

Developing a control framework for self-adjusting prosthetic sockets incorporating tissue injury risk estimation and Generalized Predictive Control

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ABSTRACT

Purpose: To perform activities of daily living (ADL), people with lower limb amputation depend on the prosthetic socket for stability and proprioceptive feedback. Poorly fitting sockets can cause discomfort, pain, limb tissue injuries, limited device usage, and potential rejection. Semi-passively controlled adjustable socket technologies exist, but these depend upon the user's perception to determine safe interfacial pressure levels. This paper presents a framework for automatic control of an adjustable transtibial prosthetic socket that enables active adaptation of residuum-socket interfacial loading through localized actuators, based on soft tissue injury risk estimation.

Method: Using finite element analysis, local interfacial pressure vs. compressive tissue strain relationships were estimated for three anatomical actuator locations, for tissue injury risk assessment within a control structure. Generalized Predictive Control of multiple actuators was implemented to maintain interfacial pressure within estimated safe and functional limits.

Results: Controller simulation predicted satisfactory dynamic performance in several scenarios, based on previous related studies. Actuation rates of 0.06 – 1.51kPa/s with 0.67% maximum overshoot, and 0.75 – 1.58kPa/s were estimated for continuous walking, and for a demonstrative loading sequence of ADL, respectively.

Conclusion: The developed platform could be useful for extending recent efforts in adjustable lower limb prosthetic socket design, particularly for individuals with residuum sensory impairment.

Keywords Adjustable prosthetic socket, Finite element analysis, Generalized Predictive Control, Interface pressure control, Transtibial

1. INTRODUCTION

The socket is the fundamental interface between a person with an amputation (PWA) and her/his prosthetic, and hence the first element of the device that determines their perception of comfort. It is responsible for direct transfer of the ground reaction force (GRF) to the musculoskeletal system during activities of daily living (ADL). The contact stresses at the interface between the prosthetic socket and the residuum skin, plus the strain of the underlying soft tissues greatly determine comfort and tissue injury risk. Poorly fitting sockets can cause discomfort and pain, and potentially limit prosthetic usage due to vascular occlusion, skin breakdown and tissue injuries such as degenerative stump ulcers, which in severe cases could lead to re-amputation or life threatening conditions [1]. Pressure-related tissue injury may initiate in the skin and advance to the underlying soft tissue layers, or begin in the internal tissues close to bony prominences and develop towards the skin surface [2], known as Deep Tissue Injury (DTI).

Generally, prosthetic sockets are bespokely fitted by specialized clinicians, and require iterative replacement to accommodate changes in residual limb volume and shape [3]. Standard transtibial socket designs present unmet challenges affecting wearer comfort. Some individuals experience pistoning [4], longitudinal movement between the prosthetic socket and the residual limb during cyclic loading. Others report sensitivity to residuum volume and shape changes, with up to 8.5% volumetric fluctuation per hour during a typical day [5, 6]. A solution may be socket designs that allow user-operated [7] or automated socket fit adjustment [8–13] or have spatially variable socket wall impedance [14], for reduction of interfacial pressure gradients that cause discomfort, and accommodation of diurnal and long-term residuum changes.

The Infinite Socket™ (LIM Innovations, CA, USA), Socket-less Socket™ (MartinBionics, OK, USA), and RevoFit™ (Click Medical, CO, USA) are manually adjustable commercially available devices. Socket size adjustments are made to flexible socket frame struts using straps, laces and clamps, or to moveable cabled panels introduced to a conventional socket. They offer benefits of easy within-day comfort-based adjustments by the user. The socket biomechanical functional outcomes and the impact of adjustments on sub-dermal tissues are, however, unknown. Also, the literature reports powered user-controlled [7], and automatically adjustable interventions aiming at reducing interfacial stresses [8, 10, 13] or compensating for limb volume fluctuations [9], or both [11, 12]. The adjustments are made using movable socket panels and motorized cables [7], or actuatable intra-socket bladders and interface pressure sensors [8–13]. These socket designs might be described as passive and semi-passive, aiming to maintain singular pre-determined user comfort and fit levels, as opposed to adjusting throughout dynamic, cyclic loading. Furthermore, they do not consider the internal tissue strain arising from the interfacial loading, which is the established predictor of DTI [15, 16]. The safety of these designs may be further improved by active control based on interfacial sensor measurements and tissue injury indicators [17], to address the cumulative effect of longer-duration loads, and to avoid the risk of users over-tightening the socket and inadvertently causing large strains of the residuum tissues beyond safe levels, especially where vascular pathologies may diminish sensation.

