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# Advances in the measurement of prosthetic socket interface mechanics: a review of technology, techniques, and a 20-year update

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## Abstract

**Introduction:** A key determinant of prosthesis use is the quality of fit of the prosthetic socket. The socket surrounds the residual limb and applies the appropriate force distribution to the soft tissues to maintain suspension, support, and stabilization as well as translate limb movement to prosthesis movement. The challenge in socket fabrication lays in achieving geometry that provides the appropriate force distribution at physiologically appropriate locations; a task dependent on the understanding of interface tissue-mechanics.

**Areas Covered:** In the last 20 years substantial advancements in sensor innovation and computational power have allowed researchers to quantify the socket-residual limb interface; this paper reviews prominent measurement and sensing techniques described in literature over this time frame. Advantages and short comings of each technique are discussed with a focus on translation to clinical environments.

**Expert Opinion:** Prosthetic sockets directly influence comfort, device use, user satisfaction, and tissue health. Advancements in instrumentation technology have unlocked the possibility of sophisticated measurement systems providing quantitative data that may work in tandem with a

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Declaration of interest

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clinician's heuristic expertise during socket fabrication. If validated, many of the emerging sensing technologies could be implemented into a clinical setting to better characterize how patients interact with their device and help inform prosthesis fabrication and assessment techniques.

**Keywords**

Prostheses; Socket; Force; Pressure; Instrumentation; Sensors; Clinical Translation

## 1. Introduction

Each year in the United States, an estimated 185,000 people undergo the amputation of a limb [1]. In 1996 estimates of prevalence suggested that 1.2 million Americans are living with limb loss [2], and in 2005 these estimates raised to 1.6 million [3]. These numbers are expected to more than double by 2050 due to the aging population and increases in the incidence of diabetes mellitus and dysvascular disease [3]. Furthermore, it was reported in 2017 that there are 57.7 million people living with limb amputation worldwide [4]. For many of these individuals, a prosthesis will be prescribed to offset the function lost with the limb, aid in the performance of daily activities, and help facilitate independence and a return to community and societal roles.

The functional goals of upper limb (UL) and lower limb (LL) prostheses are fundamentally different. UL prostheses are designed to assist during the many dexterous movements one performs with their hands and arms while interacting with their daily environment. In contrast, LL prostheses are designed for predictable cyclical applications such as weight bearing and balance during ambulatory activities. Although these goals may differ, the prosthetic socket is a universal component that acts as the interface between the limb and the various prosthesis components, regardless of the limb or level of amputation.

One of the most influential factors for the use of a prosthesis is the design of the prosthetic socket [5]. The socket functions as the point of attachment of the prosthesis to the user's residual limb (RL). It is at this crucial junction where the soft tissue of the user's RL must serve as the connection between the bone and rigid materials of the prosthesis. Traditional sockets are designed to strategically compress specific areas of the user's RL while relieving contact pressures in others or, in the case for lower limb prostheses, often the goal is to maintain full contact with the RL to ensure proper socket fit. The overall goal of the socket is to utilize the individual's morphology to achieve suspension, support, and stabilization along with mechanical stability of the prosthesis while avoiding tissue irritation, damage, or general discomfort. Additionally, in the lower limb, most users wear silicone or gel liners rolled over their residual limb prior to donning the socket. These liners help pre-shape residual soft tissues, disperse forces on the limb, and can increase comfort and suspension, support, and stabilization. In the upper limb liners are common, but suction suspension methods that do not employ this technology are also used. Regardless of the interface used, the socket must be custom designed for each patient to achieve appropriate geometry for an effective interfacial pressure distribution between the RL and socket.

### 1.1 Socket-limb interactions

The general term “socket fit” can be used to encompass the quantitative and qualitative factors that have influence on comfort, suspension, support, stabilization, and the security of the prosthesis while worn on the RL. Socket fit and specifically comfort have substantial implications on user satisfaction [6–8]. At its core, socket fit is a biomechanical concept that is highly dependent on the interaction between RL tissues and socket. Movement and loading of the prosthesis are translated through the surrounding soft tissue onto a patient’s residual skeletal structure via the socket. Therefore, the prosthesis is coupled to the user’s skeletal system through an intermediate layer of deformable soft tissue, making designing sockets that reduce relative motion in this layer a major objective. In the LL, relative motion may result in pistoning (cyclical vertical displacement of the socket on the limb in phase with weight bearing during gait), axial rotation of the socket on the limb, or other unwanted forces across the limb due to socket tilt or displacement. In the UL, relative motion of a socket on the limb may result in similar effects as the LL along with reduced range of motion and control, especially in myoelectric prostheses where control electrodes in the socket must be securely placed at specific contact locations on the residual muscles.

In practice, a method of minimizing relative motion is to utilize prominent bony structures in the RL for stability while maintaining total contact with the residual soft tissue to counter-stabilize resultant loads. Yet overly high pressure can significantly decrease comfort and increase the risk of tissue irritation or damage [9]. Additionally, multiple areas of the RL are more physiologically tolerant to higher loading, such as the patellar tendon and popliteal fossa on transtibial amputees [10], along with areas more sensitive to loading such as the distal end of the residual bones [9]. Therefore, the challenge to the prosthetist lays in designing a socket that balances suspension, support, stability, and corresponding contact pressures, all while accommodating the individual’s unique anatomy and locations on the limb to which interfacial pressures are being distributed. In clinical practice, the implications of proper design are well acknowledged and much of a prosthetist’s effort will be dedicated to the design and fabrication of the socket [9].

