Characterising the soft tissue mechanical properties of the lower limb of a below-knee amputee: a review

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Abstract This paper presents a review of existing biomechanical models and technologies relevant to the study of soft tissues of below-knee amputees. Special attention is paid to related studies on biomechanical measurements of soft tissues, including the approaches for measuring forces and pressure distributions between stump and socket, and also estimating the deformations of soft tissues under loads. Mechanical properties of soft tissues related to their time-dependent and large deformation behaviours are discussed in the context of viscoelasticity and hyperelasticity. We review techniques used to measure the shapes of residual limbs, including volume fluctuations. We also survey methods for measuring tissue deformation using magnetic resonance imaging (MRI) and camera-based devices. The motivation for this review is to highlight techniques and methods for characterising soft tissues of below-knee amputees, and to discuss their limitations in order to guide future studies.

Keywords: Soft tissue, Below-knee amputation, Lower-limb stump, Biomechanical properties, Tissue deformation

1 Introduction

There are two main approaches to characterising the geometry and mechanics of an amputee's stump. One approach relies on the knowledge of the outer geometry of the stump, and how it deforms under various loading conditions. By applying a range of forces and torques to the skin, the resulting surface displacement fields can be measured and used to infer the surface mechanical properties of the stump. An alternative approach is to fully characterise the anatomy and biomechanical properties of the constituent tissues, such as the skin, muscles, ligaments, tendons, and bones that comprise the stump [1].

In this paper, we review techniques used by researchers to characterise the various tissue components using imaging techniques, such as MRI. We assess some of the techniques for modelling deformations under various loading conditions, and the use of these data for characterising the mechanical properties of the stump.

2 Anatomy and biomechanical measurements of the stump of below-knee amputees

The first step in modelling biomechanics of the stump is to characterise the geometry and constitutive properties of its tissue components. The bony structure of the stump includes the femur, tibia, fibula, and patella or kneecap. Interactions of these bones through the knee joint are mediated by cartilage, medial/lateral menisci, ligaments/tendons (including the fibular/medial collaterals, anterior/posterior cruciates, and patellar tendon), muscles (such as deep muscle, peroneus brevis muscle, hamstrings and quadriceps), skin, adipose tissues, and synovial fluid.

Biomechanical characterisation of soft tissues requires techniques to apply and measure loads, such as distributions of pressures, shear forces, and torques. These analyses also require estimates of the unloaded geometries, measurements of the deformations of the soft tissues under loads, and estimates of the remote loading conditions and kinematic constraints surrounding the stump.

2.1 Characterisation of the reference geometry and deformations

2.1.1 Magnetic resonance imaging (MRI)

MRI has been applied in radiology as a medical imaging technique to acquire images of the anatomy and physiological processes of the human body. An advantage of MRI is the absence of X-rays and ionising radiation. Although MRI provides useful information about the geometry of soft tissue, the scanners are costly to purchase and maintain, and typically require greater technical skill to operate compared to most other imaging techniques [2]. Moreover, due to the use of strong magnetic fields, MRI cannot be performed on patients with implanted medical devices, such as neuro-stimulators, pacemakers, or drug infusion pumps.

To characterise of the geometry of a lower-limb stump fitted with a prosthetic socket, Cagle et al. [3] replaced the MRI non-compatible parts of the socket with polymeric fibre and epoxy-acrylic resin. They reported that the polymer composite was not detectable in the MR images. To improve image quality, the researchers used ultrasound gel to fill the voids such as the distal gap between the socket and prosthetic liner.

2.1.2 Camera-based digital image correlation (DIC)

Accurate measurements of deformations are essential to investigate and understand the mechanical response of tissues subjected to loads. Furthermore, effective prosthetic socket designs for below-knee amputees rely on the accurate characterisation of the geometries of the residual limbs, their shape, and volume fluctuations [4]. To achieve this, camera-based digital image correlation (DIC) techniques are frequently applied for in vivo measurement of deformations of soft tissues such as skin [5, 6].

Three-dimensional DIC (3D-DIC) is an optical-numerical technique to evaluate the dynamical mechanical behaviour (deformation over time) at the surfaces of an object, such as soft tissue. This technique can be applied for high resolution extraction of the shapes and displacements at different length scales. A range of commercial and academic 3D-DIC software tools have been developed. For multi-view analyses, which are especially favourable in biomedical applications, it is helpful to use 3D-DIC packages which offer straightforward calibration and data-merging capabilities.

