Development and validation of a 3D-printed interfacial stress sensor for prosthetic applications

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Abstract

A novel capacitance-based sensor designed for monitoring mechanical stresses at the stump–socket interface of lower-limb amputees is described. It provides practical means of measuring pressure and shear stresses simultaneously. In particular, it comprises of a flexible frame (20 mm × 20 mm), with thickness of 4 mm. By employing rapid prototyping technology in its fabrication, it offers a low-cost and versatile solution, with capability of adopting bespoke shapes of lower-limb residua. The sensor was first analysed using finite element analysis (FEA) and then evaluated using lab-based electromechanical tests. The results validate that the sensor is capable of monitoring both pressure and shear at stresses up to 350 kPa and 80 kPa, respectively. A post-signal processing model is developed to induce pressure and shear stresses, respectively. The effective separation of pressure and shear signals can be potentially advantageous for sensor calibration in clinical applications. The sensor also demonstrates high linearity (approx. 5–8%) and high pressure (approx. 1.3 kPa) and shear (approx. 0.6 kPa) stress resolution performance. Accordingly, the sensor offers the potential for exploitation as an assistive tool to both evaluate prosthetic socket fitting in clinical settings and alert amputees in home settings of excessive loading at the stump–socket interface, effectively preventing stump tissue breakdown at an early stage.

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1. Introduction

There are several million lower limb amputees worldwide, many of whom use prosthetic limbs to enable their mobility and daily activities. However, the intensive loading experienced at the residual limb can commonly lead to tissue breakdown and formation of pressure ulcers (PUs) at the residual stumps [1], known as stump ulcers. This can cause pain and discomfort to the amputee who may reject the prostheses and, in the worst case scenario, may result in life-threatening severe deep tissue injuries.

PUs represent a debilitating condition, which can affect the elderly, neuropathic, the spinal cord injured and patients in intensive care settings [2]. Residual stumps of lower limb amputees are particularly vulnerable to soft tissue breakdown for a number of reasons. (i) Many amputees suffer from co-morbidities including diabetes, peripheral vascular disease and peripheral neuropathy each of which compromises their soft tissue status and limits their healing capacity [3]. (ii) Residual stump tissues must sustain many hours of weight bearing, with equivalent peak loads of up to 270% of bodyweight during vigorous physical activities [4]. Indeed, stump soft tissues of the thigh and calf are not naturally designed to tolerate the resulting high stresses. (iii) Requirement of high quality socket fitting to minimize discomfort is a major challenge to the prosthetists [5] due to the bespoke and complex shapes of individual stumps where skin tissues overlay bony prominences [6], as well as frequent changes to the stump volume over time [7].

The underlying cause for stump ulcers is prolonged mechanical loading at the interface between the stump and the prosthetic socket [1]. Stresses in the normal (σ_n) and tangential (σ_t) directions exist at each loading point of the stump–socket interface, as shown in Fig. 1, both of which can contribute to the development of PUs. Indeed, shear loading is at least equivalent to compressive loading as an external factor affecting tissue breakdown [8]. Thus, the monitoring of both pressure and shear at this interface is crucial to enable effective prevention of stump ulcers [9]. Such interface sensors could be used to monitor stresses in different areas during walking, such as the patellar tendon and popliteal fossa areas of a trans-tibial amputee, as indicated in Fig. 1. Utilization of such sensors can also be employed to assist prosthetists, using CAD/CAM systems, to evaluate the effectiveness of socket fitting in the clinical setting [10].

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Most sensors reported to-date \cite{11-13} however, have only been designed to measure interface pressures, including a few commercial systems (e.g. Tekscan \cite{14}, or Novel \cite{15}). Other reported triaxial sensors are either built on rigid substrates \cite{16-18} unsuitable for direct exploitation at the critical stump–socket interface, or require complex manufacturing methods that preclude low cost fabrication of multiple sensor arrays \cite{19}, each of which limits their practical applications. Therefore, currently there are no practical sensors with the appropriate design features for measurement of both pressure and shear in the desired clinical setting.

This paper describes a novel interfacial stress sensor based on a capacitive mechanism, providing simultaneous measurements of $\sigma_p$ and $\sigma_s$. The exploitation of 3D printing with elastomeric materials also introduces flexible sensor frame which can potentially accommodate bespoke surface shapes, all of which represent key advantages for potential application at stump–socket interface.