### 1.2 Poor-fit and tissue damage

In both UL and LL prostheses, soft tissue irritation is a common complication. Numerous dermatologic problems related to prosthesis use have been reported including pressure ulcers, blister, cysts, edema, skin irritation, and dermatitis among others [11,12]. Tissue damage can be present at the surface or in deep tissue. Damage at the surface epidermis of the skin will typically result from shear loads imparted on the skin caused by repetitive socket displacement. Slip between the skin’s surface and the prosthetic socket results in a friction-shearing that can mechanically separate layers in the epidermis resulting in friction blisters [13]. Other common complications may include epidermal abrasion, general irritation and redness, and general mechanical damage of the residuum resulting in bruising and general soreness of affected areas.

Beyond surface tissue damage, more severe tissue injuries can occur caused by higher load applications, and therefore deep tissue injuries are more commonly reported with LL prosthesis use [14–16]. Deep tissue damage and wound formation may result from

physiologically inappropriate force distribution, shearing, and deformation of soft tissue between the residual skeletal structure and the rigid surfaces of the prosthetic socket. These conditions may occlude blood flow, as well as nutrient, oxygen, and lymphatic transport in the affected tissues. Furthermore, these conditions may promote ischemic reperfusion, all of which may result in pressure wound formation and deep tissue injury [14].

Tissue damage resulting from poor socket fit is a physiological consequence of the biomechanical conditions imparted on the RL via the socket. This has direct implications on a user's frequency of prosthesis use [12] as injuries require time to be treated and heal. Comfort is commonly identified as a crucial factor affecting the use and user satisfaction of a prosthetic device [6,8,17]. Additionally, many patients experience compromised sensory capacity in their residual limb due to nerve damage associated with either their initial injury and amputation or related disease processes such as neuropathy associated with diabetes mellitus. This further emphasizes the importance of a well-designed socket as damage to the residuum may not be detected by these populations until more severe tissue injury occurs.

### 1.3 Quantification of RL-socket mechanics

In socket design and fabrication, a comprehensive understanding of the RL-socket mechanical interactions is vital. Quantitative and empirical data holds the potential to identify anatomical locations bearing high normal and shearing loads and can also facilitate the prediction of how a socket may interact with the residuum. This has important implications on the improvement of comfort, risk of tissue injury, as well as the satisfaction and usage of the prosthesis.

A method reported in literature that is used to achieve this mechanical understanding is the use of experimental measurement techniques such as instrumented prosthetic sockets. Several review papers have been published prior to the year 2000 highlighting measurement techniques specifically in LL prostheses [18,19] as well as more recent reviews [20,21] focusing solely on technologies to measure transtibial socket forces. While there has been multiple sensors and sensor techniques highlighted in experimental and clinically focused research since then, the most recent review of these topics was published in 2001 [22]. The techniques, applications, and interpretations of findings in more recent literature are often disparate making it challenging for clinicians and researchers to draw upon the multitude of findings to make informed decisions.

### 1.4 Review objectives

In the last 20 years substantial advances have been made in sensor technologies and computational power to advance our understandings of the mechanical interactions between the prosthetic socket and the RL. The purpose of this review is to highlight *prominent recent methods* found in scientific literature that quantify RL-socket interface mechanics in both UL and LL prostheses. Prominent techniques reported in scientific literature between January 2001 and September 2022 will be discussed with a specific focus on clinical translation and applicability in a prosthesis fabrication context.

### 1.5 Search methodology

To collect relevant articles PubMed, Scopus, and Web of Science were used using *prostheses, socket, force, pressure, instrumentation, sensors*, and *clinical translation* as key words. This search included articles from 1970 and onwards. As this was a narrative review, articles containing relevant information pertaining to sensors used to capture the RL-socket forces were included. In total, 86 articles were included in this review with the goal of stating the impactful sensing technologies used in prostheses. A breakdown of the articles including the type and use of each sensing technology is provided (Table 1).

## 2. Lower limb quantification and prediction methods

### 2.1 Lower limb experimental measurement techniques

In literature, experimental measurement techniques employ multiple force and pressure sensors to capture the mechanics at the interface between the limb and the socket. Existing measurement techniques can be divided into two groups based on sensor placement [18]. Sensors can either be installed directly in (or passed through) the socket wall or inserted between the RL and socket. In the latter, if a liner is worn, the pressure sensors may be positioned between the liner and RL or between the socket and liner, a topic further explored in the discussion section. A hierarchical breakdown of measurement techniques discussed in this section is provided (Figure 1).

Several criteria must be satisfied to ensure the sensor's ability to sufficiently capture the mechanical interactions of the RL and socket. The sensor must accurately capture forces (or pressures) applied to the tissue while being minimally intrusive such that it does not change the biomechanics of the system. Care must be taken to ensure the physical geometry of the sensor does not significantly displace, deform, or otherwise alter the mechanical response of the soft tissue and prosthetic socket [23]. Additionally, sensors must be accurate for repeated measures, demonstrating stability over the biological conditions in which it will be used, such as temperature, physical geometries, and interface compliances [23].

