Development of a residuum/socket interface simulator for lower limb prosthetics

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Abstract:	Mechanical coupling at the interface between lower limb residua and prosthetic sockets plays an important role in assessing socket fitting and tissue health. However, most research lab based lower limb prosthetic simulators to-date have implemented a rigid socket coupling. This study describes the fabrication and implementation of a lower limb residuum/socket interface simulator, designed to reproduce the forces and moments present during the key loading phases of amputee walking. An artificial residuum made with model bones encased in silicone was used, mimicking the compliant mechanical loading of a real residuum/socket interface. A six degree-of-freedom (6DOF) load cell measured the overall kinetics, having previously been incorporated into an amputee's prosthesis to collect reference data. The developed simulator was compared to a setup where a rigid pylon replaced the artificial residuum. A maximum uniaxial load of 850N was applied, comparable to the peak vertical ground reaction force component during amputee walking. Load cell outputs from both pylon and residuum setups were compared. During weight acceptance, when including the artificial residuum, compression decreased by 10%, while, during push off, sagittal bending and anterior-posterior shear showed a 25% increase and 34% decrease, respectively. Such notable difference by including a compliant residuum further highlighted the need for such an interface simulator. Subsequently, the simulator was adjusted to produce key load cell outputs briefly aligning with those from amputee walking. Force Sensing Resistors (FSRs) were deployed at load-bearing anatomic locations on the residuum/socket interface to measure pressures and were compared to those cited in literature for similar locations.

	The development of such a novel simulator provides an objective adjunct, using commonly available mechanical test machines. It could potentially be used to provide further insight into socket design, fit and the complex load transfer mechanics at the residuum/socket interface, as well as to evaluate the structural performance of prostheses.

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Abstract

Mechanical coupling at the interface between lower limb residua and prosthetic sockets plays an important role in assessing socket fitting and tissue health. However, most research lab based lower limb prosthetic simulators to-date have implemented a rigid socket coupling. This study describes the fabrication and implementation of a lower limb residuum/socket interface simulator, designed to reproduce the forces and moments present during the key loading phases of amputee walking. An artificial residuum made with model bones encased in silicone was used, mimicking the compliant mechanical loading of a real residuum/socket interface. A six degree-of-freedom (6DOF) load cell measured the overall kinetics, having previously been incorporated into an amputee's prosthesis to collect reference data.

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Keywords

Lower limb, prosthetics, residuum, socket, interface, simulator

Introduction

A comfortable, well-fitting socket is integral to the health of an amputee's residuum[1]. In some cases, the residuum will be exposed to excess loads at the residuum/socket interface, leading to the potential development of blisters, skin inflammation and pressure ulcers[1-3]. Currently, prosthetists generally depend on subjective expertise and feedback from the amputee to produce well-fitting sockets. Indeed, there is a general lack of objective means to quantitatively examine how changes of socket design, fit and limb setup may affect residuum tissue loading.

As a consequence, many studies have focused on the measurement of interface stress[2, 4-7] using various sensor systems. However, the reported values of interface pressures, for a given anatomic location on a residuum, for example at the popliteal depression, range considerably from 35kPa[2] to 244kPa[8]. This is due, in part, to the large intra-subject variability in amputee residua included in the studies. Indeed, even the residuum of an individual amputee can fluctuate in volume, with values of up to 8%[9] depending upon the time of day, the environmental conditions and the time following their amputation[10], all of which will affect interfacial stress values. Although these factors will clearly influence the clinical evaluation of socket fit, the variation will also hinder valid comparisons of interface measurement systems and socket design approaches. This has motivated the development of lab-based simulators based on international guidelines, typically ISO 10328[11]. This standard simplifies the complex loading profile during walking, into two discrete loading events, termed Conditions 1 and 2. These conditions simulate the forces and moments associated with the prosthetic during the *'weight acceptance'* (WA) and *'push-off''* (PO) phases of walking, respectively, corresponding with the two peaks in the vertical ground reaction force (GRF). However, ISO 10328 was designed to assess the structural integrity of the components[12], as opposed to evaluation of loading at the residuum/socket interface, thus it is often implemented with a rigid socket coupling[13]. A gait simulator using industrial robotics has recently been reported[14], in which objective pressure measurements at the residuum/socket interface were conducted and correlated with the levels of comfort. However, the large size and cost of such a specific system, significantly limit its wide applicability. Accordingly there is a need to provide a realistic, relatively low-cost simulator to be used in conjunction with mechanical test machines, which are readily available in research labs.

This paper describes the design and fabrication of a lower limb prosthetic simulator that can provide a representation of the residuum/socket interface by including an artificial residuum with bony prominences incorporated within a soft tissue analogue. It was also designed to accommodate the key peak loading events during gait, equivalent to the WA and PO phases of walking. The development of such a simulator and associated test arrangements provide effective and practical approaches to build lab-based tools, which offer potential in assessing socket fit, interface stress and their dependence on prosthetic components, alignment etc.

Methods

Simulator development

Figure 1a shows a schematic of the trans-tibial simulator design with key components identified, including a trans-tibial artificial residuum, matching socket, a six degree-of-freedom (6DOF) load cell and upper and lower alignment plates. The simulator was designed to be compatible with a uniaxial mechanical test machine (8800 series, Instron Ltd., High Wycombe, UK). Ball-and-socket joints were used at the upper and lower points of load application to allow for movement of the simulator during compression, without generating bending forces and moments in the test machine. Attached to each of these were alignment plates, which can be arranged to produce WA and PO phases. Since it has been shown that prosthetic feet provide limited propulsion in the PO phase[15], the lack of a foot in this simulator was not envisaged to detrimentally affect the comparative results. With the exception of the residuum/socket interface and the ball-and-socket joints, as shown in Figure 1a, all other components were linked via rigid connectors. The prosthetic socket was aligned ‘neutrally’ so that the upper plate was parallel with the bottom plate.

A truncated trans-tibial knee joint was encased in silicone to form the trans-tibial artificial residuum (Figure 1b-c). Following surgical guidelines for trans-tibial amputations[16], model bones (UK3BS, Somerset, UK) were cut to the desired size. In particular, the sectioned tibia was approximately 110mm distal to the tibial tubercle, while fibula was obliquely cut to a length of 90mm from fibula end to fibula head. These two bones were then joined together, with a model femur and patella, using an industrial adhesive to form a rigid, neutral-angled knee joint (Figure 1b). A matching anatomical moulding tool, created by a senior prosthetist, was subsequently draped over the cast of a trans-tibial amputee, measuring 340mm in circumference at the patella tendon, with a residuum length of 150mm (Figure 1c). The mould was used to encase the truncated bones with purpose-made silicone material (Bentley Advanced Materials, Feltham, UK), with a compressive modulus of ~146kPa. This was designed to represent a homogenous approximation of soft tissues, which at the lower limb residuum have been reported to range from 50 to 150 kPa[17-19]. The use of silicone has also been proven successful for simulating tissue while maintaining constant volume[20] and thus has been used to develop residuum limb manikins[21]. There are also practical advantages of using silicone as opposed to biological materials, such as animal flesh or cadaveric residuum, which would need to be preserved. In addition, silicone can be easily moulded to comply with the complex shapes of the truncated bones and residuum, thus reproducibly simulating the real scenario of the residuum/socket interface.