2. Methods

A parallel plate capacitor was designed to transduce mechanical deformation. The main structure of the sensor is composed of a flexible mechanical frame built in-between top and bottom capacitance electrodes, as shown schematically in Fig. 2. The sensor design utilized commercially available 3D rapid prototyping materials and processes to provide versatile and cost effective fabrication of the mechanical frame. In this case, Object 350 Connex\textsuperscript{TM} rapid prototyping machine (Stratasys Ltd.) was used and an elastomeric TangoBlack\textsuperscript{TM} material was chosen to build the sensor frame.

2.1. Sensor design principle

The mechanical frame adopts a $3 \times 3$ array of filleted pillars in the design (Fig. 2d) to enhance both flexibility of the sensor and design freedom. 3 separate electrodes exist on the top surface (i.e. $E_x$, $E_y$, and $E_z$) with one bottom common electrode ($E_{com}$) attached to the sensor (Fig. 2b). Thus, three capacitors, $C_x$, $C_y$, and $C_z$, are formed by $E_x$, $E_y$, and $E_z$ each paired with $E_{com}$ respectively. Dimensions and alignment of these electrodes, as shown in Fig. 2c, are designed such that $E_x$ is centralized with but smaller than $E_{com}$, whilst $E_y$ and $E_z$ only partially overlap with $E_{com}$. When subjected to applied loads in the form of pressure and shear (Fig. 2d), the frame deforms with resulting changes to both the separation distance ($d$) and overlapping area ($A$) of the respective electrodes. Capacitance $C$ is governed by:

$$C = \varepsilon_r \varepsilon_0 \frac{A}{d} \quad (1)$$

where $\varepsilon_r$ is relative permittivity of the intermediate material which is a constant, while $\varepsilon_0$ is permittivity of vacuum. Upon application of $\sigma_s$, the overlapping area $A_z$ remains constant. Therefore, the change of $C_z$ (i.e. $\Delta C_z$) is only induced by the decrease of $d$ (i.e. $\Delta d$) and is dependant on $\sigma_p$. $\Delta C_z$ is accordingly expressed as:

$$\Delta C_z = \varepsilon_0 \varepsilon_r \frac{A_z \Delta d}{d(d - \Delta d)} \quad (2)$$

where $\Delta C_z = C_{z\text{final}} - C_{z\text{initial}}$ and $d_{\text{final}} = d_{\text{initial}} - \Delta d$. By contrast, $C_x$ and $C_y$ experience changes in both $d$ and $A$ induced by $\sigma_p$ and $\sigma_s$, respectively. For example, the change of capacitance $C_x$ ($\Delta C_x$) can be calculated from:

$$\Delta C_x = \varepsilon_0 \varepsilon_r \frac{\Delta A_x d + A_x \Delta d}{d(d - \Delta d)} \quad (3)$$

where $\Delta A_x = A_{x\text{final}} - A_{x\text{initial}}$. By rearranging Eq. (2) for $\Delta d$, Eq. (3) becomes:

$$\Delta C_x = \varepsilon_0 \varepsilon_r \frac{\Delta A_x}{d} + \frac{\Delta C_z}{A_z} \frac{\Delta A_x + A_x}{A_z} \quad (4)$$

Thus the measured $\Delta C_x$ and $\Delta C_z$ signals can lead to the corresponding values of $\Delta A_x$, equivalent to the x-component of $\sigma_s$. An equivalent estimation yields the y-component of $\sigma_s$. Nonetheless, the relationship between $\Delta A$ and x-direction $\sigma_s$ is strongly dependant on the nonlinear stress–strain behaviour of the elastomeric TangoBlack\textsuperscript{TM} composition of the mechanical frame. Therefore, to derive the pressure and shear values from the sensor signals, it is important to evaluate key mechanical properties of the sensor frame as detailed in Section 2.2.3.

2.2. Sensor fabrication

The mechanical frame was fabricated by 3D printing using TangoBlack\textsuperscript{TM} material. A double cladded flexible PCB sheet (C.I.F., Buc, France), which is comprised two Cu layers (each $\approx 70 \mu$m thick) separated by a flexible insulation layer ($\approx 70 \mu$m thick), was used for all the electrodes. The double sided PCB sheet permitted the fabrication of the patterned electrodes and the grounded shielding layers for the top and bottom electrodes, as shown in Fig. 2d. The
shielding layers are particularly important to minimize signal to noise levels of any miniaturized sensors at this level of capacitance [20]. A suitable electrode pattern was achieved through a lithographic process by selectively covering the copper with layers of negative photoresist and subsequent etching the flexible PCB.