Solav et al. [7] presented the MultiDIC technique, suitable for multi-view setups. For reconstructing the dynamical behaviour of surfaces from multiple stereo-camera pairs, MultiDIC integrates robust 2D-DIC software with effective calibration procedures. They have developed a 12-camera setup to test the efficiency of the MultiDIC method. One limitation of this study was the use of cheap camera modules to test the efficiency of the method. Accordingly, the precision reported was modest. Future investigations should characterise the performance of MultiDIC using higher quality optics. Use of only a single multi-view setup and calibration object, as well as the fact that the technique does not provide a real-time displacement or strain measurements, also limits the applications of this approach.

Using an image-based system, Solav et al. [8] proposed a new approach to measure residual limb deformation with a multi-camera system to acquire simultaneous images of the stump surface. To acquire accurate time-varying deformation fields of the stump surface, the analyses of these images were conducted using an open-source 3D-DIC toolbox. The researchers obtained the measurements on transtibial amputee stumps during knee flexion, swelling upon socket removal, and muscle contraction. There were four main limitations of this study. Firstly, the approach is a time-intensive process, requiring that the limb be speckled with ink before the measurements are made. Secondly, the measurement could not be performed when the stump was inside the socket, since the method is optical in nature. Thirdly, the synchronisation latency among the cameras (~30 ms), contributing to the 3D reconstruction error, had not been accounted for. This could be addressed by substituting the software-controlled synchronisation with hardware triggers. Fourthly, results were obtained for only a single subject, so further research is required for verification of the results reported in the study.

2.1.3 Sensors for measuring single point displacements for static or quasi-static samples

Flynn et al. [9] presented an experiment for determining the mechanical characteristics of in vivo human skin using a custom-built force-sensitive 3D micro-robot consisting of a probe that could move quickly within a work volume. The micro-robot exerted load on the anterior forearm and the posterior upper arm, and would also be suitable for use on the stump. In another study, Flynn et al. performed an experiment in which the facial skin of five individuals was exposed to a set of deformations using the micro-robotic device. The Ogden hyperelastic constitutive relation [10] and quasi-linear viscoelasticity were used for developing a finite element model and simulating the experiments. They analysed force-displacement curves of the probe-tip, and concluded that the skin has significantly anisotropic, viscoelastic, and nonlinear mechanical properties. They showed the dependency of the response of the upper arm skin on the orientation of the arm. The primary limitation of these studies was that only normal load was applied to measure the displacement, with non-normal loadings not considered. The researchers also did not consider skin deformations using multiple probes, which limited the types of deformation that could be induced.

Sengeh et al. [11] presented a 3D viscoelastic characterisation of a transtibial stump based on in vivo indentations and MRI data. They used a robotic in vivo indentation system for inducing displacements at 18 selected locations. They also evaluated the nonlinear elastic/viscoelastic mechanical behaviours of the soft tissues using the inverse finite element method. The nonlinear elastic behaviours were modelled using the Ogden hyperelastic relations for which the strain energy function, *W*, is presented in Eq. (1), and viscoelastic behaviours were captured according to quasi-linear viscoelasticity. They reported the material parameters for the soft tissues of the stump. However, the indenter used in this research had a geometry with sharp edges, which resulted in convergence problems in simulations. Because of the indenter shape and size, accurate capture of data was difficult in regions of high curvature. Use of a spherical and smaller indenter may help for loading around uneven surfaces. A further limitation of the evaluation represented in this paper is that the tissue deformation had not been validated. It may be better to apply the techniques of surface deformation measurement based on camera-based DIC.

$$W = \sum_{p=1}^{N} \frac{\mu_p}{\alpha_p} (\lambda_1^{\alpha_p} + \lambda_2^{\alpha_p} + \lambda_3^{\alpha_p}) \tag{1}$$

where *p*, μ_p and α_p are material constants and $\lambda_j \; (j = 1, 2, 3)$ are principal stretches.

2.2 Techniques and sensors for measuring the loads acting on the stump

Devices designed for measuring the loads applied to the stump may be categorised as single-point or arrays of sensors. Any force probing will affect neighbouring probes because soft tissues deform significantly in response to the forces that we wish to use, while this issue might not be raised in a single load sensor. In the category of an array of sensors, each sensor might have interference with the other sensor in the array. However, the main reason of using an array of sensors instead of a single sensor is to simultaneously obtain the data from stump-socket interface, while the stump is subjected to the load, and this cannot be implemented by just using a single sensor.

2.2.1 Sensors for measuring forces and/or torques at a single point

The Fitsocket Robot devised by a group at the Massachusetts Institute of Technology (MIT) is comprised of a transducer for applying a normal force on the stump, while other transducers are used to constrain the motion of the posterior part of the stump [11]. Flynn et al. [9] used a custom-made microrobot for applying the loads to investigate the effects of shear forces on the skin and obtaining shear stiffness.