An alignment jig was used during the moulding process to ensure the truncated knee alignment, within the residuum, based on the surgical guidelines[16] (Figure 1b). A matching total surface bearing, pin-lock suspension socket was made for the residuum, by a senior prosthetist, using standard casting and rectification procedures. The artificial residuum was covered with a soft silicone liner (Chas A Blatchford & Sons, Basingstoke, UK), utilising the pin lock suspension, before being placed within the matching socket in order to represent the real scenario at the interface.

The 6DOF load cell represented an integral part of the simulator. Its axes were aligned to the anatomical planes (Figure 1d), providing simultaneous measurement of the forces in three axes i.e. compression, anterior-posterior (AP) shear and medial-lateral (ML) shear, and the moments acting around these axes i.e. axial torque, sagittal bending and coronal bending. The load cell was first incorporated into an amputee's prosthetic limb to collect reference data during walking. The load cell data from the amputee were then used to provide benchmarks for the kinetic parameters of the simulator, in a similar manner to that previously reported[22-24]

Load cell reference data from an amputee

Measurements were made with the load cell, during a series of level walks at a self-selected speed by a male amputee volunteer (28 years old, 75kg). The data were collected and provided by Chas A Blatchford & Sons, in accordance with the tenets of the Declaration of Helsinki. In addition, the participant was asked to walk over a ground-mounted force plate (Kistler Group, Winterthur, Switzerland) with a view to obtaining peak values of vertical GRF for WA and PO phases. The mean peak vertical GRF values for WA and PO phases were approximately 850N each, which was used to as the load input to the uniaxial test machine during simulator tests. Under this load, mimicking GRF, three load cell channels i.e. compression, sagittal bending and AP shear, were selected as guidance for simulator tuning, since they are the key kinetic components in the sagittal plane. It is worth noting that the vertical component of GRF would vary if the simulator was to be designed based on different amputees.

The vertical GRF is a key factor affecting the biomechanics at the residuum/socket interface[25]. In this work, although the simulator residuum was of different geometry to that of the amputee involved in the walking test, the procedure has been simplified by adopting the vertical GRF as input for the test machine load, while the peak values of the three key load cell outputs (compression, sagittal bending and AP shear) provided approximate guidance for the simulator tuning, with a view to briefly replicating the interface biomechanics.

Simulator tuning

Figure 2 illustrates how the simulator generated the forces and moments of the two phases. Upmost care was taken to ensure the location of the load cell in the simulator was equivalent to that used during amputee walking tests. Taking the centre of the load cell as the reference frame origin (red dot in Figure 2), a central axis runs along the length of the prosthetic (blue dashed line in Figure 2). The simulator is designed to work on uniaxial test machines and as a consequence, the line of load application (red solid line in Figure 2) runs in a straight line from the connection between the upper plate and the test machine, to the connection between the lower plate and the test machine. The line of load application is decomposed onto a two-dimensional plane (i.e. sagittal and coronal), as shown by the red dotted lines in Figure 2a and b, respectively. The relative position of the force (red dotted line) in a given plane to the central axis (blue dashed line), effectively determines forces and moments measured by the load cell. The planar angle (θ_{cor} – black arc in Figure 2a) between the in-plane force and central axis are defined as θ_{cor} (Figure 2a) and θ_{sag} (Figure 2b), respectively. θ_{cor} determines how the force can be further decomposed into the compression and ML shear, while θ_{sag} determines how the force can be distributed between compression and AP shear. The perpendicular distance (black solid line in Figure 2a) from the force in the coronal plane (red dotted line in Figure 2a) to the reference frame origin is the moment arm for coronal bending, while similarly the moment arm in the sagittal plane is shown in Figure 2b. Altering the relative positions between the upper and lower plates leads to a change in the line of load application and, consequently, the three key load cell outputs could be 'tuned' to be of a similar approximate range to the reference data collected from the amputee tests.

Testing protocol

In order to investigate the difference between rigid and compliant socket couplings, initially, a rigid aluminium prosthetic pylon (Figure 3a), of the same length (340mm) as that of the artificial residuum, was used in place of the residuum on the simulator. The approximate peak vertical GRF obtained during the amputee walking test was used as an input to define a uniaxial compressive load of 850N applied to the pylon simulator. The approximate ranges taken from the three key load channels during the amputee walking test were used as guidance, by which to assist the tuning of the simulator. The ball-and-socket joints, between the upper and lower plates and the test machine (Figure 1), allowed rotation to ensure that no damaging moments could be transferred to the test machine. This tuning was performed for both WA and PO phases, respectively. Subsequently, the pylon was replaced by the artificial residuum (Figure 3b-c) and simulator was arranged identically to the respective pylon tests. The compression test was performed and the load cell outputs recorded. By comparing all six channels load cell outputs between pylon and artificial residuum scenarios, the effect of the compliant residuum/socket interface to the kinetics were studied.

Further testing was performed to showcase one of the potential applications using such a lab based simulator, i.e. studies of interface stresses during WA and PO phases. Force Sensing Resistors (FSRs) (Interlink Electronics Inc., Westlake Village, CA, USA) were located at the key anatomical loading sites[4, 5, 7], namely patella tendon, popliteal depression and fibula head (Figure 3d) on the artificial residuum. The artificial residuum simulator was then tuned so that its key load cell outputs briefly represented similar ranges to those measured during the amputee walking test. Particular attention was made of the measurements in the sagittal plane (e.g. compression, sagittal bending and AP shear) and, in particular, the compression output. The sagittal plane incorporates the vertical direction, thus the kinetics which act to support the body's centre of mass (COM), and the direction of progression, thus the kinetics which act to propel COM forward. The WA and PO phases are the points in the gait cycle where the force required to support the COM (the vertical component of GRF) is at a maximum and the compression output measures the largest components of these supporting forces. Subsequently, pressure measurements from FSRs were recorded and compared with counterparts reported in literature.

Results

Rigid vs Compliant socket coupling

Table 1 shows the mean peak values from the load cell outputs, obtained from the pylon and artificial residuum simulator setups, respectively, while the positions of the upper and lower plates were kept the same.

It was clear that the data for the pylon and artificial residuum simulators showed differences in key outputs (Table 1). For example, for the WA phase, the compression force on the load cell was 871N for the pylon setup and 787N for the artificial residuum setup, representing an approximate 10% reduction when using a compliant socket coupling. For the PO phase, the sagittal bending was -56Nm for the pylon and -70Nm for the artificial residuum, representing approximately a 25% increase in magnitude. Also in the PO phase, AP shear was 157N for the pylon but only 104N for the residuum, approximately a 34% reduction (Table 1).