#### 2.1.1 Sensors inserted between RL and Socket

**2.1.1.1 Commercially available systems:** Several studies used commercially available systems that were specifically designed to quantify LL socket interface forces (or pressures). The most popular system used in clinical literature is the Tekscan VersaTek or F-Socket systems (Tekscan, Boston, MA, USA) [21,24–26]. Other systems found in literature include the TACTILUS tactile pressure sensor system (Sensor Products Inc., Madison, NJ, USA) [27], Rincoe socket fitting system (RG Rincoe and Associates, Golden, CO, USA) [28], Novel pliance pressure sensor system (Novel gmbH, Munich, Germany) [29,30], Flexiforce A201 (Tekscan, Boston, MA, USA) [31,32], the Loadpad mobile FSR (model No. L3210, NovelGmbH, Munich, Germany) [33], and the INSIGHT system (Adapttech Inc, Birmingham, United Kingdom) [34]. Excluding the Novel pliance system, most commercially available systems employ thin (as thin as 0.18mm [35]) flexible pressure sensors comprised of force sensitive resistor (FSR) arrays or printed circuits that can be inserted between the RL and socket. These systems are designed for ease of use in a clinical or socket fabrication setting and include real-time visualization of pressures,

automatic report generation, and manufacture-provided software to perform calibration, data collection, and analysis.

FSRs and printed circuit technologies are an attractive option for clinicians and researchers as they have a thin profile, low monetary cost [35,36], and often require minimal signal processing prior to extracting data. While effective for measuring normal pressures, these technologies have several known limitations including hysteresis [32,35,37], drift error [28,32], and sensitivities to shearing forces, temperature, curvature, substrate compliances, and response to loading rate [23,32,36,38,39]. Values for drift error, accuracy error and hysteresis ranged from 4%−33.2%, 2.8%−92%, and 0.02%−41.88% respectively. These values can all be found in the supplementary tables (Supplemental Table 1). Compensatory strategies to minimize sensor error may be taken such as calibrating sensors in an environment as close to their intended use as possible [23]. However, these low cost, widely available sensors are still an attractive option for clinical and research prosthesis applications.

**2.1.1.2 Sensors used in experimental research systems:** Experimental systems that can be inserted between the RL and socket are commonly based on FSRs, which change resistance with the application of force [23]. These thin-film polymer sensors have been used for numerous experimental applications in LL prosthesis research.

In current literature, FSRs have been implemented in multiple different configurations to highlight pressure development in the prosthetic socket. These forces have been used to identify mechanics such as ambulation during gait cycle, RL-socket pressures, FSR accuracy, donning and doffing pressures, overall device comfort, and how well the socket fit the patient [31,32,40–45]. In studies that use experimental pressure sensors, the system is often manufactured after commercial models using micromachining techniques and can collect other forms of data such as temperature, light, or shear force.

**2.1.2 Sensors placed in the socket wall—**As the sensors discussed in this section must be installed into the participant's prosthetic socket, the development of a commercially available system is largely unfeasible. Most of the experimental sensor profiles are too large to be practically inserted between the socket and RL without disrupting or deforming the natural biomechanical state of the residuum. Therefore, the most common approach is to create holes in the socket to pass the sensor through, such that it sits flush with the interior of the socket surface. Care must be taken during installation as protrusion of the sensors into residual tissue may falsely inflate the force values captured by the sensor [9,46]. In literature, common sensors used for this application are force transducers which are described below.

**2.1.2.1 Force Transducers:** Force transducer is a general term that represents a large category of force sensing technologies. The most common subset of force transducer is the elastic element load-cell. In these sensors, strain gauges are mounted to a deformable element with known geometry and modulus of elasticity. The force applied to the sensor is determined through integration of the strain gauge readings and theoretical deformation-based calculations are used to infer the applied load.

While the application of force transducers has been reported in literature as early as the 1970s [47–49], significant advancements were made in the 1990s when research groups developed a series of force transducer socket measurement systems [50–54]. Unlike FSRs, printed circuits, or other previous prosthesis force transducer systems, these systems allow for measurement of normal and shear forces experienced at the interface between the socket and the residual limb [50,51,54–56]. In the past 20 years, numerous force transducers capable of measuring normal and shearing forces have been reported [57,58], and are typically integrated into LL prosthetic sockets to highlight gait forces [58–60]. A typical experiment will use multiple sensors tethered to a data acquisition system to illustrate forces on the prosthetic socket at specific locations during daily activities or contrast the biomechanical impact of prosthesis components [60,61] or fabrication techniques [59,62].

The application of force transducers holds many practical advantages over FSR or printed circuit technologies. Values for the drift error, accuracy error, and hysteresis were found to range from 0.35%−1.35%, 0.25%−07.1%, and 0.5%−8% respectively. While it is good to note that compared to FSRs these values were not as well reported in the literature, this technology is illustrated to be inherently more accurate, exhibits less hysteresis, and can capture normal and shear force values. However, like FSRs, force transducers are only capable of measuring forces at a single spatial point. While installing multiple sensors is a possible solution, the installation process may change the material properties of the prosthesis or the socket-participant interface [20], a limitation also noted with FSRs. Values for key parameters of these sensors can be found in the supplementary tables (Supplemental Table 2).

**2.1.3 Other Sensor Types—**As sensor technology involves, more types of sensors are developed that can be used to capture pressure changes that push the field forward and begin to change technologies. These are described below.