2.2.2 Techniques to measure spatial distributions of loads acting on the stump

The stresses distributed at the interface between the prosthesis and residual limb are generally combinations of shear and normal stresses. High stresses at the interface may lead to decreased blood flows and skin-related problems. Thus, measuring shear stress is as significant as the measurement of normal stress. The first measurements of the shear stresses at the stump/socket interface were reported by Appoldt et al. [12], who used tangential pressure transducers embedded in the walls of the socket. This system was limited due to its inability to measure both shear and normal stresses simultaneously.

Sanders and Daly [13] designed a system for simultaneously measuring the stump–socket interface stresses in three orthogonal directions. They positioned the force sensors at different locations inside the prosthetic socket of a below-knee amputee to measure the stresses during walking. The transducers were oriented in orthogonal directions over 6.35 mm diameter sensing areas. The shear stresses at the interface were measured from the estimated differences in bending moments between the strain gauge locations. The normal stresses were measured using full-bridge diaphragm strain gauge networks. Despite being able to measure the shear and normal stresses simultaneously, their use of piston-based transducers for stress measurements was limited by their bulky size and complex instrumentation. Moreover, a source of error arises from the deflection of these transducers under load, leading to the deflection of skin from its initial position, which results in errors in estimating shear stress from their measurements.

Force-sensing resistors (FSRs) can be used for measuring the dynamic stump–socket interface pressure of walking transtibial amputees. Generally, an FSR is a force sensor whose resistance reduces by exerting a normal force. FSRs can be constructed with different shapes and can estimate the changes in applied loads. Stresses are measured by dividing the estimated load by the surface areas of the sensors. Convery and Buis [14] arranged 350 pressure sensors over the inner surface of the socket to estimate the dynamic interface pressure during the gait cycle. They claimed that these compound sensors indicated that the use of their hydro cast prosthetic socket led to lower pressure gradients during dynamic loads compared to a patellar-tendon-bearing (PTB) socket. One limitation of their study was that Convery and Buis [14] investigated the pressure field distribution only during the stance phase of the gait cycle, whereas the swing phase was not studied.

Piezo-resistive FSRs are good candidates for medical applications [15] because they are thin, flexible, and conformable devices. Since they can be configured as thin and flexible sheets, piezo-resistive sensors can be placed within the socket for monitoring the pressures [16]. Arrays of FSRs can be used for monitoring the spatial distributions of stresses at the stump–socket interface. As an example, Ruda et al. [17] arranged five sensors embedded within a thin acetate sheet to monitor the pressures at the stump–socket interface. However, because of the very small surface areas of FSRs, the stress estimates were somewhat unreliable.

Capacitive sensors have also been used for pressure monitoring at the stump–socket interface. A prototype capacitance pressure sensor was introduced by Polliack et al. [18] for prosthetic socket application, where 16 sensors were arranged on a silicone substrate. They reported a mean hysteresis error of 12.93 % ± 4.63 %. However, these capacitance pressure sensors were unidirectional and could only be used to estimate the applied pressure. Laszczak et al. [19] developed a novel capacitive sensor for measuring the shear and normal stresses at the stump–socket interface. The design of the sensor was based on the change of the area and height of the sensor's frame, which indirectly affects capacitance within the sensor. The area of applied load on the sensor was 20 mm by 20 mm, and they assumed that the area was under uniform shear and normal stresses, which is not strictly correct in any location at the stump-socket interaction. In particular, parts of the stump or socket with high curvature, will be subject to large errors in the estimated stresses using this sensor. In this study, the application of the sensor was limited to quasi-static behaviour, although there is an obvious demand to develop it to measure deformation over time.

Fibre Bragg grating (FBG) sensors have high sensitivity, durability, immunity to electromagnetic interference, resistance to aggressive environments [20], and have been applied to measure various quantities including pressure, force, strain, temperature, and humidity. The stiffness of the polymer matrix affects the performance of an FBG sensor for stress estimation. Various matrix materials were studied by Al-Fakih et al. [21] to optimise the accuracy of stress measurement at the stump–socket interface. The results demonstrated that the use of a harder and thicker matrix material in the socket led to greater accuracy and sensitivity. In another study by the same group [22], FBG elements were placed in thin layers of epoxy-based sensing pads for in-socket stress measurement. The FBG-instrumented epoxy pads were embedded in silicone polymers to make pressure sensors. The efficacy of the FBG-epoxy sensors was tested by inserting and inflating heavy-duty balloons into the sockets using compressed air to simulate the conditions of a transtibial amputee's patellar tendon bar. However, like most piezo-resistive pressure sensors, these FBG-based pressure sensors could only be used to estimate the normal stresses.

