in approximately 2-3 minutes, while enabling the gathering of internal and external residual limb geometric data.

As noted earlier surface scanners have reached a high level of reliability and speed for geometric quantification of residual limbs. However, the main unresolved challenge is the lack of knowledge as to what constitutes an accurate residual limb shape and volume for comfortable and functional socket manufacturing. Up until now the closest shape we can capture to the shape of a residual limb within a socket is the shape defined in a pressure cast during static loading. Casting during dynamic loading may be a possible avenue to further explore the behaviour of the loaded soft tissue in relation to the underlying bone.[66, 80, 81]

Management of residual limb volume fluctuation

The residual limb experiences both short and long term volume fluctuations, which cause socket fit to deteriorate, resulting in excessive shear and normal load over the residual limb, socket pistoning, and gait deviations.[7, 54, 82] Various methods have been proposed for evaluation of residual limb volume changes (see the previous section and Sanders et al.[7]).

Many attempts have been made to develop solutions for residual limb volume fluctuation including active adjustable sockets that regulate volume based on measurement of in-socket sensors including inflatable inserts using the F-socket system (Tekscan, Inc USA) or inflatable pressure actuators,[83-86] a fluid bladder with a mechanically controlled circuit,[87] controlled Magneto-Rheological (MR) fluid bladders for both volume adjustment and socket stiffness control,[88] socket with panel adjustable either manually or by a motor,[89] motor actuated adjustable panel socket via a control system based on data collected by an inductive sensor,[90, 91] and VASS with variable vacuum pressure as a surrogate measure of volume change reflecting pistoning during walking.[51] Also, a few adjustable socket systems are commercially available; for example, the Infinite Socket™ adjustable, custom-moulded, four-strut design combined with a textile brim and tensioner (LIM Innovations, San Francisco, CA, USA), and RevoFit™ manual adjustable socket (RevoFit™, Steamboat Springs, CO) for transfemoral residual limbs, and immediate fit socket system (iFIT Prosthetics, USA) for transtibial residual limbs.[92]

A series of studies by Sanders et al. reveal interesting findings that may be used in a practical active panel socket for volume management without adversely affecting socket fit and comfort.[93-96] The findings show that standing and low-intensity activity result in volume loss.[94] In transtibial sockets with pin suspension, intermittent doffing (i.e. eliminating liner pressure) may provide volume accommodation.[93, 94] Using an adjustable panel, the researchers demonstrated that small continual adjustment within a user's accepted socket size range (i.e. ± 5% residual limb volume changes from the neutral socket volume) may be used to adjust and possibly maintain residual limb fluid volume and limb position within socket.[95] Finally, using inductive sensors, it was shown that using a socket with motorised adjustable panels, limb fluid changed proportionally to the changes in the socket volume within optimal socket size setting.[96]

In another study, increase in posterior residual limb fluid volume was demonstrated by creating negative pressure on the residual limb using a socket with three adjustable panels that were pulled outward via a motor mounted to the outside of the socket.[97] Residual limb in-socket volume fluctuation was measured using bioimpedance while the person with amputation wore either VASS or suction suspension sockets during a 5.5-hour protocol of multiple interval activity.[98] Although the overall volume change was not significantly different between sockets, the results indicated that the rate of fluid volume in at least one residual limb region was increased when using VASS.[98] The authors also noticed an intra-individual variation in the magnitude of overall residual limb fluid difference between VASS and suction sockets and suggested that a tuning system could be employed for a personalised optimisation of vacuum level because effectiveness varies between individuals and daily activities. Vacuum pressure measurement using microprocessor-controlled VASS was sensitive enough to detect differences of 1.5% or smaller in global volume.[52] These results indicate that active monitoring and adjusting of vacuum pressure may be achieved using a single controller as a method for both measurement and management of residual limb volume fluctuations.