2.3. Mechanical characterization of the elastomer

Stress–strain properties of TangoBlack™ were repeatedly characterized over a strain range from −30% to 50% (corresponding to stress region of −0.95 MPa to 0.80 MPa), based on ISO guidelines for tension (BS ISO 37:2011) and compression (BS ISO 7743:2011). The experimental results of the elastomer aligned well with a Neo-Hookean material model with a Lamé constant of 1.5 MPa, which is thus adopted for all subsequent FEM analysis.

2.4. FEA mechanical and electromechanical evaluation of the sensor

Comsol Multiphysics™ was employed to conduct the FEA evaluation of the mechanical deformation of the frame. Typical peak stress values reported at stump–socket interface, i.e. $\sigma_p \approx 342$ kPa [21] and $\sigma_s \approx 80$ kPa [17] were applied to the top surface of the frame while the bottom of the frame was fixed. The application of load resulted in strains of magnitudes of 5% in normal and 7% in tangential directions. The minimum and maximum principal stresses of $-0.633$ MPa and $0.230$ MPa were generated along the edge of the frame (Fig. 3c) and in the pillars (Fig. 3b). These stresses were within the material safe range between $-0.95$ MPa and $0.80$ MPa. Accordingly, the designed mechanical frame of the sensor was considered suitable to withstand typical loads at a stump–socket interface.

FEA electromechanical assessment of the sensor was conducted using Comsol™. A cylindrical air domain was added, which completely encompassed the sensor. The model was then solved sequentially with a segregated solver, to estimate $\Delta C$ under the combined loads of $\sigma_p$ (within the range $0$–$400$ kPa) and $\sigma_s$ ($0$–$150$ kPa).

2.5. Experimental evaluation of the sensor

The electromechanical performance of the fabricated sensors was characterized using a mechanical test system (ElectroPuls E1000, Instron Ltd., High Wycombe, UK). A handheld Agilent U1733C LCR meter was attached to and synchronized with the Instron system to measure the corresponding $\Delta C$. A purpose-made platen with adjustable inclination angle was employed to provide resultant stresses with components $\sigma_p$ and $\sigma_s$. Prior to any data acquisition, a specific tare load was applied to the sensor for 30 s. Subsequently, 150 repeated measurements were conducted, where an average of those is presented in this paper. This strategy minimized any possible transient response resulting from the viscoelastic behaviour of the Elastomer.

3. Results

Through the FEA it was observed (Fig. 4a) that $\Delta C_x$ is dependent on $\sigma_p$ but independent of $\sigma_s$. As a result, the conversion from $\Delta C_x$ to $\sigma_p$ can be deduced from a linear model,

$$\sigma_p = 1.207 \times 10^{18} \Delta C_x$$  \hspace{1cm} (5)

$\Delta C_x$ is also obtained through FEA as shown in Fig. 4b and a linear model is again shown to be appropriate. It is observed that while $y$-intercepts of the fitted lines are dependent on the respective $\sigma_p$,

the slopes are independent of $\sigma_p$. Thus, the following equation can be derived,

$$\Delta C_x = f(\sigma_p) + g \times \sigma_s$$ \hspace{1cm} (6)

where $f(\sigma_p)$ is linearly dependant on $\sigma_p$, and $g$ is a constant. By inputting the parameters, $f$ and $g$, into Eq. (6), the following equation is obtained,

$$\Delta C_x = \sigma_p \times 0.1683 \times 10^{-18} - \sigma_s \times 0.5190 \times 10^{-18}$$ \hspace{1cm} (7)

By rearranging Eq. (7), the influence of $\Delta C_x$ and $\Delta C_s$, on $\sigma_s$ is found to be,

$$\sigma_s = (0.3914\Delta C_x - 1.9268\Delta C_s) \times 10^{18}$$ \hspace{1cm} (8)