There were also large differences in the other load cell outputs. In the WA phase, the ML shear was -45N for the pylon and -57N for the residuum, representing a difference of 27%. In the PO phase, the corresponding values were -45N and -60N, representing an approximate 33% difference. Also in the PO phase, coronal bending changed from -7Nm to -12 Nm; approximately a 71% change (Table 1).

Residuum pistoning is a well-recognised feature associated with lower limb amputees[26]. The displacement output from the uniaxial test machine was approximated to a measure of the pistoning. While there was negligible vertical displacement for the pylon setup (all connections were rigid), when 850N was applied to the artificial residuum maximum vertical displacements of approximately 8 ± 1mm and 12 ± 1mm, were recorded for WA and PO phases, respectively.

Interface pressure measurement using the developed simulator

Figure 4 shows a comparison of the peak values on three key load cell outputs during the amputee walking test and those measured on the tuned artificial residuum simulator. The focus of the tuning was to briefly achieve approximate sagittal plane kinetics, in particular compression output, which was close to the amputee test values. This output (Figure 4a) was reproduced to within 7% difference for both the WA and PO phases.

Table 2 summarises the ranges of peak pressure measurements recorded from the FSRs when applying a uniaxial load up to a maximum of 850N, to the artificial residuum simulator. These are compared with reported data by Yeung et al.[4], adjusting for an amputee of approximately the same weight as the amputee in the present study.

Discussion

Initially, both the pylon and the residuum simulators had the same upper and lower plate alignments, therefore any differences in load cell outputs, as shown in Table 1, were solely attributed to the presence of the compliant socket coupling introduced by the inclusion of artificial residuum. The residuum consists of silicone mimicking compliant tissue characteristics which, to a certain degree, permit a degree of deformation at the interface. As the uniaxial load was increased to its maximum value of 850N, the residuum could rotate within the socket, similar to real amputee scenarios[27]. Rotation in the sagittal plane could affect the three key load cell outputs (compression, sagittal bending and AP shear) by effectively changing the planar angle between the line of load application, when decomposed onto the sagittal plane, and the load cell central axis (θ_{sag} – shown by the black arc in Figure 2b). This, in turn, meant that the sagittal moment arm changed (black solid line in Figure 2b). During the WA phase, this rotation increased θ_{sag}, in a direction anterior to the central axis (blue dashed line in Figure 2), resulting in a relative change in the nature of the load applied in terms of the compression and shear axes. This was reflected by an increase in magnitude for AP shear, from -105N for the pylon to -122N for the residuum and a correspondent decrease in the compression value, from 871N for the pylon to 787N for the residuum. During the PO phase, the rotation of the residuum in the sagittal plane acted to increase compression (from 886N for the pylon to 897N for the residuum) while decrease AP shear (from 157N for the pylon to 104N for the residuum). The sagittal bending also increased in magnitude during PO (from -56N for the pylon to -70N for the residuum). This was a result of the rotation effectively increasing the length of the sagittal bending moment arm (black solid line in Figure 2).

Possible rotation in the coronal plane during the WA and PO phases could have caused changes in other load cell outputs. In this case, the rotation was in the same direction for both phases, since the line of load application was always medial at the upper plate, relative to the reference frame origin (red dot in Figure 2). This led to an increase in angle between the line of load application, when decomposed onto the coronal plane, and the load cell central axis (θ_{cor} – black arc in Figure 2a). Consequently, the magnitude of ML shear increased in both phases (-45N and -45N for the pylon, compared to -57N and -60N for the residuum – see Table 1). It also increased the moment arm in coronal bending (black solid line in Figure 2a), resulting in an increase, in the PO phase, in the magnitude of coronal bending between the pylon (-7Nm) and the residuum (-12Nm) simulators.

In order to create a simulator setup that mimicked interface dynamics from real amputee walking, the artificial residuum simulator was tuned, with a view to briefly approximate the three key peak load cell outputs to the amputee test. During the simulator tuning, the priority was to focus on compression values, because this axis provides the largest contribution to COM support (Figure 4a), and at the same time ensuring outputs in sagittal bending and AP shear outputs were in similar ranges for amputee tests and simulator setups (Figure 4b and c). Figure 4 shows that AP shear during PO presented greatest difference between the amputee test (113N) and the simulator (178N). This is likely because that only the upper and lower plates were used to tune the simulator, while in real amputee scenarios, other effects, such as socket fit and alignment, could also affect the kinetics. Thus, for future work, more comprehensive means to tune the simulator will be investigated by incorporating these effects. Nonetheless, for this study, the simulator was set up, as show in Figure 4, to briefly reproduce amputee walking kinetics so that interface pressure could be studied.

FSR measurements at various residuum locations are shown in Table 2. In the WA phase, the weight of the amputee is largely borne on the posterior region of the residuum[28], resulting in a high pressure of 101~187kPa recorded at the popliteal depression. During the PO phase, however, the weight is transferred to the anterior surface the residuum, leading to highest pressure at the patella tendon (100~188kPa). Additionally, during PO phase, the residuum rotates within the socket in the sagittal plane, so as to produce a *‘kicking’* action, which propels the prosthetic forwards through swing phase. This rotation results in high pressures at the popliteal depression[28] (144~165kPa). The pressure at the fibula head is affected by the medial-lateral motion of the body's COM during walking. During WA phase, the body COM is moving laterally[29], increasing pressure on the fibula head of the residuum (75~160kPa). By contrast, during the PO phase, this pressure is reduced (100~137kPa), as the COM moves in a medial direction[29].

The pressure ranges are similar to those previously reported by Yeung et al[4], adapted for an amputee of similar weight (Table 2). Any minor differences could be attributed to the fact that the silicone based artificial residuum may not have proved an exact representation of the soft tissues of the amputee residuum. Additionally, many other factors such as differences in the quality of the fit of the sockets, residuum geometry and prosthetic alignment would have all contributed to differences in measured pressures. Thus, only the approximate ranges of the peak values at the three locations were compared, with a view to demonstrating the brief alignment between simulator interface pressure and clinical amputee tests. Nonetheless, the FSR results suggest that the developed interface simulator provides a good representation of the mechanical loading environment at the residuum/socket interface, which aligns with that experienced in amputee walking tests.

The amount of pistoning measured for the artificial residuum during loaded conditions was approximately 8mm and 12mm for WA and PO phases, respectively. These values are of similar magnitude to that (6 ± 4mm) previously reported[26]. A degree of variation in displacement range would be predicted as this measure is dependent on many factors, such as socket fit, fluctuations of residuum geometry and volume and prosthetic component alignments etc. It is envisaged that, aside from the total surface bearing socket utilized in this work, it would also be interesting to repeat the protocol using other socket and liner types, such as a patella tendon bearing (PTB) socket and a foam liner, with a view to comparing interface biomechanics. It is worth noting that, in comparison to the previously reported simulators, such as the robotic gait simulator[14], the present system was designed specifically to replicate the WA and PO phases of the gait. Thus, its current design will not reflect temporal changes in loading throughout the complete gait cycle. However, in this work, WA and PO phases were chosen based on ISO 10328, as GRF reaches peak values in these phases and consequently extreme levels of load are exerted at the residuum/socket interface. The compatibility of the simulator with commonly available test machines facilitates its adoption in a wide range of lab-based tests and studies.