Interface pressure is practically measurable but it does not necessarily correspond with high tissue strain [18], or directly indicate DTI risk [2]. The purpose of this study is to describe a framework for developing an adaptive socket system that incorporates an actuatable residuum/socket interface to actively modulate interfacial pressure within estimated safe tissue strain levels. Finite element analysis (FEA) was used to predict the relationships between internal strain and socket-limb interfacial pressure at specific anatomical regions of the residual limb, at several instants during the gait cycle. These relationships were used as training data for tissue injury risk assessment to determine control targets for socket interface actuation. Generalized Predictive Control (GPC) was simulated in MATLAB (MathWorks®, USA), and optimized to minimize cumulative residuum tissue injury risk.

2. METHODS

A. Finite Element Analysis

A previously reported FE model [19] was adapted for this study (Fig. 1), to evaluate the relationships between predicted internal tissue strain and interfacial pressure at three anatomical regions of interest (ROI), to provide training data for actuator control based on minimizing tissue damage risk. Briefly, the model was developed from MRI scans of a person with unilateral transtibial amputation wearing a gel liner, segmented and meshed in Scan-IP software (Scan-IP N-2018.03, Synopsys Inc., USA) to represent liner, bones, soft tissue (combining muscles, skin and subcutaneous fat), patella and quadriceps tendons, and intra-articular structures. A socket model was generated by replicating the liner external surface up to the participant's normal socket brim-line, and applying a non-uniform 0 to 2% cross-sectional area scaling factor about the residual tibia's axis, to represent a simplified Total Surface Bearing (TSB) [20] design.

Quasi-static 2D sagittal plane loading was applied to the model with a proximal force (F_z), an anterior force (F_x) and an extension moment (M_y) (Fig. 1), for approximation of typical prosthetic use during the stance phase of gait [21]. The load values were

extracted from studies of dynamic load-cell data for unilateral transtibial prosthesis users walking at self-selected speed [22, 23]. The applied quasi-static loads represented the heel strike, foot flat, mid stance, heel off and toe off stages of gait. The loads were applied across a circular region of nodes at the base of the socket whilst the model was constrained at the proximal cut surface of the femur and the quadriceps tendon.