**2.1.3.1 Capacitive Sensors:** A capacitive sensor is comprised of two conductive substrate layers separated by a deformable dielectric layer. Compression of the sensor results in a change of distance between the two conductive layers and thus a change in capacitance proportional to the displacement resulting from compression which can then be used to infer the applied load [63]. Several studies report on capacitive sensor design and applications in prosthetic sockets. Multiple experimental capacitive sensors have been reported that span elastomeric foam, textiles, and 3D printed materials. From benchtop tests, these sensors have illustrated promising dynamic results including drift error, accuracy error, and hysteresis in the range of 4.4%−24.3%, 1.7%−9.96%, and 6.8%−12.95% respectively. Comparatively to current commercially used FSRs, these sensors typically demonstrate high accuracy, the ability to capture shear and normal stresses, reduced hysteresis and drift, and high measurement stability [64–71]. Values for key parameters from these tests can be found in the supplemental material (Supplementary Table 3).

Given these promising results, it is evident why researchers may gravitate towards novel capacitive sensors for prosthetic socket applications. Typically, they achieve higher sensitivity, lower temperature dependency, more robust structure, lower power consumption, better frequency response and a larger dynamic range than FSR or printed circuit technology

[20]. However, using multiple capacitive sensors in close proximity on a prosthetic socket may increase the sensor's susceptibility to crosstalk noise, field interactions and fringing capacitance [72]. Thus, more advanced electronics and filtering may be necessary to ensure the accuracy of the system. Additionally, many of these sensors have not been applied directly to a prosthetic socket, tested with a participant with limb difference, or validated against other technologies. This limitation paired with the largely experimental nature of many capacitive sensing technologies restricts their ability to translate into a clinical setting or for the information gleaned from prior literature to be applied in a clinically relevant context. Although promising, further work is necessary to examine the performance of many capacitive technologies in real-world prostheses and benchmark these systems against commercially-available clinically-implementable systems.

**2.1.3.2 Fiber Optic Sensors:** As instrumentation technology has continued to advance, so has the innovation of novel force and pressure sensors. In recent years, multiple sensors have been designed and proposed for incorporation in prosthetic socket systems. One such innovation involves sensors using Fiber Bragg grating elements, denoted as fiber optic sensors. Conceptually, these sensors use an optical fiber that transmits nearly all wavelengths of light with negligible attenuation. Only light around a specific wavelength will be reflected; known as the Bragg wavelength. Perturbations introduced to the fiber, such as force or strain will result in a shifting of the Bragg wavelength. This shift can be used to infer the nature of the perturbation including applied forces in both normal and shearing directions [73].

The application of fiber optic sensors such as Fiber Bragg grating has been suggested in numerous medical and biomedical applications including prosthetic sockets [74–78]. During benchtop testing, it was found that fiber optic sensors offer many advantages including high sensitivity, high resolution, small size, low weight, and minimal hysteresis [77]. Values for these parameters can be found in the supplemental material (Supplemental table 3). When tested inside of a prosthetic socket, this system illustrated the same properties as were found in benchtop tests and yielded higher pressure readings than a Tekscan printed circuit system [79]. These sensors can capture both normal and shear strains simultaneously inside the prosthetic socket accurately, up to 20 Newtons, when embedded in polyethylene foam [74]. However, while Fiber Bragg and other optical sensing systems show promising potential, the largely experimental nature of this technology in a prosthesis system warrants further investigation to determine it will show efficacy in clinical or real-world applications environment.

**2.1.3.3 Fluid Filled Sensors:** Another technology that has been proposed for use with prosthetic sockets is fluid filled (bubble) sensors. These sensors infer applied loads through the measurement of pressure changes in a fluid filled compartment of the sensor [38,80,81]. This technology can be used to adjust the volume inside of the socket to better fit the patient [81]. In benchtop testing and under cyclical loading, these sensors have been shown to outperform other technologies such as FSRs when evaluating sensor drift and hysteresis [38]. Like the Fiber Bragg sensor discussed previously, this technology has demonstrated favorable results for incorporation into a prosthetic socket [38]; yet it remains largely

experimental and has only been benchtop tested. Current research has yielded drift error and hysteresis values ranging from 1.8%−2.3% and 2.8%−10%, respectively, demonstrating promise for these sensors (more information can be found in Supplemental Table 3). However, further investigation of sensor performance while exposed to the environmental variables of a prosthetic socket is still necessary to evaluate sensor efficacy.

**2.1.3.4 Electronic Skin (E-Skin):** Another emerging sensor technology that has been tested in recent years is electronic skin (E-skin) which refers to a flexible electronic device which mimics human skin and uses this characteristic to adhere to a patient and collect biophysical data [82]. The benefit of E-skin sensors is their ability to detect and record normal pressure, shearing pressure, and losses due to friction or slip. The large range of data types collected by the sensor can decrease the amount of individual modality-specific sensors otherwise needed to capture socket comfort more completely [83]. While promising, this sensor is adhered to the patient's skin directly which may affect the mechanics of the socket and may lead to skin irritation. Further, little testing has been conducted on these sensors to illustrate important characteristics of the sensor necessary for clinical integration. Thus, further testing on this technology is required before clinical translation.