It is thus envisaged that the approach adopted in the development of a residuum/socket interface simulator, could be potentially beneficial to both researchers and clinicians. Such simulators could be applied in lab settings to assess the biomechanical state at the critical residuum/socket interface for lower limb amputees. For example, these results could be used in conjunction with human studies to provide more information regarding interface dynamics. This could then be exploited in Finite Element Analyses to provide a more comprehensive predictive model. Such a simulator could also be used to evaluate socket fit and prosthetic component performance in the clinical setting. Patient-specific artificial residua could be fabricated and the simulator could be used to identify the long-term impact of a particular socket design.

Conclusion

This work presents a practical approach for the design, fabrication and testing of a lower limb prosthetic simulator, which has the potential to predict biomechanical conditions at the residuum/socket interface. Our results suggest that such a simulator can be ‘tuned’ to simulate walking in stance phase and interface mechanics for specific lower limb amputees. In general, such simulators could be potentially exploited as a lab-based tool to assess interface biomechanics, socket fit, tissue viability etc. without the extensive involvement of amputee participants. This could be particularly advantageous for the assessment of amputees with various comorbidities e.g. gait pathologies and peripheral neuropathy.

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Conflicts of interest

There are no conflicts of interest in this study.

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Development of a residuum/socket interface simulator for lower limb prosthetics

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Original Article

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Abstract

Mechanical coupling at the interface between lower limb residua and prosthetic sockets plays an important role in assessing socket fitting and tissue health. However, most research lab based lower limb prosthetic simulators to-date have implemented a rigid socket coupling. This study describes the fabrication and implementation of a lower limb residuum/socket interface simulator, designed to reproduce the forces and moments present during the key loading phases of amputee walking. An artificial residuum made with model bones encased in silicone was used, mimicking the compliant mechanical loading of a real residuum/socket interface. A six degree-of-freedom (6DOF) load cell measured the overall kinetics, having previously been incorporated into an amputee's prosthesis to collect reference data.

The developed simulator was compared to a setup where a rigid pylon replaced the artificial residuum. A maximum uniaxial load of 850N was applied, comparable to the peak vertical ground reaction force component during amputee walking. Load cell outputs from both pylon and residuum setups were compared. During weight acceptance, when including the artificial residuum, compression decreased by 10%, while, during push off, sagittal bending and anterior-posterior shear showed a 25% increase and 34% decrease, respectively.

Such notable difference by including a compliant residuum further highlighted the need for such an interface simulator. Subsequently, the simulator was adjusted to produce key load cell outputs briefly aligning with those from amputee walking. Force Sensing Resistors (FSRs) were deployed at load-bearing anatomic locations on the residuum/socket interface to measure pressures and were compared to those cited in literature for similar locations.

The development of such a novel simulator provides an objective adjunct, using commonly available mechanical test machines. It could potentially be used to provide further insight into

socket design, fit and the complex load transfer mechanics at the residuum/socket interface, as well as to evaluate the structural performance of prostheses.

Keywords

Lower limb, prosthetics, residuum, socket, interface, simulator

Introduction

A comfortable, well-fitting socket is integral to the health of an amputee's residuum[1]. In some cases, the residuum will be exposed to excess loads at the residuum/socket interface, leading to the potential development of blisters, skin inflammation and pressure ulcers[1-3]. Currently, prosthetists generally depend on subjective expertise and feedback from the amputee to produce well-fitting sockets. Indeed, there is a general lack of objective means to quantitatively examine how changes of socket design, fit and limb setup may affect residuum tissue loading.

As a consequence, many studies have focused on the measurement of interface stress[2, 4-7] using various sensor systems. However, the reported values of interface pressures, for a given anatomic location on a residuum, for example at the popliteal depression, range considerably from 35kPa[2] to 244kPa[8]. This is due, in part, to the large intra-subject variability in amputee residua included in the studies. Indeed, even the residuum of an individual amputee can fluctuate in volume, with values of up to 8%[9] depending upon the time of day, the environmental conditions and the time following their amputation[10], all of which will affect interfacial stress values. Although these factors will clearly influence the clinical evaluation of socket fit, the variation will also hinder valid comparisons of interface measurement systems and socket design approaches. This has motivated the development of lab-based simulators based on international guidelines, typically ISO 10328[11]. This standard simplifies the complex loading profile during walking, into two discrete loading events, termed Conditions 1 and 2. These conditions simulate the forces and moments associated with the prosthetic during the *'weight acceptance'* (WA) and *'push-off''* (PO) phases of walking, respectively, corresponding with the two peaks in the vertical ground reaction force (GRF). However, ISO 10328 was designed to assess the structural integrity of the components[12], as opposed to evaluation of loading at the residuum/socket interface, thus it is often implemented with a rigid socket coupling[13]. A gait simulator using industrial robotics has recently been reported[14], in which objective pressure measurements at the residuum/socket interface were conducted and correlated with the levels of comfort. However, the large size and cost of such a specific system, significantly limit its wide applicability. Accordingly there is a need to provide a realistic, relatively low-cost simulator to be used in conjunction with mechanical test machines, which are readily available in research labs.

This paper describes the design and fabrication of a lower limb prosthetic simulator that can provide a representation of the residuum/socket interface by including an artificial residuum with bony prominences incorporated within a soft tissue analogue. It was also designed to accommodate the key peak loading events during gait, equivalent to the WA and PO phases of walking. The development of such a simulator and associated test arrangements provide effective and practical approaches to build lab-based tools, which offer potential in assessing socket fit, interface stress and their dependence on prosthetic components, alignment etc.

Methods

Simulator development

Figure 1a shows a schematic of the trans-tibial simulator design with key components identified, including a trans-tibial artificial residuum, matching socket, a six degree-of-freedom (6DOF) load cell and upper and lower alignment plates. The simulator was designed to be compatible with a uniaxial mechanical test machine (8800 series, Instron Ltd., High Wycombe, UK). Ball-and-socket joints were used at the upper and lower points of load application to allow for movement of the simulator during compression, without generating bending forces and moments in the test machine. Attached to each of these were alignment plates, which can be arranged to produce WA and PO phases. Since it has been shown that prosthetic feet provide limited propulsion in the PO phase[15], the lack of a foot in this simulator was not envisaged to detrimentally affect the comparative results. With the exception of the residuum/socket interface and the ball-and-socket joints, as shown in Figure 1a, all other components were linked via rigid connectors. The prosthetic socket was aligned ‘neutrally’ so that the upper plate was parallel with the bottom plate.