Work is underway developing electroactive polymer (EPA) networks capable of actively expanding or contracting at low voltages, offering impact resistance and pressure sensing.[99] It has been suggested that EPA can be used in liners or sockets for automatic socket volume adjustment.[99] Also, a ferrous polymer can be used as an inductive sensor (0.50 mm thickness) and as a magnetically permeable target to measure socket wall and liner distance, and decrease socket volume by approximately 2.1%.[100]

Overall, VASS with a controller and the active panel socket with an in-socket sensor appears to be viable clinical options for management of diurnal residual limb volume flutuation; though, further developments are needed to make them commercially available.

Socket liner material

The advent of elastomeric liners resulted in a substantial improvement in residual limb loading, and efficacy of prosthetic suspension systems.[14, 15, 101] Liner material properties have been studied ex-vivo under tension, compression, shear and friction loading conditions.[37, 102-106] The results indicated that soft liners improve cushioning over bony prominences, protect skin against breakdown and provide better suspension.[37, 101, 103]

Polyethylene closed-cell liners showed better durability but had a lower coefficient of friction compared to silicon or polyurethane.[102] Stiffer liners provide a faster response to movement and would be preferred for residual limbs with excessive soft tissue.[103] Thicker liners can distribute the load more evenly across the residual limb and reduce peak pressure over bony areas (e.g. the fibula head); however, they may compromise the user's stability during functional activities.[107]

Despite the existence of literature reporting the experience of individuals with amputation,[101, 108] confounding factors, methodological rigour and issues with validity and reliability of outcomes preclude meaningful clinical decision making.[36] The findings of ex-vivo tests need to be confirmed by human subject experiments to establish liner prescription clinical guidelines. Furthermore, changes in liner properties as a result of wear and tear and prolonged exposure to perspiration and body heat have yet to be explored.[37] Future studies are also needed to explore additive manufacturing (AM) and subsequent evaluation of customised elastomeric liners.[109-112] Manufacturing multi-material liners with variable stiffness and/or thickness could also be explored once advances in AM technology emerge. Such a liner would provide greater cushioning over thicker soft tissue or sensitive areas but results in a trade-off between comfort and socket-residual limb coupling stiffness.

Heat and perspiration management

The use of elastomeric liners to improve load distribution over the residual limb comes at the cost of increased heat build-up inside the socket. Thermal discomfort and perspiration are common problems for prosthesis users that can result in skin problems and adversely affect socket-residual limb mechanics.[8, 113, 114]
Recent strategies explored to mitigate heat and perspiration inside the socket include perforated silicon liners,[115, 116] an automatic system consisting of a cooling pipe dissipating the heat to an external heat sink,[117] additive manufacturing of a socket incorporating helical cooling channels and an air pump,[118] a heat pipe with fluid and wicking system,[119] a smart thermoregulatory system using a thermoelectric heat pump,[120, 121] phase change material (PCM),[122, 123] and a PCM liner in combination with an air pump in a proof of concept additive manufactured socket.[124] Finally, a vacuum was created between proximal and distal regions of the socket using a pump and electromagnetic control system to create airflow between the liner and the skin expelling heat and perspiration.[125]

Williams et al. compared thermal conductivity of a liner made of thermally conductive silicon, a plain silicon liner, and a hybrid liner in a controlled laboratory setting and found no significant difference between liners.[126] The authors concluded that passive heat transfer may not mitigate heat unless a higher thermally conductive liner or an active heat-dissipating system can be made.[126]

Aside from perforated (e.g. Silcare Breath, Blatchford, UK) and PCM liners (SmartTemp®, Ohio Willow Wood, OH, USA), none of the above-mentioned strategies has yet been developed enough to be clinically feasible. VASS appears to be a promising solution and further development is needed to adapt the current VASS system to incorporate a heat and moisture dissipating mechanism; a potential approach may include a perforated PCM liner coupled with VASS.