**2.1.4 Summary of Findings—**From the articles used in this narrative review, most experimental measurement studies characterized the pressures developed in transtibial prosthetic sockets. Further, while many of the sensors used in experiments were FSRs, other sensing technologies that were highlighted included force transducers, capacitive sensors, Fiber Bragg sensing technologies, fluid filled sensors, and E-skin. It was found that the majority of the FSRs used in experiments were commercially purchased while most of the other sensing technologies were experimentally developed. Collectively from literature published in the last 20 years and prior, normal pressure values ranged from 12.5 – 760 kPa and shear stresses ranged from approximately 45 – 78 kPa have been reported [9,18,33,68,84]. These wide ranges may be attributed to the fact that many studies reported forces applied to the limb while others report on pressures applied to the limb which is inherently dependent on the surface area of the sensor. Some of the studies also chose to test these sensors during benchtop testing rather than on participants allowing the authors to increase forces to loads that would not be seen in a prosthesis. Further variation in these values can be expected across patients resulting from individual anatomy, socket fit, the prosthesis components used, placement of the sensors, and activities being performed during testing. Additional technical variation may be introduced by factors such as sensor accuracy, sensitivity, hysteresis, and drift as well as the calibration, signal conditioning, and data acquisition techniques employed in an individual sensor system. These technical variations are highly important to the collection of accurate and repeatable data. From the literature, it was found that generally FSRs illustrate the highest drift error, hysteresis, and accuracy error comparatively to other sensors. However, it is good to note that these values were obtained over a variety of different testing methods which may not be representative of how these sensors are commonly used. Furthermore, error values for the other types of sensors were often not reported in the literature, pointing to the fact that the newer, experimental sensors require further testing. Key values for each type of sensor from the literature are summarized

in the supplementary tables (Supplement Tables 1–3). A table summarizing the pros and cons of the sensors found from the articles is provided (Table 2).

## 3. Upper Limb RL-Socket Mechanics

In the United States, UL loss accounts for an estimated 35% of those living with limb amputation [3]. Although the prevalence is less than that of the LL, there are disproportionately fewer studies quantifying RL-socket mechanics for those wearing UL prostheses. Similar to the LL, UL prosthesis comfort and function are closely tied to the mechanics of prosthesis fit. The ability of an UL prosthesis user to accurately control and position their prosthesis will ultimately be dependent on achieving an appropriate pressure distribution across the RL. Achieving the appropriate force distribution of residual soft tissues can improve a user's range of motion. Further, in myoelectric prostheses, the socket also plays a key role in the active control of electric components. It is also good to note that the UL and LL are two vastly different interfaces. For example, the forces developed in the UL along with the surface area of the limb will both be smaller in the UL than what is seen LL prostheses leading to a need for sensors that may be sized differently and can capture smaller loads than what is seen in LL prostheses. Thus, it is important to consider these differences when developing sensing technologies for UL prostheses.

Current UL socket fabrication processes rely heavily on heuristic practices. To date, limited literature has helped provide a rudimentary understanding of socket interface mechanics. Experiments found in literature primarily use a TekScan pressure system as a means of measuring pressure values between the RL and the prosthetic socket of UL amputee participants. This data has been used to correlate discomfort seen in UL prostheses as well as describe locations bearing maximum pressures [35]. Studies have used fluid filled systems to regulate contact forces in the socket itself [85,86]. Despite the very limited literature, it is evident that many of the measurement techniques developed for LL prostheses can be adapted to empirically describe the UL. As mentioned previously, many of these techniques may have to be adjusted in consideration of the fact that the LL and UL are two completely different interfaces and may require appropriate selection and adaptation of sensor systems to provide the most accurate data. Yet, like the LL, we suggest that the socket forces developed in UL prostheses are just as critical to providing patients with a functional well-fit device. In leveraging, adapting, and implementing many of the technologies seen in LL prostheses to the UL, there exists the potential to establish a fundamental mechanical understanding to help guide quantitatively based socket design and fabrication practices.

## 4. Discussion

Clinically, the ability to understand and predict the mechanical interactions of the RL and socket can quantitatively inform socket design decisions and fabrication practices. The implication on improved socket fit is acknowledged in literature with two reoccurring objectives; the first being the characterization of forces, stresses, or pressures developed in the RL's soft tissues caused by the prosthetic socket during various activities of daily living (such as gait or sitting), and the second being the characterization of these values to evaluate prosthesis components, socket designs, or fabrication techniques. Although decades

of research have been conducted around prosthesis fit and interface mechanics, socket fabrication still relies heavily on the highly skilled and often heuristic expertise of the prosthetist with little analytical data available to quantify the quality of fit.

The vast variability in terms of patient anatomy and potential prosthesis components often prevents the findings of a single study being applied across multiple patients in the clinic. This means that although many studies characterize the interactions of the RL-socket interface for a limited patient sample, a clinician cannot confidently rely on literature to address the unique challenges of an individual patient. These challenges may be addressed in a variety of ways including not only reporting on the socket pressure results, but also comprehensively reporting clinically relevant descriptors of the residual limb such as limb length, the amount and compliance of soft tissue present, areas of sensitivity on the limb, and the presence of skin irritation or break down, among many others. Additionally, studies with larger cohorts of participants with limb loss and/or the performance of standardized clinically relevant experimental activities will allow for comparison across experiments and provide further confidence in the findings of individual tests. This is important as many studies reporting on the development of novel sensing technologies often perform disparate benchtop testing activities or testing with limited patient populations and do not begin taking steps toward larger experiments in clinical environments or in real-world prosthesis applications.