A truncated trans-tibial knee joint was encased in silicone to form the trans-tibial artificial residuum (Figure 1b-c). Following surgical guidelines for trans-tibial amputations[16], model bones (UK3BS, Somerset, UK) were cut to the desired size. In particular, the sectioned tibia was approximately 110mm distal to the tibial tubercle, while fibula was obliquely cut to a length of 90mm from fibula end to fibula head. These two bones were then joined together, with a model femur and patella, using an industrial adhesive to form a rigid, neutral-angled knee joint (Figure 1b). A matching anatomical moulding tool, created by a senior prosthetist, was subsequently draped over the cast of a trans-tibial amputee, measuring 340mm in circumference at the patella tendon, with a residuum length of 150mm (Figure 1c). The mould was used to encase the truncated bones with purpose-made silicone material (Bentley Advanced Materials, Feltham, UK), with a compressive modulus of ~146kPa. This was designed to represent a homogenous approximation of soft tissues, which at the lower limb residuum have been reported to range from 50 to 150 kPa[17-19]. The use of silicone has also been proven successful for simulating tissue while maintaining constant volume[20] and thus has been used to develop residuum limb manikins[21]. There are also practical advantages of using silicone as opposed to biological materials, such as animal flesh or cadaveric residuum, which would need to be preserved. In addition, silicone can be easily moulded to comply with the complex shapes of the truncated bones and residuum, thus reproducibly simulating the real scenario of the residuum/socket interface.

An alignment jig was used during the moulding process to ensure the truncated knee alignment, within the residuum, based on the surgical guidelines[16] (Figure 1b). A matching total surface bearing, pin-lock suspension socket was made for the residuum, by a senior prosthetist, using standard casting and rectification procedures. The artificial residuum was covered with a soft silicone liner (Chas A Blatchford & Sons, Basingstoke, UK), utilising the pin lock suspension, before being placed within the matching socket in order to represent the real scenario at the interface.

The 6DOF load cell represented an integral part of the simulator. Its axes were aligned to the anatomical planes (Figure 1d), providing simultaneous measurement of the forces in three axes i.e. compression, anterior-posterior (AP) shear and medial-lateral (ML) shear, and the moments acting around these axes i.e. axial torque, sagittal bending and coronal bending. The load cell was first incorporated into an amputee's prosthetic limb to collect reference data during walking. The load cell data from the amputee were then used to provide benchmarks for the kinetic parameters of the simulator, in a similar manner to that previously reported[22-24]

Load cell reference data from an amputee

Measurements were made with the load cell, during a series of level walks at a self-selected speed by a male amputee volunteer (28 years old, 75kg). The data were collected and provided by Chas A Blatchford & Sons, in accordance with the tenets of the Declaration of Helsinki. In addition, the participant was asked to walk over a ground-mounted force plate (Kistler Group, Winterthur, Switzerland) with a view to obtaining peak values of vertical GRF for WA and PO phases. The mean peak vertical GRF values for WA and PO phases were approximately 850N each, which was used to as the load input to the uniaxial test machine during simulator tests. Under this load, mimicking GRF, three load cell channels i.e. compression, sagittal bending and AP shear, were selected as guidance for simulator tuning, since they are the key kinetic components in the sagittal plane. It is worth noting that the vertical component of GRF would vary if the simulator was to be designed based on different amputees.

The vertical GRF is a key factor affecting the biomechanics at the residuum/socket interface[25]. In this work, although the simulator residuum was of different geometry to that of the amputee involved in the walking test, the procedure has been simplified by adopting the vertical GRF as input for the test machine load, while the peak values of the three key load cell outputs (compression, sagittal bending and AP shear) provided approximate guidance for the simulator tuning, with a view to briefly replicating the interface biomechanics.

Simulator tuning

Figure 2 illustrates how the simulator generated the forces and moments of the two phases. Upmost care was taken to ensure the location of the load cell in the simulator was equivalent to that used during amputee walking tests. Taking the centre of the load cell as the reference frame origin (red dot in Figure 2), a central axis runs along the length of the prosthetic (blue dashed line in Figure 2). The simulator is designed to work on uniaxial test machines and as a consequence, the line of load application (red solid line in Figure 2) runs in a straight line from the connection between the upper plate and the test machine, to the connection between the lower plate and the test machine. The line of load application is decomposed onto a two-dimensional plane (i.e. sagittal and coronal), as shown by the red dotted lines in Figure 2a and b, respectively. The relative position of the force (red dotted line) in a given plane to the central axis (blue dashed line), effectively determines forces and moments measured by the load cell. The planar angle (θ_{cor} – black arc in Figure 2a) between the in-plane force and central axis are defined as θ_{cor} (Figure 2a) and θ_{sag} (Figure 2b), respectively. θ_{cor} determines how the force can be further decomposed into the compression and ML shear, while θ_{sag} determines how the force can be distributed between compression and AP shear. The perpendicular distance (black solid line in Figure 2a) from the force in the coronal plane (red dotted line in Figure 2a) to the reference frame origin is the moment arm for coronal bending, while similarly the moment arm in the sagittal plane is shown in Figure 2b. Altering the relative positions between the upper and lower plates leads to a change in the line of load application and, consequently, the three key load cell outputs could be 'tuned' to be of a similar approximate range to the reference data collected from the amputee tests.

Testing protocol

In order to investigate the difference between rigid and compliant socket couplings, initially, a rigid aluminium prosthetic pylon (Figure 3a), of the same length (340mm) as that of the artificial residuum, was used in place of the residuum on the simulator. The approximate peak vertical GRF obtained during the amputee walking test was used as an input to define a uniaxial compressive load of 850N applied to the pylon simulator. The approximate ranges taken from the three key load channels during the amputee walking test were used as guidance, by which to assist the tuning of the simulator. The ball-and-socket joints, between the upper and lower plates and the test machine (Figure 1), allowed rotation to ensure that no damaging moments could be transferred to the test machine. This tuning was performed for both WA and PO phases, respectively. Subsequently, the pylon was replaced by the artificial residuum (Figure 3b-c) and simulator was arranged identically to the respective pylon tests. The compression test was performed and the load cell outputs recorded. By comparing all six channels load cell outputs between pylon and artificial residuum scenarios, the effect of the compliant residuum/socket interface to the kinetics were studied.

Further testing was performed to showcase one of the potential applications using such a lab based simulator, i.e. studies of interface stresses during WA and PO phases. Force Sensing Resistors (FSRs) (Interlink Electronics Inc., Westlake Village, CA, USA) were located at the key anatomical loading sites[4, 5, 7], namely patella tendon, popliteal depression and fibula head (Figure 3d) on the artificial residuum. The artificial residuum simulator was then tuned so that its key load cell outputs briefly represented similar ranges to those measured during the amputee walking test. Particular attention was made of the measurements in the sagittal plane (e.g. compression, sagittal bending and AP shear) and, in particular, the compression output. The sagittal plane incorporates the vertical direction, thus the kinetics which act to support the body's centre of mass (COM), and the direction of progression, thus the kinetics which act to propel COM forward. The WA and PO phases are the points in the gait cycle where the force required to support the COM (the vertical component of GRF) is at a maximum and the compression output measures the largest components of these supporting forces. Subsequently, pressure measurements from FSRs were recorded and compared with counterparts reported in literature.