Interface pressure and shear stress

Excessive and or prolonged interface stresses result in tissue breakdown.[105] A primary objective of interface stress measurement studies has been comparing different prosthetic socket fit and comfort, assessing the effect of socket design parameters, inputting data into Finite Element Analysis (FEA) to predict interface stress and or to understand the interface biomechanics, and assessing the effects of alignment and components other than the socket on interface stress.[39, 105, 127-133]

Four main types of sensors have been utilised to measure interface stress; (a) strain gages such as diaphragm deflection transducers and plunger piston-type gages, (b) piezoresistive sensors, (c) capacitive sensors, and (d) optical sensors such as Fiber Bragg Grating (FBG) sensors and optoelectric sensors.[129, 132] Early interface stress measurements were limited to a few specific areas of the residual limb; were unable to simultaneously measure shear and normal stresses; imposed difficulty with calibration, accuracy and hysteresis; and were mostly limited to pressure measurement during static conditions. Moreover, holes in the socket wall or liners were required to accommodate the pressure sensors. There have also been problems with sensor movement, cross-talk between sensors, and interference with the residual limb and socket interaction.[127, 131]

To address some of the above-mentioned challenges a few approaches have been explored. A backpropagation Artificial Neural Network (ANN) has been suggested.[134-136] ANN require examples of data to be trained so that it can predict the full-field interfacial pressure from strain data collected from the exterior surface of the socket. However, there are limitations due to the lack of a standard method for selecting the most efficient ANN parameters, lengthy and expensive ANN training, and the need for ANN retraining after each socket modification. Another suggested approach is using additive manufacturing of elastomeric material to manufacture flexible sensor frames to conform to the shape of the socket for measurement of shear and normal stresses at the socket-residual limb interface.[137] The sensor demonstrated pressure and shear signal linearities comparable to those of commercially available sensors.[137] Further, Fiber Bragg Grating (FBG) sensors have been used.[138-140] These sensors are flexible, reliable, with high sensitivity and minimum hysteresis and enable simultaneous measurement of different variables such as force, pressure, shear, temperature and humidity, which makes them a potential choice for use in smart and active sockets.

Residual limb displacement within a socket

The stiffness of the user-prosthesis coupling is defined by the socket geometry, flow property of the liner material, the soft tissue compliance, the coefficient of friction between liner and residual limb, and the suspension system. Suitable socket shape, choice of liner and suspension system can help minimise the slippage or undesired displacement between the residual limb and socket; movements that trigger soft tissue breakdown. To evaluate the efficacy of the suspension system, and appropriateness of socket fit, previous studies have used radiography, ultrasound, CT, photographic methods and motion analysis systems to measure socket-bone, socket-liner, and liner-soft tissue displacements in static, simulated loading and dynamic conditions.[133, 141] Vertical displacement, i.e. pistoning, is the most frequently measured displacement mainly to evaluate the efficacy of suspension systems (see section *clinical research of effectiveness* and Eshraghi et al.[141]).

Assessment of the residual limb bone and soft tissue displacement in relation to the liner or the socket can help to understand the residual limb-socket mechanics and evaluate different socket designs. In the late 1990's, using CT, Commean et al. measured residual limb skin slippage and tibia movement inside a socket under different loading conditions to assess socket fit.[142] Recently, Optical 2D-motion sensor arrays have been used to measure residual limb displacement inside the socket in vertical, anterior-posterior and transverse rotational directions relative to gait cycles.[143, 144] A combination of magnetic and optical motion capture systems was also used to assess socket residual limb pistoning during gait.[145] An inductive sensor was used for measurement of distal residual limb displacement in VASS and suction sockets.[51] Using motion capture systems and markers placed on a pin liner within a transparent socket, rotational displacement, pistoning and regional liner deformation were measured.[146] Using whole-body inverse kinematic, inverse dynamics and motion detection data, residual limb-socket load and displacement were estimated.[147] Low profile inductive sensors were laminated inside the socket wall, and using a liner with a ferromagnetic flexible target and a portable controller, the distances between the liner and socket were measured at various locations to give insight into liner-socket displacement.[148] As noted previously, data derived from microprocessor-controlled VASS may be used to quantify and monitor socket fit.[52] Future studies could explore the effects of different socket designs, liner material and tissue compliance on multidirectional socket displacement and local soft tissue movement relative to the gait cycles, prosthetic alignment and components for a better understanding and management of socket-residual limb interactions.[143]