A further challenge lays in advanced sensors lacking accessibility for the clinician and/or few being translated beyond the benchtop. In bridging this gap, two key issues must be addressed. First the system must be accurate and reliable enough that the clinician will have confidence in the result being presented. Secondly, the system must be packaged for ease of use; the system must be able to be operated effectively without over burdening the user with excessive training requirements and complexity. The clinician could then rely on this empirical data to help inform the design and fabrication of the prosthetic socket. However, it is good to note that achieving a well fit socket does not solely rely on sensors and often extends beyond quantitative measures and to the clinician’s skill and expertise for socket fabrication. As quantitative measurement values act as a tool to help in socket fabrication, a common language between patients, prosthetists, and those prescribing devices is extremely vital and should be fostered. A way to achieve this common language would be to employ a valid questionnaire [87].

For researchers and clinicians, selection of the appropriate measurement system has important implications on the possible data that can be collected. Commercially available pressure measurement systems, such as the Tekscan F-Socket, have seen the most use in clinical literature relative to the other quantification techniques reviewed. A possible explanation is the ease of use of these systems. Unlike pressure sensors that need to be installed through the socket wall, most commercially available systems can be inserted between the RL and socket. This allows the clinician to evaluate socket fit without permanently altering the socket to install sensors. Therefore, such systems can be readily employed, in a non-destructive fashion, in a patient’s existing (or newly fabricated) socket to aid in evaluation of socket fit. Additionally, such systems typically include user interfaces that require only modest technical training and knowledge; addressing another significant

challenge present in most to experimental sensor systems. Yet, many commercially available technologies possess inherent limitations in terms of accuracy, hysteresis, sensor drift, or sensitivity to their environment which vastly alter the accuracy of the results. From the literature, these technical parameters were dependent on the experiment as well as the sensor that was used. It was illustrated that FSRs demonstrate the highest reported drift error (33.2%), hysteresis (41.88%), and accuracy error (92%) during use. However, it good to note that these values were found during vastly different types of experiments ranging from demonstrating the different calibration techniques [39] to obtaining maximum pressures during walking to gauge device comfort [33]. While force transducers, capacitive sensors, optical sensors, fluid filled sensors, and E-skin all demonstrated lower drift error, hysteresis, and accuracy error, much of the literature did not state these key values due to the nature and scope of the paper itself. Thus, it is difficult to draw conclusions as to which sensor exhibits the lowest error metrics as each experiment. From the current literature, it is shown that FSRs demonstrate notable hysteresis, drift error, and accuracy error that can be accounted for by proper calibration. However, other sensing technologies inherently exhibit less error but also require further testing to be accurately compared to current commercial devices and for clinical translation.

Although many of these limitations are minimized using a variety of emerging experimental sensor systems, the implementation pipeline is often extremely complex. Implementation may require sensor integration with a data acquisition system, programming custom software to accommodate calibration, signal conditioning, and data collection, among others, prior to clinically relevant data being synthesized; most of which present significant barriers to those without highly specialized technical expertise. Furthermore, user comfort is another major aspect to consider when making any changes to the socket. As these sensors are in direct contact with the patient, when the prosthesis is loaded, the patient's contact with the sensor system may cause discomfort not normally seen in these assistive devices. Thus, it is pertinent to consider of the sensor changes the mechanics of the prosthesis when incorporating these systems into prostheses.

In this review we categorized sensors relative to their location in the RL-socket system. The reviewed literature reported on participants with transtibial, transfemoral, transradial, and transhumeral amputations along with shoulder disarticulation. Recorded maximum pressure values from these participants ranged from 45 – 550 kPa, 300 – 350 kPa, 28 – 29 kPa, 12.5 – 52 kPa, and 21 – 27 kPa, respectively for each level of amputation. This data has been recorded and is shown in the supplementary material (Supplementary Tables 1–3). These values exhibit a large range dependent on the amputation level, position of the sensor on the RL, and experimental procedure. The captured data is further influenced by whether a sensor is placed directly against the user's residual soft tissue or installed in the wall of the socket. If a sensor is inserted such that it is in direct contact with the residual limb, it holds the advantage of being able to capture resultant forces (or pressures) applied directly to the soft tissues. In systems where sensors must be installed into the socket wall, the forces being applied to the socket wall are captured. Further, the use of a liner also adds a level of complexity to sensor placement. From our review, articles that noted patients using a liner most often implemented the sensors underneath the liner such that the sensor was in direct contact with the patient's RL [24–27,29,30,33,35,42,44,86]. This technique is

more common because in the event a patient uses a liner, socket-mounted sensor placement will not capture the true forces acting on the user's soft tissue. However, placing the sensors in direct contact with the patient's skin and underneath the liner of the socket may also influence the prosthesis fit, resulting contact forces on the residual limb, and cause discomfort. Additionally, most sensors thin enough to be inserted between the RL and socket with minimal protrusion cannot capture shear stresses acting on that tissue. However, within the last decade 3D printing technologies have unlocked the possibility of socket design to seamlessly integrate wearable sensors. This technology has yet to be fully tested, but this idea may help reduce challenges in future developments.