Results

Rigid vs Compliant socket coupling

Table 1 shows the mean peak values from the load cell outputs, obtained from the pylon and artificial residuum simulator setups, respectively, while the positions of the upper and lower plates were kept the same.

It was clear that the data for the pylon and artificial residuum simulators showed differences in key outputs (Table 1). For example, for the WA phase, the compression force on the load cell was 871N for the pylon setup and 787N for the artificial residuum setup, representing an approximate 10% reduction when using a compliant socket coupling. For the PO phase, the sagittal bending was -56Nm for the pylon and -70Nm for the artificial residuum, representing approximately a 25% increase in magnitude. Also in the PO phase, AP shear was 157N for the pylon but only 104N for the residuum, approximately a 34% reduction (Table 1).

There were also large differences in the other load cell outputs. In the WA phase, the ML shear was -45N for the pylon and -57N for the residuum, representing a difference of 27%. In the PO phase, the corresponding values were -45N and -60N, representing an approximate 33% difference. Also in the PO phase, coronal bending changed from -7Nm to -12 Nm; approximately a 71% change (Table 1).

Residuum pistoning is a well-recognised feature associated with lower limb amputees[26]. The displacement output from the uniaxial test machine was approximated to a measure of the pistoning. While there was negligible vertical displacement for the pylon setup (all connections were rigid), when 850N was applied to the artificial residuum maximum vertical displacements of approximately 8 ± 1mm and 12 ± 1mm, were recorded for WA and PO phases, respectively.

Interface pressure measurement using the developed simulator

Figure 4 shows a comparison of the peak values on three key load cell outputs during the amputee walking test and those measured on the tuned artificial residuum simulator. The focus of the tuning was to briefly achieve approximate sagittal plane kinetics, in particular compression output, which was close to the amputee test values. This output (Figure 4a) was reproduced to within 7% difference for both the WA and PO phases.

Table 2 summarises the ranges of peak pressure measurements recorded from the FSRs when applying a uniaxial load up to a maximum of 850N, to the artificial residuum simulator. These are compared with reported data by Yeung et al.[4], adjusting for an amputee of approximately the same weight as the amputee in the present study.

Discussion

Initially, both the pylon and the residuum simulators had the same upper and lower plate alignments, therefore any differences in load cell outputs, as shown in Table 1, were solely attributed to the presence of the compliant socket coupling introduced by the inclusion of artificial residuum. The residuum consists of silicone mimicking compliant tissue characteristics which, to a certain degree, permit a degree of deformation at the interface. As the uniaxial load was increased to its maximum value of 850N, the residuum could rotate within the socket, similar to real amputee scenarios[27]. Rotation in the sagittal plane could affect the three key load cell outputs (compression, sagittal bending and AP shear) by effectively changing the planar angle between the line of load application, when decomposed onto the sagittal plane, and the load cell central axis (θ_{sag} – shown by the black arc in Figure 2b). This, in turn, meant that the sagittal moment arm changed (black solid line in Figure 2b). During the WA phase, this rotation increased θ_{sag}, in a direction anterior to the central axis (blue dashed line in Figure 2), resulting in a relative change in the nature of the load applied in terms of the compression and shear axes. This was reflected by an increase in magnitude for AP shear, from -105N for the pylon to -122N for the residuum and a correspondent decrease in the compression value, from 871N for the pylon to 787N for the residuum. During the PO phase, the rotation of the residuum in the sagittal plane acted to increase compression (from 886N for the pylon to 897N for the residuum) while decrease AP shear (from 157N for the pylon to 104N for the residuum). The sagittal bending also increased in magnitude during PO (from -56N for the pylon to -70N for the residuum). This was a result of the rotation effectively increasing the length of the sagittal bending moment arm (black solid line in Figure 2).

Possible rotation in the coronal plane during the WA and PO phases could have caused changes in other load cell outputs. In this case, the rotation was in the same direction for both phases, since the line of load application was always medial at the upper plate, relative to the reference frame origin (red dot in Figure 2). This led to an increase in angle between the line of load application, when decomposed onto the coronal plane, and the load cell central axis (θ_{cor} – black arc in Figure 2a). Consequently, the magnitude of ML shear increased in both phases (-45N and -45N for the pylon, compared to -57N and -60N for the residuum – see Table 1). It also increased the moment arm in coronal bending (black solid line in Figure 2a), resulting in an increase, in the PO phase, in the magnitude of coronal bending between the pylon (-7Nm) and the residuum (-12Nm) simulators.

In order to create a simulator setup that mimicked interface dynamics from real amputee walking, the artificial residuum simulator was tuned, with a view to briefly approximate the three key peak load cell outputs to the amputee test. During the simulator tuning, the priority was to focus on compression values, because this axis provides the largest contribution to COM support (Figure 4a), and at the same time ensuring outputs in sagittal bending and AP shear outputs were in similar ranges for amputee tests and simulator setups (Figure 4b and c). Figure 4 shows that AP shear during PO presented greatest difference between the amputee test (113N) and the simulator (178N). This is likely because that only the upper and lower plates were used to tune the simulator, while in real amputee scenarios, other effects, such as socket fit and alignment, could also affect the kinetics. Thus, for future work, more comprehensive means to tune the simulator will be investigated by incorporating these effects. Nonetheless, for this study, the simulator was set up, as show in Figure 4, to briefly reproduce amputee walking kinetics so that interface pressure could be studied.

FSR measurements at various residuum locations are shown in Table 2. In the WA phase, the weight of the amputee is largely borne on the posterior region of the residuum[28], resulting in a high pressure of 101~187kPa recorded at the popliteal depression. During the PO phase, however, the weight is transferred to the anterior surface the residuum, leading to highest pressure at the patella tendon (100~188kPa). Additionally, during PO phase, the residuum rotates within the socket in the sagittal plane, so as to produce a *'kicking'* action, which propels the prosthetic forwards through swing phase. This rotation results in high pressures at the popliteal depression[28] (144~165kPa). The pressure at the fibula head is affected by the medial-lateral motion of the body's COM during walking. During WA phase, the body COM is moving laterally[29], increasing pressure on the fibula head of the residuum (75~160kPa). By contrast, during the PO phase, this pressure is reduced (100~137kPa), as the COM moves in a medial direction[29].

The pressure ranges are similar to those previously reported by Yeung et al[4], adapted for an amputee of similar weight (Table 2). Any minor differences could be attributed to the fact that the silicone based artificial residuum may not have proved an exact representation of the soft tissues of the amputee residuum. Additionally, many other factors such as differences in the quality of the fit of the sockets, residuum geometry and prosthetic alignment would have all contributed to differences in measured pressures. Thus, only the approximate ranges of the peak values at the three locations were compared, with a view to demonstrating the brief alignment between simulator interface pressure and clinical amputee tests. Nonetheless, the FSR results suggest that the developed interface simulator provides a good representation of the mechanical loading environment at the residuum/socket interface, which aligns with that experienced in amputee walking tests.