Smart monitoring system

Current clinical practice, although based on years of empirical evidence, relies for the most part, on practitioners' expertise and clinical judgement, users' subjective feedback and comments, for assessment, treatment prescription and follow-up evaluation. Monitoring and sensing technologies have the potential to complement current clinical practice approaches by improving therapeutic, diagnostic and prognostic outcomes.[149, 150]

Instrumented socket inserts incorporating sensors (proximity, force and inductive), wires and circuity have been employed to collect field data on socket-residual limb variables.[151] A wireless system with flexible support for up to 32 force sensors, an analogue frontend reader and a low power microprocessor controller was also designed capable of continuous measurement of interfacial load for up to 8 hours.[152] As noted earlier, 3D printing with elastomeric material was used to manufacture flexible sensor frames for pressure and shear measurement.[137] An inductive proximity sensor[153] and bioimpedance[154] have also been used for monitoring residual limb volume changes and activity in the community.

In a stakeholder event, participants expressed a preference for a lightweight monitoring system for short-term use that would enable measurement of in-socket temperature and pressure.[155] A potential monitoring system has to be of a minimal disturbance to the user and may initially be considered for a certain group of users; for example, people with vascular disease and older adults.

Automated data-driven socket design

In the 1980s Computer-Aided Design and Computer-Aided Manufacturing (CAD/CAM) and Finite Element Analysis (FEA) were introduced to the field of prosthetics.[156] Improvements in pressure measurement techniques, advances in the understanding of soft tissue stress and strain behaviour, and the advent of reliable computers and manufacturing technologies provided the field with the opportunities to better understand the biomechanics of the socket-residual limb interface and to explore approaches for automated data-driven manufacturing of prostheses.

Several attempts were made to design a patient-specific data-driven socket in a research environment.[157-162] Goh et al. developed a CAD/FEA programme and used a commercial CAD surface scanner to create a 3D model.[157] The internal bone geometry was determined using an anthropometric method. The researchers then validated the FE model against experimentally measured data showing fast and accurate analysis. Lee and Zheng also used quantitative pressure and pain data, and MRI images of a residual limb as an input data for an FEA to fabricate a socket.[158] Another group manufactured a variable impedance socket using additive manufacturing technology based on an MRI image of the residual limb.[159] The shape of the socket geometry in relation to the bone was defined based on inverse correlation of tissue thickness over the tibia bone. In later works, the same group of researchers quantified mechanical properties of the residual limb soft tissue using a computer-controlled multi-indentation device.[160-162] Then, using an inverse FEA, the 3D model of a socket was designed, evaluated, and used for additive manufacturing.

Despite the promising results of the above-mentioned endeavours, several technological challenges must be addressed before FEA can be introduced in the clinics (see next section). The current clinical CAD/CAM systems contain a surface scanning device to digitise 3D model of the residual limb; computer software to modify the 3D model into a desired socket shape, and a CAM to fabricate the modified CAD model. This conceptually replicates the conventional socket design in a digitised form; the design process is still iterative and subjective based on the prosthetists experience.[66, 130, 163] Nevertheless, the CAD system offers the possibility for storage of digital 3D model of residual limb for future evaluation of prosthetic management in an environmentally friendly manner as it eliminates material waste.

Finite Element Analysis

Many research groups have reviewed decades of research findings in prosthetic socket FEA.[39, 131, 163-166] Early FEA studies were mostly method development.[131, 163, 166] An extensive recent review of the topic highlights FEA findings and development in (a) modelling pre-loading from socket donning, and friction/slip, (b) modelling of residual limb soft tissue internal mechanics, e.g. viscoelasticity/hyperelasticity, deep tissue injury, and thermal analysis, (c) identification of residual limb tissue characteristics, e.g. creep, stress relaxation and pain tolerance threshold, (d) proposals for incorporating FEA into the socket fit and assessment, and (e) analysis of osseointegrated prostheses.[164].

Further research is needed to enable commercial CAD/CAM with computational modelling of the optimal socket design based on quantitative data. To be feasible, the accuracy and validity of FEA in the prediction and evaluation of socket fit must be confirmed. FE predictions depend on reliable data about geometry, material, and soft tissue properties, and loading and boundary conditions.