Translation of experimental sensing technology toward clinical application requires fundamental barriers to be addressed. For any novel system, development and validation in an actual prosthetic limb worn by a patient is a crucial step. In doing so, limitations specific to prosthesis use, that might not be foreseen or captured during benchtop testing, can be caught and addressed in follow up development. After this, considerations for ease of use in a clinical setting must be pursued by addressing significant barriers such as the requirement for highly specialized training and intrusive installation procedures.

## 5. Conclusion

The prosthetic socket is a critical junction where a patient's soft tissue of their stump interacts directly with the rigid materials of their device. Developing a deeper understanding of this junction can provide clinicians and prosthetists relevant information to further promote the delivery of well fit, comfortable, and functional devices. Over the last 20 years, multiple sensing technologies have been developed or matured, making it possible to collect and implement this information. Technologies reported in literature include those that implement force sensitive resistors, force transducers, capacitive sensors, and a multitude of novel or experimental instrumentation techniques. Despite commercially available thin-film sensing technologies being readily employed in clinical and research settings, these sensors systems often exhibit hysteresis, drift errors, and many are only capable of measuring normal forces. While numerous experimental technologies have been reported in the last 20 years that address these limitations, they often lack validation in real-world prostheses and/or clinical settings. This is due to the variance between participants and the lack of larger population sample size reported in literature. Although early evidence is often encouraging, future work to validate and refine many of these experimental systems is currently necessary prior to translating their benefits to the clinic.

## 6 . Expert Opinion

Prosthetic sockets directly influence comfort, device use, user satisfaction, and tissue health of the RL. Fabrication of this vitally important component is dependent on an appropriate understanding of the interface mechanics between the RL and socket. Substantial advancements in instrumentation technology have unlocked the possibility of sophisticated measurement systems providing quantitative data that may work in tandem with a clinician's heuristic expertise during socket fabrication. Furthermore, such data would be incredibly valuable to the assessment of socket fit long after device fabrication. If proven

useful, many of the emerging sensing technologies could be implemented into a clinical setting and provide novel data to better characterize how a patient's RL interacts with their prosthetic socket; and thus, help inform prosthesis fabrication and assessment techniques.

Advances in sensing technologies and computational power have facilitated numerous new sensing techniques to quantify the mechanical interactions between a prosthetic socket and the soft tissue of the residual limb. Among many others, these include novel applications of thin film resistive technologies, capacitive sensing techniques, force transducers, pneumatic sensors, optical techniques, and even high-resolution E-Skin materials. Yet many of state-or-the-art technologies described in current literature are largely experimental and lack clinical accessibility. Two critical barriers currently exist. First, experimental systems must be rigorously validated to lend confidence to the quantitative information provided to the clinician. With future clinical and real-world testing, challenges not seen during benchtop testing may arise and can then be corrected to create more robust, reliable, and trustworthy measurement systems. The second barrier is the need for clinically amenable user-interfaces that minimize both the system complexity and the need for highly specialized technical training. Naturally, as advanced measurement systems are translated from the laboratory to the clinic this challenge may be reduced in the future. However, this process will inevitably require careful consideration for how a clinician, and even possibly the patient, may interact with the collected data, and how best to present relevant information to individual end-user groups. By addressing these two major limitations, the gap between advanced engineering technologies and clinical translation can begin to be reduced.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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## Article Highlights

- An introduction to how a patient interacts with their prosthesis and the importance of the prosthetic socket.
- The types of sensors typically used to measure and illustrate the interactions between the residual limb and the prosthetic socket.
- Current commercially available and experimental sensing technologies that have been used to measure the interaction between a patient's residual limb and their prosthesis.
- A review of the benefits and drawbacks of the technologies being used or developed and what benefits future work in this field can provide.