The electromechanical characteristics of the sensor derived from experiment, i.e. the capacitive response $\Delta C$ as a function of
\( \sigma_p \) and \( \sigma_s \) (Fig. 5), exhibits excellent agreement with the FEA prediction as indicated in Eqs. (5) and (8). Noteworthy, however, is a slight deviation particularly at high stress values, which could be attributed to the distinction between the Neo-Hookean model and the real, hyper-elastic behaviour of the elastomeric material. Nonetheless, as shown in Fig. 5, experimental results align well with the FEA prediction \( (R^2 = 0.99 \) and 0.93 for \( \sigma_p \) and \( \sigma_s \) respectively). As predicted by the FEA model (Eq. (5)), \( \sigma_p \) can be obtained directly from \( \Delta C_s \), which is independent of \( \sigma_s \) (Fig. 5a). On the other hand, Fig. 5b indicates that \( \sigma_s \) can be obtained from \( \Delta C_s \) and \( \Delta C_x \), by inputting these values into Eq. (8). As predicted by Eq. (7), \( \Delta C_x \) is linear with respect to \( \sigma_s \), while the y-intercept varies with \( \sigma_p \).

Fig. (5)c reveals the same data, offset by the first term in Eq. (7) \( (\sigma_p \times 0.1683 \times 10^{-18}) \), to account for the influence of \( \sigma_p \) on the y-intercept of \( \Delta C_s \). In this collapsed view, all the data points follow a single line, which agrees with FEA prediction, as highlighted by the second term in Eq. (7) \( (\sigma_s \times 0.5190 \times 10^{-18}) \). This confirms that the value of \( \sigma_s \) can be made independent of \( \sigma_p \) in these sensors by offsetting signals generated from corresponding \( \sigma_p \). Fig. 5c also demonstrates that removing the influence of \( \sigma_p \) on \( \Delta C_s \) allows for accurate measurements of \( \sigma_s \) by making it independent of \( \sigma_p \).

4. Discussion

The fit and design of prosthetic sockets and corresponding comfort levels of the prosthesis remains a major issue for lower-limb amputees. A poor socket fit, which is implicitly associated with loading distribution over the stump–socket interface, often leads to compromised viability of skin and underlying soft tissues, with a potential development of stump ulcers. To minimize the associated risk, it is critical to monitor both pressure and shear distribution at the stump–socket interface. This study details the development and validation of a novel sensor, which fulfils both technical and practical requirements for its potential applications.

The electromechanical tests indicated that, when a representative load at the stump–socket interface is applied to the designed sensors, \( \Delta C \) signals have been detected which can be resolved into \( \sigma_p \) and \( \sigma_s \) values, respectively. In particular, capacitance signals from the shear electrodes are detectable, albeit at a much lower magnitude than that recorded from the pressure electrodes. Both \( \sigma_p \) and \( \sigma_s \) show highly linear relationships with their corresponding \( \Delta C \) signals (5% and 8% errors respectively), where pressure signal linearity, i.e. 5%, is at least equivalent to the linearity quoted for Tekscan sensors [6]. The developed post-signal processing effectively separates pressure and shear measurements, respectively, as indicated in Fig. 5a and c. Such characteristics are
extremely advantageous for future signal circuitry designs, as well as for de-coupling and appropriate calibration of \( \sigma_p \) and \( \sigma_r \) in actual prosthetic applications. By contrast, other reported polymer-based (i.e. PDMS) sensors exhibit non-linear stress–strain behaviour [19], which will necessarily affect the complexity and accuracy of the associated electronics. Thus the present results suggest that the utilization of rapid prototyping elastomers provides both low-cost manufacturing and the potential to demonstrate improved functionality in clinical applications.

Furthermore, the electromechanical behaviour of the present sensors agrees well with FEA predictions (\( R^2 = 0.99 \) and 0.93 for pressure and shear respectively). It is noteworthy that the derived constants in Eqs. (5) and (8) are primarily dependant on the overall design of the sensor, namely materials, geometries, etc., which can be readily modified for subsequent prosthetic sensor optimisation, as well as for instrumented insoles to minimize the risk of diabetic foot ulcers. Thus, the present sensor design and its derivatives offer a paradigm shift in general PU prevention and soft tissue research.