The amount of pistoning measured for the artificial residuum during loaded conditions was approximately 8mm and 12mm for WA and PO phases, respectively. These values are of similar magnitude to that (6 ± 4mm) previously reported[26]. A degree of variation in displacement range would be predicted as this measure is dependent on many factors, such as socket fit, fluctuations of residuum geometry and volume and prosthetic component alignments etc. It is envisaged that, aside from the total surface bearing socket utilized in this work, it would also be interesting to repeat the protocol using other socket and liner types, such as a patella tendon bearing (PTB) socket and a foam liner, with a view to comparing interface biomechanics. It is worth noting that, in comparison to the previously reported simulators, such as the robotic gait simulator[14], the present system was designed specifically to replicate the WA and PO phases of the gait. Thus, its current design will not reflect temporal changes in loading throughout the complete gait cycle. However, in this work, WA and PO phases were chosen based on ISO 10328, as GRF reaches peak values in these phases and consequently extreme levels of load are exerted at the residuum/socket interface. The compatibility of the simulator with commonly available test machines facilitates its adoption in a wide range of lab-based tests and studies.

It is thus envisaged that the approach adopted in the development of a residuum/socket interface simulator, could be potentially beneficial to both researchers and clinicians. Such simulators could be applied in lab settings to assess the biomechanical state at the critical residuum/socket interface for lower limb amputees. For example, these results could be used in conjunction with human studies to provide more information regarding interface dynamics. This could then be exploited in Finite Element Analyses to provide a more comprehensive predictive model. Such a simulator could also be used to evaluate socket fit and prosthetic component performance in the clinical setting. Patient-specific artificial residua could be fabricated and the simulator could be used to identify the long-term impact of a particular socket design.

Conclusion

This work presents a practical approach for the design, fabrication and testing of a lower limb prosthetic simulator, which has the potential to predict biomechanical conditions at the residuum/socket interface. Our results suggest that such a simulator can be 'tuned' to simulate walking in stance phase and interface mechanics for specific lower limb amputees. In general, such simulators could be potentially exploited as a lab-based tool to assess interface biomechanics, socket fit, tissue viability etc. without the extensive involvement of amputee participants. This could be particularly advantageous for the assessment of amputees with various comorbidities e.g. gait pathologies and peripheral neuropathy.

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Conflicts of interest

There are no conflicts of interest in this study.

Word count (Introduction-Conclusion): 4233

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Figures

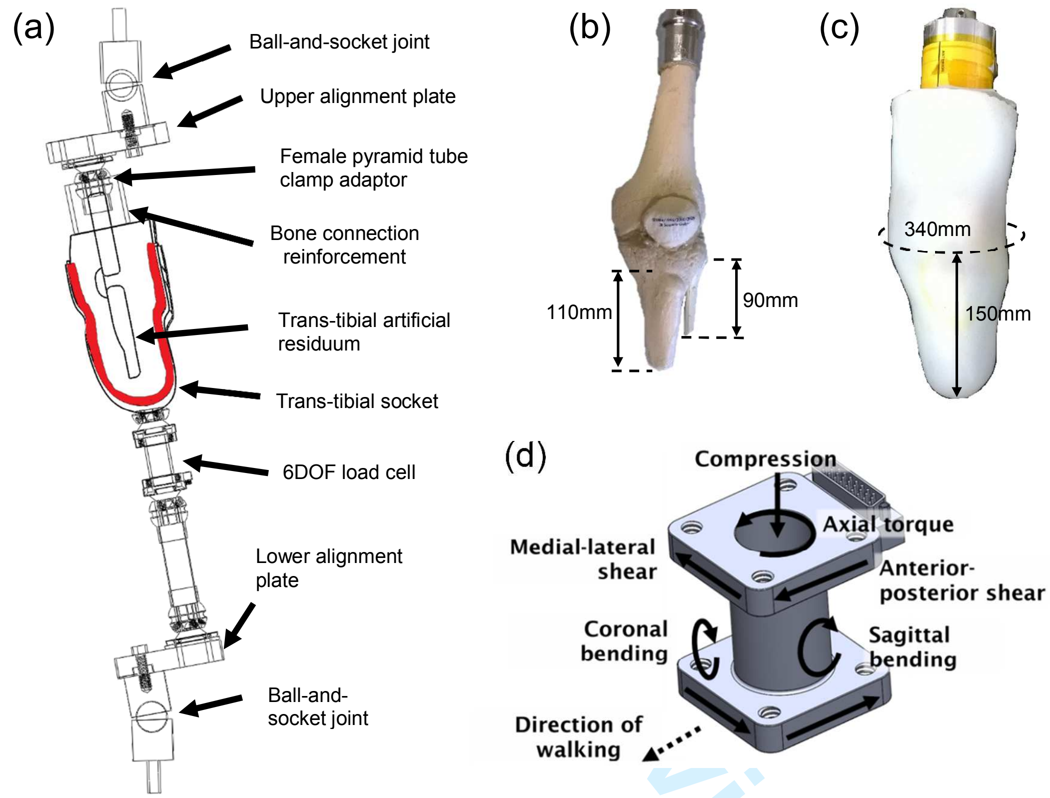

Figure 1. (a) A schematic of residuum/socket interface simulator design, highlighting the residuum/socket interface, (b) the truncated model knee joint, (c) the artificial trans-tibial residuum, and (d) an illustration of the axes and moments measured by the six degree-of-freedom (6DOF) load cell.