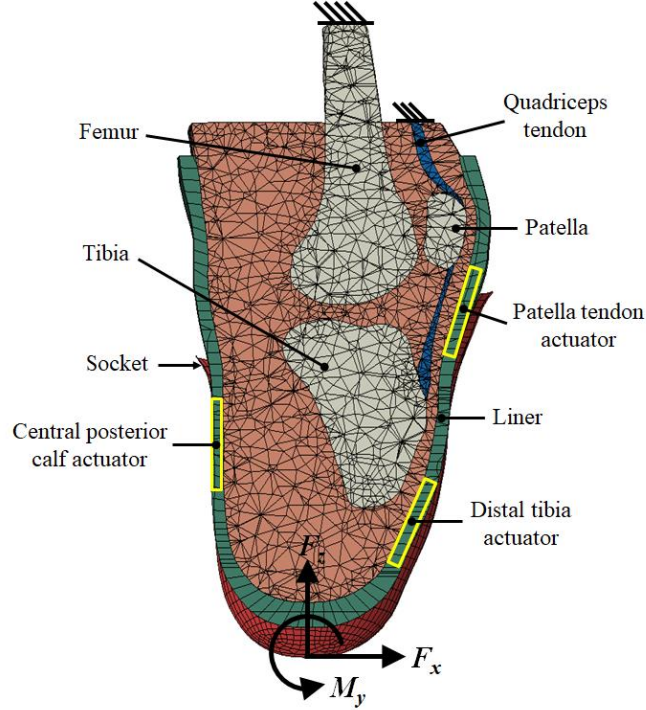


Fig. 1. A sagittal section of the FE model illustrating geometry, loading configuration and boundary conditions, plus the regions of interest for actuation: the patella tendon (PT), central posterior calf (PC) and tibia distal tip (DT).

Estimates of pressure at the residuum surface and internal strain within the soft tissue at the ROI were extracted from the model. 95th percentile values were used to avoid any single-node concentrations that may occur as artefacts of loading. The minimum principal strain, ϵ_3 , and maximum shear strain, γ_{max} , were inspected. The predicted interfacial pressure-compressive strain relationships were used to build surrogate models for tissue injury risk evaluation for actuator control.

B. Interface Actuation Model

Suitable techniques for functional interface actuation within an active socket system should have measurable, easily interpretable and controllable mechanical and/or electrical parameters. In this study, liquid bladder socket inserts were implemented, connected to a controllable ideal pressure source, capable of delivering and maintaining the desired pressure level. This actuation method was modelled in the Simulink environment (MATLAB R2016a, MathWorks®, USA) as a hydro-mechanical transducer system. It was estimated as an ideal transducer with incompressible fluid, and Pascal's law was applied assuming small fluid displacements. The pressure applied on the residuum surface at any instant is directly measurable using an interface sensor, and considered to be equal to the pressure in the fluid insert. Liquid socket bladders typically contain water as the primary medium [5]. The relevant variables used to model this actuator were derived from the properties of water, taken at 35°C, close to the average residuum skin temperature (34.1°C) after 30 minutes of treadmill walking with a prosthesis [24] (Table I).

TABLE I
REPRESENTATIVE INTERFACE ACTUATOR PROPERTY MODELLING VALUES FOR WATER AT 35°C

Property	Value
Density, ρ (kg.m ⁻³)	993.7
Kinematic viscosity, ν (m ² .s ⁻¹)	7.45 x 10 ⁻⁷
Bulk/Volume modulus, K @ atmospheric pressure (Pa)	2.24 x 10 ⁹
Thermal conductivity, k @ 1 bar (W/m.K)	621.6 x 10 ⁻³

C. GPC Implementation for Interface Actuation

A suitable control scheme for the adaptive socket system described in this study requires particular characteristics in order to

meet operational requirements: accommodation of multiple variables, sensors and actuators, capability for real-time, bounded control, capability to estimate unobservable states, and capacity for disturbance rejection for elements external to the system, such as gait information and prosthetic alignment effects. Generalized predictive control is a model-based control method [25], which is widely adopted in industry due to its capability to handle multivariable, high model order and unstable open loop systems, dead time, and maintaining good stability margins [26, 27]. This control approach computes current control inputs based on anticipated future input demands and predicted model behaviour over a finite horizon, n_y , into the future. The predicted output is derived from a plant model (1) and is dependent on the current measured variable and input. Matrix methods are used to recursively derive the equations for n -steps ahead prediction. At each sampling instant, a new control output prediction, $y_{\rightarrow k+1}$ (2) is computed based on anticipated future control targets, and the control input is adjusted accordingly. Level of model fidelity directly affects the allowable number of reliable control moves, n_u , at each step for dynamic performance optimization during transients [27].

$$A(z)y_k = b(z)\Delta u_k \quad (1)$$

$$y_{\rightarrow k+1} = H\Delta u_{\rightarrow k} + P\Delta u_{\leftarrow k-1} + Qy_{\leftarrow k} \quad (2)$$

where $A(z) = a(z)\Delta(z)$ and $\Delta(z) = 1 - z^{-1}$, k is the current sample step, Δu is the vector of control input increments, and H, P, Q are the prediction matrices.