A reliable, safe and accessible method is needed for quantification of residual limb geometry. Current imaging methods of internal and external structure quantification are either unsafe or inaccessible and costly (see section *Residual limb geometry quantification* for summary of imagine methods). A potential approach could employ methods proposed in Goh et al.[157] described earlier. To enhance accuracy the FEA also needs to model soft tissue hyper-viscoelasticity, anisotropy and inhomogeneity, taking into account tissue pressure pain/comfort threshold. Further, accuracy is influenced by adding factors such as socket-residual limb mechanics, socket induced soft tissue preloading, load types, static and dynamic gait conditions, bone-soft tissue kinematics, heat and perspiration inside the socket, prosthetic alignment and components, residual limb volume fluctuation, tissue adaptation, muscle contraction, age and health conditions, and liner/socket material properties. Considering the current state of science and technology it seems impossible to include all the above factors in a model. However, exponential advances in computing technology may make it possible in the future.

Achieving a high level of accuracy raises another issue that is concerned with lengthy solver time, cost and requirement for specialised expertise to use FEA software. FEA solutions could be developed including as many of the above factors in the design process to validate a fast and user-friendly simpler model. As an example, using a statistical shape model, a surrogate model was developed capable of real-time prediction of residual limb shape and socket design.[167]

Another approach for quantitative automated socket design could be based on artificial intelligence and knowledge-based system approaches. A rectification map was created as a socket fabrication template in CAD/CAM.[168] Also, the design experience of several prosthetists was employed to develop an algorithm to build a quantitative compensation model for socket design based on tissue characteristics of the residual limbs.[169] A research group proposed automatic rectification based on empirical rules.[170] The method established a correlation between the local rectification quantitative data and qualitative scores of soft tissue tonicity, activity levels and subject weight. Then, performance was assessed by FEA and a socket was manufactured using additive manufacturing. For such an algorithm to be successful, a large amount of data is required to train the system.

Tissue response to load

Quantification of, and understanding the relationship between, soft tissue behaviour under different loading conditions, its mechanical properties and load-induced pain/comfort threshold could improve quantitative socket design and evaluation using FE and virtual prototyping.

There are a few hypotheses, with varying levels of evidence, about tissue response to excessive load including (a) arterial blockage resulting in local ischemia and anoxia, (b) toxic substances build-up in the tissues as a result of a disturbance in the lymphatic system, (c) reperfusion injuries and reactive hyperemia, and (d) cellular necrosis as a result of mechanical insults.[171] There is an inverse relationship between the magnitude of the load and loading duration that results in tissue breakdown.[172] Shear force accounts for 40% of pressure ulcers[173] and addition of shear to pressure increases the susceptibility of tissue to breakdown.[174] Cyclic loading and unloading results in more skin breakdown than constant loading alone, most likely due to cumulative reperfusion and reactive hyperemia.[171] However, if a load is applied within certain magnitude and duration windows tissue adaptation may happen.[105]

Soft tissue exhibits anisotropic, inhomogeneous and non-linear viscoelasticity properties that change by anatomical location, muscle contraction, tissue composition, ageing, and pathological conditions.[64, 171, 175] Indentation measurement, ultrasound, MRI, CT, and computational modelling (e.g. reverse FEA) have all been used for quantification of soft tissue properties.[64] Indentation has been the most commonly used technique for in-vivo measurement of mechanical properties of the soft tissue.[64, 176] However, there are concerns with the validity of indentation measurement including the effect of indentor misalignment, muscle contraction, indentation rate, and being limited to measurement over a few anatomical locations. To address the limitation of previous methodologies, a multi-indentor device, comprised of 14 indentors with a known angle-of-attack and position and force controller, has been developed.[162] The device circumferentially surrounds the residual limb to form an actuator ring to characterise soft tissue hyper-viscoelasticity.