3 Identifying the mechanical properties of the tissues of the lower limb

Finite element (FE) analysis is an approach widely used in bioengineering to estimate the stresses and strains in complicated mechanical systems, and has proven to be a useful tool for prosthetic socket design. Since the first development of FE models of the transtibial residual limb and prosthetic socket [23], several models have been developed to improve prosthesis design [24]. The stump–prosthesis interface was the focus of the first substantial efforts using computational biomechanics for prosthetic research. The earliest studies used two-dimensional (2D) models to explore the load transfer between the stump and the prosthetic socket [25, 26]. Later studies used 3D models for the stump–prosthesis interface [27-36].

Interface modelling is useful for estimating the stump–prosthesis pressures and stresses, which are important since they relate to potentially measurable quantities, assisting model validation. The interface pressures and stresses in the earliest studies were predicted by applying static loads to the stump [26, 27-30, 32-34, 37, 38]. In some studies, quasi-dynamic analyses have been performed to investigate interface pressures [31]. However, it should be stated that the finite element models developed in cited studies are not fully dynamic models, whereas the interaction between the prosthetic socket and residual limb is a highly dynamic process [39].

The selection of the contact model can have a significant effect on the stump–prosthesis interface simulation. Some studies have addressed the issues related to large relative tangential displacements by using contact elements that differ in their contact partner identification techniques [28], and by application of explicit finite element formulation [33]. In these studies, the coefficient of friction (COF) value was considered in the range of 0.415 to 0.7 [27-30, 33]. However, other studies have assumed frictionless contact between the stump and the socket [40-42]. Most studies refer to two experimental COF reports: Sanders et al. [40] carried out static COF measurement between skin, socks, and conventional sockets, and Zhang and Mak [41] carried out similar dynamic COF measurements. A limitation of these studies was that the COF measurements were performed in dry conditions and at ambient temperatures. Future measurements should preferably incorporate the influences of elevated temperature and the presence of moisture due to sweat at the skin surface, which have been reported to have significantly variable influences on COF, as explained by Derler and Gerhardt [42].

Many early investigations [26-30, 36] used linear constitutive relations for modelling the mechanical response of the soft tissues of the stump. Linear elasticity is adequate for a material that deforms and recovers in a linear manner in response to applied loads. For infinitesimal strains, this behaviour can be specified based on generalised Hooke's law, including the Young's modulus (E) and the Poisson's ratio ($-1 \leq \nu \leq 0.5$). As the ratio of transverse to axial strain, Poisson's ratio is related to the compressibility of materials. With high water content, soft tissues are generally assumed to be incompressible ($\nu = 0.5$). However, this limiting value can lead to numerical instabilities in finite element computations, so researchers have typically used values $0.45 \leq \nu \leq 0.49$ in linear elasticity models of soft tissues. The mechanical response of bone has also been represented using linear elasticity, using the values 10 GPa $\leq E \leq$ 15.5 GPa and $0.28 \leq \nu \leq 0.30$ [27, 29, 30, 33, 35, 36, 38], or bone has been assumed to be rigid in some studies [28, 32]. Many investigations of limb surface stresses, based on linear elastic models of soft tissues, used the values $E = 200$ kPa and $\nu = 0.49$ following the work of Zhang et al. [47].

Soft tissues generally undergo large strains and exhibit nonlinear stress-strain behaviour during physiological loading. It is thus important that finite strain theory should be adopted to describe the large deformation of soft tissues. Owing to the recent progress in applied material models for the soft tissues, linear elastic simplifications have been broadly replaced by models that include hyperelasticity and viscoelasticity, albeit subject to the assumptions of homogeneity and isotropy (the skin exhibits heterogeneous properties, and skin and the muscle, as a composites of cells and collagen, respond anisotropically to loads). Hyperelasticity postulates the existence of a strain energy density (SED) function [43], which relates the strains of tissues to their corresponding stress values [44]. The biomechanical properties of soft tissues such as skin, fat, and muscle can be wellcharacterised using hyperelastic models [45]. Various constitutive relations have been suggested for modelling hyperelastic materials such as Saint Venant–Kirchhoff, neo-Hookean, Mooney-Rivlin, Ogden, and Yeoh relations [46]. One of the simplest hyperelastic constitutive relations is the Saint Venant–Kirchhoff model, which is an extension of the geometrically linear elastic constitutive relation to the geometrically nonlinear regime. Saint Venant–Kirchhoff and Mooney-Rivlin models can be used for phenomenological descriptions of observed behaviour, while the neo-Hookean model is a mechanistic model derived from arguments about underlying structure of the material. The constitutive parameters of these models can be tailored to reproduce particular stress-strain behaviours using inverse finite element methods to interpret biomechanical measurements. Several recent investigations used hyperelasticity to represent and study soft tissue stresses [32, 33, 35, 37, 48]. Portnoy et al. proposed an approach that has been adopted by the majority of subsequent investigations [49]. They used a compressible neo-Hookean model for fat and muscle with various levels of stiffness, an incompressible neo-Hookean model for scar tissue, and an incompressible extended Mooney-Rivlin model for the skin. It should be noted that the identified studies used SED functions taken from general material characterisation studies, rather than patient-specific information.