The characterisation of the sensors was limited to quasi-static behaviour, although there is a clear requirement to extend it to dynamic behaviour. Thus future work will estimate both fatigue behaviour to evaluate sensor lifetime at the stump–socket interface and stress–strain hysteresis to estimate their temporal resolution. Additionally, it is envisaged that clinical experiments will also be conducted, to evaluate reliability and repeatability of the sensors. Nevertheless, the static results alone are very promising and exhibit a great potential for future commercialisation.

From Eqs. (5) and (8), we can evaluate the sensitivity and resolution of the designed sensor for stump–socket interface measurements. The mean capacitance signal noise, primarily induced by the LCR meter, was 7fF and 9fF standard deviations for \( \sigma_p \) and \( \sigma_r \) respectively, values comparable to those previously reported [19]. However, we envisage these values could be reduced by up to an order of magnitude by developing a custom-built circuitry employing commercially available Capacitance to Digital Converter chips. Indeed values for current sensor resolutions of 0.6 kPa (0.2 N) and 1.3 kPa (0.5 N) for \( \sigma_p \) and \( \sigma_r \) respectively, are achievable. These resolutions are important when considering the reported pressure value of 8 kPa sufficient to cause soft tissue ischaemia [24]. Other studies have shown that shear applied to the skin can reduce blood flux, by an equivalent amount as pressure alone [8]. The pressure and shear measurement resolutions of 0.6 kPa and 1.3 kPa respectively are much lower than 8 kPa and thus the sensor could be potentially exploited as a valuable tool for indicating early risk of soft tissue breakdown, effectively enabling a prevention strategy.

The influence of spatial resolution of interfacial sensors on measurement accuracy is highly complex, depending on a host of factors including the local curvature of the contacting body i.e. the residual stump and the load distribution over the stump, adjacent to bony prominences. To the best of our knowledge, no ideal spatial resolution has been established for stump–socket applications. However for planar foot applications, a large range of sensor diameters has been proposed from 1.7 mm to 17.4 mm [25,26] in consideration of the sensor overall performance as a trade-off between the edge effects and loading distribution. Thus we believe the outline dimensions of our proof-of-concept sensor design (i.e. 20 mm × 20 mm) could be potentially suitable for application at the stump–socket interface, albeit further dimension optimisation may still be required in future work. It is also important to note that the main sensor material (Lamé constant of 1.5 MPa) has compressive stiffness of approximately one order of magnitude higher than that of typical stump tissues (20–240 kPa [27]), thus presenting further potential for use at the stump–socket interface. Furthermore, current sensor thickness is comparable to if not smaller than that of other transducers used for prosthetic monitoring [16].

Furthermore, it is important to note that, since the main frame is fabricated using low cost and versatile 3D printing technique, the sensor is not only flexible, easy to scale and light weight, but also has the potential to be fabricated in many shapes (i.e. non-planar surface). As such, corresponding sensor arrays can also be readily manufactured leading to potential load mapping over the critical area of the interface. It is envisaged that such sensor arrays have a potential to both be used in assisting the initial prosthetic socket design and fitting, and to monitor performance over the duration of prosthesis usage. The latter will enable the monitoring of stump volumetric changes as a function of time and activity, leading to significant benefit for lower limb amputees. Detailed research in the direction of sensor compliance with various non-planar surfaces, issues associated with sensor flexibility and formation of sensor matrices will be conducted in the future work.

5. Conclusions

A miniaturized capacitive sensor dedicated to measuring both pressure and shear stress at the interface of a residual stump and prosthetic socket was designed, built and validated. 3D printing techniques of an elastomeric material, TangoBlack™, were adopted for the fabrication of the main frame of the sensor which can potentially lead to flexible and bespoke shaped sensors that are advantageous for their potential applications at the stump–socket interface. Both FEA and experimental tests were conducted to validate the sensor performance when subjected to up to 350 kPa pressure and 80 kPa shear load, respectively, which are typical loads reported at the stump–socket interface. Furthermore, excellent linearity for both pressure (≈5%) and shear (≈8%) signals were observed which are comparable with those reported values from commercial systems that are commonly used to monitor pressure loads at stump–socket interface (6% [22]). A post-signal processing model is also presented to effectively separate pressure and shear measurements which can be beneficial for their independent calibrations for future prosthetic applications. All these promising results suggest that the reported sensors have strong potential for effective pressure and shear loading measurements at the critical stump–socket interface.

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Ethical approval

Not required.

Conflict of interest

None declared.

References