Load induced pain varies between anatomical location and from person to person.[105, 171] Generally, the method involves measuring minimum pressure causing discomfort or pain (pressure threshold) and maximum tolerable pressure.[177] Animal experiments suggest a sigmoid-type pressure duration tolerance curve exists; for example, muscle damage occurs after a short exposure to pressure >32 kPa whereas 5KPa pressure can be tolerated for a long time.[171] To understand the behaviour of residual limb tissue, studies of pressure and shear force tolerance curves for different tissue types and anatomical location are needed.[171]

Radcliff qualitatively defined tolerant and sensitive areas of a residual limb as a design principle for the PTB socket.[12] Studies have shown that the magnitude of pressure at the popliteal area correlates with patients' discomfort level[178, 179] and pressure-induced pain is lower in the popliteal area than over the patellar tendon.[88] Use of a PTB socket can result in degeneration, neovascularity and morphological changes in the patellar tendon.[180] The load-tolerance levels of the distal ends of residual limbs have also been reported in previous studies.[181, 182] In a Hydrostatic socket, high peak pressures in the anterior proximal region, and longer durations of submaximal loading in the lateral proximal region and the anterior and medial distal regions, were factors related to discomfort.[183]

Understating cumulative tissue damage as a result of loading and subsequent oxidative reperfusion and inflammation, and the relationship between load-unloading cycles, the tissue healing process and tolerance threshold from persons with amputation are needed.[171, 184] Owing to advances in powerful computing technologies, full field FEA including all the previously described important factors, are needed to evaluate correlation and predictability of certain measurements taken in a clinical environment and be used for socket design and evaluation.

Additive Manufacturing

Additive manufacturing has the potential to bring a paradigm shift in socket and prosthesis design and manufacturing. This technology enables the creation of complex geometric sockets, using less material, in a shorter time, while eliminating the need for an intermediate plaster mould, hand laminating and finishing procedures. In a review paper, Chen et al. concluded that in a limited clinical evaluation, AM demonstrated the capability of fabricating well-fitting lower limb prosthetic sockets with adequate strength, mostly using Nylon 11 and 12 in Selective Laser Sintering, and Polypropylene in Fused Deposition Modeling.[185, 186] Sockets could be made to have: compliant features in order to lower average or peak pressure over bony prominences or pressure-sensitive areas of the residual limb;[187, 188] wall hardness with an inverse relationship to tissue compliance, i.e. less compliant tissue resting against a softer wall material, and vice versa;[159] and inflatable/deflatable elements[189] or printed inserts[190] to accommodate volume fluctuations of the residual limb.

Multimaterial AM technology could make it possible to fabricate the socket and or prosthesis in materials of varying stiffness.[191] Additive manufacturing could offer opportunities for manufacturing customised elastomeric liners[109-111] and printing electrodes and sensors for smart and active monitoring and measurement of interface mechanics.[192, 193] However, future work is needed to integrate AM with current CAD systems potentially compatible with FEA. The high initial cost of AM equipment and material, slow printing speed, and material strength are challenges that may be addressed by using central fabrication AM facilities, metal, fibre-reinforced, or multi-material AM, and cloud-based systems.[186, 194, 195]

Osseointegration

Osseointegration (OI) is a direct attachment of a prosthesis to the skeletal structure via an intramedullary implant.[196] During the last 30 years OI has become a clinically viable procedure.[197] Potential candidates are individuals who have complications with, and are unable to use, their prosthetic socket. Generally, the implant anchoring systems involve a threaded connection, a press-fit interface or contain interosseous pins.[198]

A great deal of literature reporting benefits and complications of OI in observational studies exists, and as a result, several reviews have been conducted recently.[9, 10, 199-204] Studies indicate that OI may improve walking ability, stability, functional capacity and quality of life in individuals with amputation who cannot tolerate their prosthetic socket.[9, 199, 201-203] A few studies reported pain complaint usually associated with weight-bearing and some users raised concerns with the relatively long post-surgical rehabilitation time.[9] Phantom limb pain may not improve when using an OI prosthesis[9] and the effect of OI on emotional state is not clear.[201] Compared to prosthesis with a socket, OI may be cost-effective based on conservative estimates with a large degree of uncertainty.[201]