In general, the predicted maximum stump–socket interface stresses under stance and gait loading were remarkably higher in the earlier studies that assumed linear elastic response of the soft tissues, compared to the stresses predicted by the more recent hyperelastic models. Specifically, the studies based on linear elasticity reported the maximum interface pressures in the range of 90 kPa to 783 kPa [27, 38], while the studies using hyperelasticity reported the maximum interface pressures in the range of 1.54 kPa to 119 kPa [33- 35]. Most studies applied a normal uniaxial load to reproduce the stance phase and neglected the shear stress, but one source of difference in these pressures may be the various magnitudes of the loads applied to the stump. It should be noted that the earlier studies neglected the effect of pre-stresses applied to the stump. Lee et al. [30] presented a new practical technique for modelling the contact interfaces by considering the friction/slip conditions and pre-stress exerted on the limb within rectified sockets. The pre-stresses were predicted by moving the penetrated limb surface onto the inner surface of the socket. Then, by keeping the pre-stresses, the loading during the stance phase was simulated when the loads were applied on the knee joint. They reported that maximum normal and shear forces decrease over the regions where socket undercuts are created.

Time-dependence of soft tissue loading in stump FE models has received relatively little attention in the research literature. Some investigations have considered the viscoelastic effects related to stress relaxation. Non-viscoelastic models are not able to determine the absorbed/dissipated energy by the prosthesis due to the fact that energy absorbing damping effects have been neglected. Characterisation of the viscoelastic response enables the examination of transient influences of stress relaxation. For example, Portnoy et al. [32] estimated the risks of soft tissue injuries using a Prony series expansion to represent stress relaxation and creep of the soft tissues.

Silver-Thorn [50] conducted in vivo rate-controlled indentation experiments and stress relaxation tests on the soft tissues of the stump. They showed that the bulk soft tissue responses to compressive loads are nonlinear and rate-dependent. Notable stiffness (Young’s modulus) variation between five individuals was also observed. They demonstrated that biomechanical simulations of bulk soft tissues require consideration of nonlinear viscoelastic constitutive relations. Tönük and Silver-Thorn [51] evaluated a suitable set of nonlinear viscoelastic material parameters for the soft tissues using a Prony series expansion and a linear Kelvin–Voigt model of viscoelasticity. They identified a range of viscoelastic parameters based on data from creep and relaxation experiments. Sengeh et al. [11] presented a 3D viscoelastic characterisation of a transtibial stump based on in vivo indentations. They evaluated the nonlinear viscoelastic mechanical behaviours of the soft tissues using inverse finite element methods. The nonlinear elastic behaviours were modelled using Ogden hyperelastic relations, and viscoelastic behaviours were captured according to a two-parameter relaxation function. They identified the material parameters for soft tissues of the stump and found less spatial variability in calculated properties for their test participant than Tönük and Silver-Thorn [51] had observed. Further investigations are needed to study the effects of suddenly applied or shock loads, for which viscous damping plays an important role in the transient mechanical behaviour of the stump.

4 Conclusion

This paper has reviewed recent advances in lower limb amputee modelling based on finite element studies that have considered the interface pressures between the residual limbs and prosthetic sockets. Most studies have considered only the effects of normal uniaxial loads, while neglecting shear loads. The majority of studies have been based on static or quasi-static analyses, whereas the interaction between the prosthetic sockets and residual limbs is typically a highly dynamic process. Although there are recent advances in methods of determining biomechanical properties of soft tissues, there is still an urgent need to develop instrumentation and computational tools to enable characterisation of the individual-specific geometry and tissue mechanical properties in lower limb amputees. For the soft tissues of the lower limb, the viscoelastic effects related to time-dependent material behaviour, and the nonlinear, anisotropic hyperelastic mechanical response to the large deformations that occur during physiological loading, should also be considered to develop more realistic predictions of the biomechanical interactions between the stump and socket that can be used to improve the design of prostheses on a per-patient basis.

5 References

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