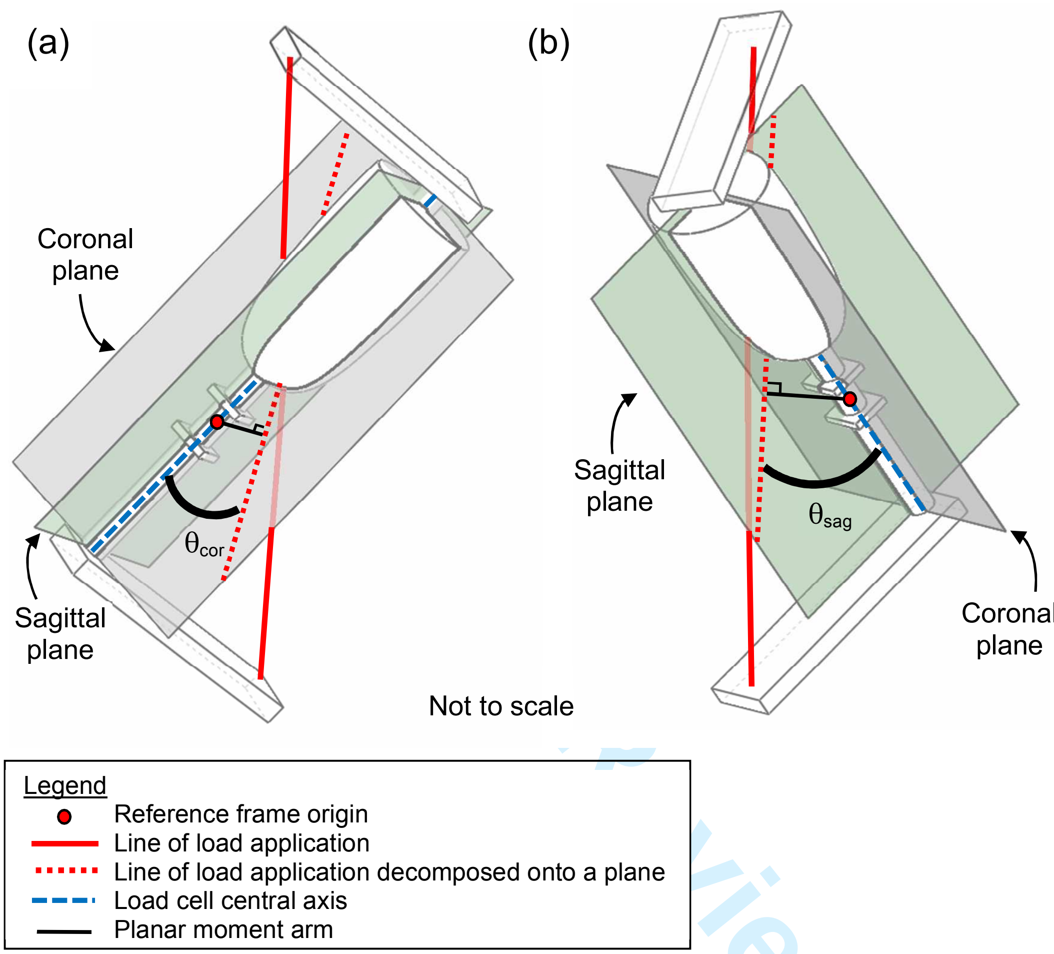

Figure 2. (a) A schematic of the residuum/socket simulator in the weight acceptance (WA) phase and (b) a schematic of the residuum/socket simulator in the push off (PO) phase. The line of load application is decomposed onto the coronal and sagittal planes. The angles between this planar force and the load cell central axis (θ_{cor} and θ_{sag} for the coronal and sagittal planes, respectively) are shown. The perpendicular distance from this planar force and the reference frame origin is the moment arm.

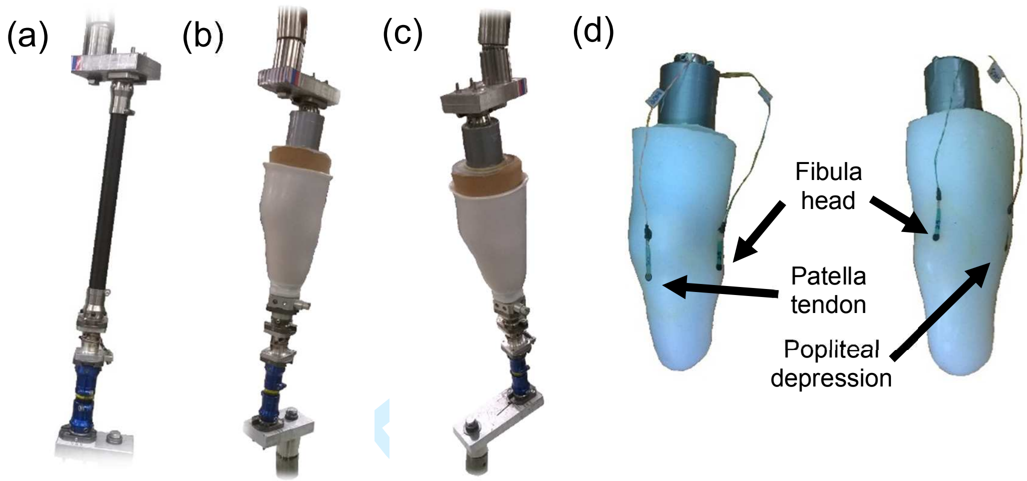

Figure 3. (a) The simulator with a pylon in place of the artificial residuum, (b) the residuum/socket simulator in the weight acceptance (WA) phase, (c) the residuum/socket simulator in the push off (PO) phase, and (d) positions of the force sensing resistors (FSRs) on the artificial residuum.

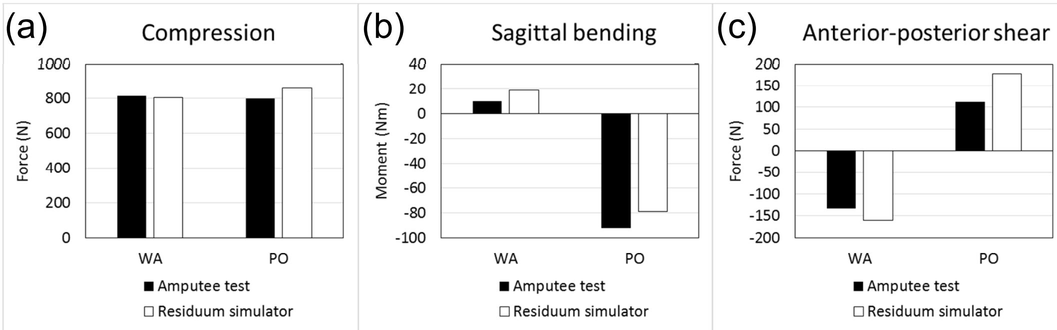

Figure 4. Three key six degrees-of-freedom load cell outputs: (a) compression, (b) sagittal bending, and (c) anterior-posterior (AP) shear. For each output, the charts show the weight acceptance (WA) and push off (PO) mean peak measurements recorded during the amputee walking test (black bars) compared to the artificial residuum simulator (white bars) after it had been 'tuned'.

Tables

Simulator phases	Load cell outputs	Pylon	Artificial residuum
WA	Compression (N)	871	787
	Anterior-Posterior shear (N)	-105	-122
	Medial-lateral shear (N)	-45	-57
	Axial torque (Nm)	1	2
	Sagittal bending (Nm)	19	17
	Coronal bending (Nm)	-11	-13
PO	Compression (N)	886	897
	Anterior-Posterior shear (N)	157	104
	Medial-lateral shear (N)	-45	-60
	Axial torque (Nm)	-3	-3
	Sagittal bending (Nm)	-56	-70
	Coronal bending (Nm)	-7	-12

Table 1. Peak values of six degree-of-freedom (6DOF) load cell outputs from the pylon and artificial residuum simulator setups, during weight acceptance (WA) and push off (PO) phases, respectively.

Simulator phases	Anatomical location on the residuum	Simulator peak pressure (kPa)	Yeung et al. peak pressure (kPa)
WA	Patella tendon	87~117	89~115
	Popliteal depression	101~187	132~160
	Fibula head	75~160	103~133
PO	Patella tendon	100~188	118~160
	Popliteal depression	144~165	103~163
	Fibula head	100~137	81~110

Table 2. The ranges of FSR peak values measured at different locations of the artificial residuum in comparison with those from real amputee tests by Yeung et al[4], adjusted for amputee weight, during weight acceptance (WA) and push off (PO) phases, respectively.