The common complication of OI is a minor infection at the skin-implant interface that can be treated with antibiotics.[9, 199] Although serious adverse events such as periprosthetic or overall fractures, implant loosening, osteomyelitis, revision surgery or implant removal are rare, they pose a serious clinical concern.[9, 10, 199] Three long-term follow up studies (5 years, >9years and 15 years) indicate that although improvement in patient-reported outcomes have been reported since OI was first introduced, there are still concerns with tissue infection[205, 206] and the mechanical properties of the implant[206, 207] possibly related to higher activity.[207] Additionally, loss of bone density is associated with implant removal.[208]

One should note that a substantial proportion of evidence regarding OI comes from observational studies with overlapping study samples.[199-201] Osseointegration is prescribed to people experiencing problems with their prosthetic socket and those who do not have vascular disease. However, there is a lack of evidence as to the effects of different implant anchoring systems both in terms of clinical outcome and from a biomechanical perspective, e.g. degree of osseointegration, infection prevention. Future development could be directed towards the improvement of the surgical protocol and shortening rehabilitation period; improving implant designs to enhance the bone ingrowth to reduce loosening; increasing the implant safety mechanism; infection control and prevention strategy; mechanical properties of the implant for intense activities.

More recently a distal-weight-bearing implant has been developed consisting of a femoral stem placed inside the femoral intramedullary canal and a spacer that is connected to the stem using a screw/plug.[209, 210] The implant is located beneath the distal soft tissue of the residual limb enabling distal weight-bearing showing an improvement in distance and speed of walking.[209, 210] An FEA and laboratory simulation of a similar conceptual implant with a distal fluid-filled elastomer bladder showed an increase in distal weight-bearing and decrease in pressure and shear forces at the proximal regions of the residual limb.[211] More evaluation and longer-term studies are needed regarding benefits and possible complications before wider exploitation of these concepts are possible**.**

In 2013, the standard OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees) implant was upgraded to eOPRA (enhanced OPRA) and included implanted electrodes to provide biological signals for bidirectional communication between an upper limb prosthesis and the user's neuromuscular system.[212] Later, the system was further developed to include a controller capable of decoding motor intent and providing sensory feedback.[213] Also, an agonist-antagonist myoneural interface (AMI) has been proposed to enable voluntary control and proprioceptive feedback in lower limb OI prostheses.[214] The AMI consisted of two subdermal grafts linking agonist-antagonist muscles to imitate dynamic interaction found within an intact limb. Further research is needed to explore OI facilitation of neuromuscular integration for enhanced prosthetic control, proprioception and sensory feedback.[214-218]

Conclusions

Nearly 50 years ago, in the first issue of Prosthetics and Orthotics International, Dr. Fishman stated that the study of physics, materials sciences, and mechanics are necessary for the design of prostheses and orthoses, and that a qualified practitioner requires knowledge of biology, anatomy, kinesiology, pathology, biomechanics and pathomechanics when fitting a device to a human being.[1] In the intervening years, clinical practice and research proved that Dr fishman was correct. However, more recently new field of study such as engineering, computer modelling, artificial intelligence, additive manufacturing and electronics have begun to play an important role in enhancing our understanding and fabrication of prosthetic sockets. In the near future, sensing, monitoring and actuator technologies may facilitate socket fit improvement, control of volume and heat, and residual limb health. Prosthetic sockets that incorporate sensing, monitoring and actuator technologies will likely be manufactured through a fully automated, person-specific and data-driven process using powerful computer modelling, reliable quantification of residual limb geometry and mechanical properties, artificial intelligence and simulation techniques, and additive manufacturing; the combination of which will bring a paradigm shift in the user-prosthesis resulting in intelligent sockets. Through improvement in mechanical features of OI implants, advancements in infection control and prevention strategies, and the potential for neuromuscular integration, OI will likely become appealing to more people with amputation. Regardless, it is unlikely that one method (OI or sockets) will significantly overtake the other given the heterogenous needs and preferences among the population with amputation.

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