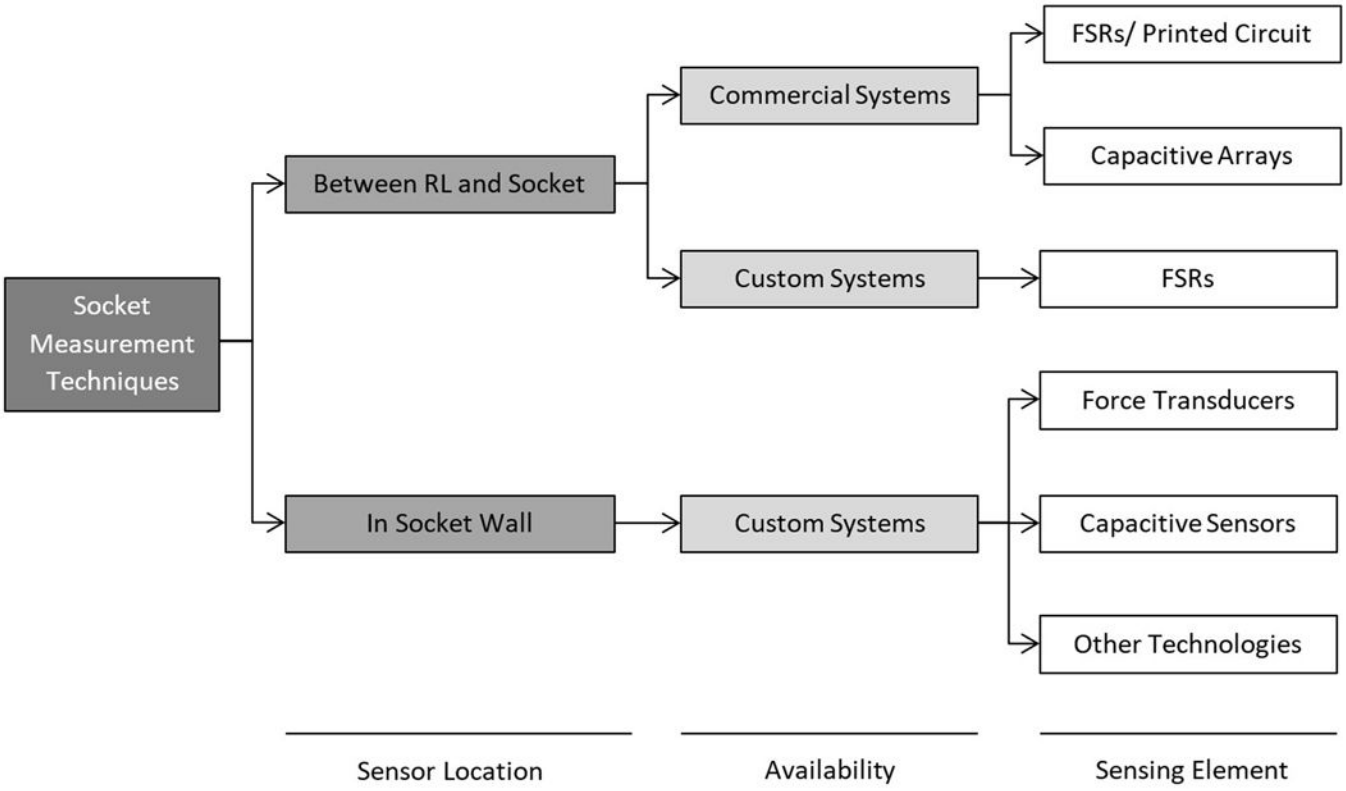


**Figure 1:**
A hierarchical breakdown of experimental measurement techniques, where FSR denotes force sensitive resistor.

**Table 1.**

Breakdown of the sensors that were used in the articles. Number presented in that table denote specific scientific articles in the order they are presented throughout the text of this review. The table is further broken down to highlight if the sensors were commercially available or experimental and if tests included a patient with limb deficiency or were purely performed on a benchtop. If the tests included a patient with limb difference, the level of the limb difference is further noted as transtibial (TB), transfemoral (TF), transradial (TR), transhumeral (TH), or shoulder disarticulation (SD).

| Sensor | Commercial | Experimental | Evaluation | Level | | | | |
|---|---|---|---|---|---|---|---|---|
| FSR | 22, 23, 24, 25, 26, 27, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 43, 81 | 30, 42 | **Limb Deficiency** | **TB**: 23, 25, 26, 30, 32, 39, 40, 41, 43 | **TF**: 24, 38, 42 | **TR**: 33 | **TH**: 33, 81 | **SD**: 33 |
| | | | **Benchtop** | 22, 27, 31, 34, 35, 36, 37 | | | | |
| Capacitive | 28, 29, 36 | 60, 61, 62, 63, 64, 65, 66, 67 | **Limb Deficiency** | **TB**: 28, 29, 61, 66 | **TF** | **TR** | **TH** | **SD** |
| | | | **Benchtop** | 36, 60, 62, 63, 64, 65, 66, 67 | | | | |
| Fiber Bragg Grating | 36 | 70, 73, 74 | **Limb Deficiency** | **TB** | **TF** | **TR** | **TH** | **SD** |
| | | | **Benchtop** | 36, 68, 73, 74 | | | | |
| Force Transducers | 44, 47, 53, 55, 57 | 45, 46, 48, 49, 50, 51, 52, 54, 55, 56, 58, 59, 79 | **Limb Deficiency** | **TB**: 45, 46, 48, 49, 50, 52, 53 54, 56, 57, 58, 59, 79 | **TF** | **TR** | **TH** | **SD** |
| | | | **Benchtop** | 44, 47, 51, 55 | | | | |
| Fluid Filled | 36 | 75, 76, 80 | **Limb Deficiency** | **TB** | **TF** | **TR** | **TH** | **SD** |
| | | | **Benchtop** | 36, 75, 76, 80 | | | | |
| E-Skin | | 78 | **Limb Deficiency** | **TB** | **TF**: 78 | **TR** | **TH** | **SD** |
| | | | **Benchtop** | 78 | | | | |

**Table 2.**

The advantages and disadvantages of the reviewed sensors.

| Sensor | Advantages | Disadvantages |
|---|---|---|
| FSR | Low cost, well documented, multiple commercial products, thin profile | Only normal pressure, hysteresis, drift error, sensitive to shearing forces, temperature, curvature, and loading rates |
| Capacitive | High accuracy, high sensitivity, large dynamic range, low hysteresis, low error drift, low temperature dependence, low power consumption | High noise when in close proximity to each other, largely experimental |
| Fiber Bragg Grating | High sensitivity, high resolution, small size, low weight, low hysteresis, can measure normal and shear forces | Only accurate at lower forces, largely experimental |
| Force Transducers | Measures normal and shear forces, high accuracy, low hysteresis | Can only measure forces at a single point, largely experimental |
| Fluid Filled | Low sensor drift, low hysteresis | Largely experimental |
| E-Skin | Can collect multiple types of data such as normal and shear forces, temperature, light, etc., large dynamic range | Largely experimental |