Control inputs are determined by minimizing a cost function, J , (3), (4) such that control action (5) and closed-loop performance minimize overall interfacial pressure magnitudes and tissue injury risk. This minimization tends towards stability for a given horizon and allows for optimization to achieve a balance between adequate system sensitivity and the aggressiveness of control action. Optimization also involves application of a weighting constant, λ , that expresses the relative significance of control inputs compared to the tracking errors [28]. Only the first element, E_1 , in the future control increments vector $\Delta u_{\rightarrow k}$ (the optimum input trajectory) is applied at each sampling instant.

$$J = \sum_{k=1}^{n_y} e_{\rightarrow k+1}^T e_{\rightarrow k+1} + \lambda \sum_{k=1}^{n_u} \Delta u_{\rightarrow k}^T \Delta u_{\rightarrow k} \quad (3)$$

$$e_{\rightarrow k+1} = r_{\rightarrow k+1} - y_{\rightarrow k+1}$$

where r is the vector of control targets, the safe target pressures at the residuum interface for each actuator location, generated from a tissue injury risk evaluation protocol described below. e denotes the vector of tracking errors.

$$\min_{\Delta u_{\rightarrow k}} J \equiv \text{grad } J(\Delta u_{\rightarrow k}) = 0 \quad (4)$$

$$\Delta u_k = E_1^T (H^T H + \lambda I)^{-1} H^T [r_{\rightarrow k+1} - P\Delta u_{\leftarrow k-1} - Qy_{\leftarrow k}] \quad (5)$$

The input waveforms applied for simulating the adaptive socket system in Simulink[®] were determined from interfacial pressures arising from corresponding loading regimes, estimated using FEA. Residuum tissue injury risk due to loading was estimated by applying the surrogate models generated from the FEA, and a dynamic saturation block model that incorporated the sigmoid strain-time threshold curve published by Gefen *et al.* [16]. The dynamic saturation block model bounded the range of the input signal to upper and lower limits, with the strain injury threshold [16] applied as the upper bound. The predicted strain upon socket donning determined the lower bound, to represent maintaining the socket suspended upon the residuum. Furthermore, as an initial step, an input signal of 600 kPa, about twice the maximum interfacial pressure value predicted for standard gait (Fig. 2A), was applied to generate estimates of local interfacial pressure-time safety thresholds for all ROI. The endurance limits for early and delayed onset tissue damage due to large compressive strains are defined as within 0 – 63±37 minutes and 176 – 285±55 minutes, respectively [16].

The actuator plant model was converted into CARIMA (Controlled Auto Regressive and Integrated Moving Average) model transfer function of the form outlined in (1) [25, 27]. The controller was initiated at the pressure expected upon socket donning at the selected ROI, and the output sampling time was 15 seconds. Optimization was carried out to meet design goals of fast rise time

and no overshoot, by examining the influence of the control weighting constant, λ , for satisfactory performance without over-aggressive actuation. Desirable control action was defined as that which minimizes overall pressure magnitudes, actuation rates and pressure changes in order to minimize tissue strain injury risk, reduce the overall power consumption of the system, and in case large, fast actuations may cause wearer discomfort. Additionally, suitable values of the control horizon n_u and the feedforward horizon n_a were determined by experiment through control performance evaluation. n_a allows for identification of key future control target changes not covered within the control horizon. In designing for target tracking and control optimization with GPC, an increase in λ demands increase in n_u that in-turn may require an increase in n_a and/or n_y . Large values of n_y and n_a resulted in increased output deviation from the target, whereas large values of n_u resulted in finer control moves per step and faster actuation. It was expected that values of n_y , n_u and n_a should vary across the ROI, due to distinct interfacial pressure-strain relationships, and between different locomotive modes.

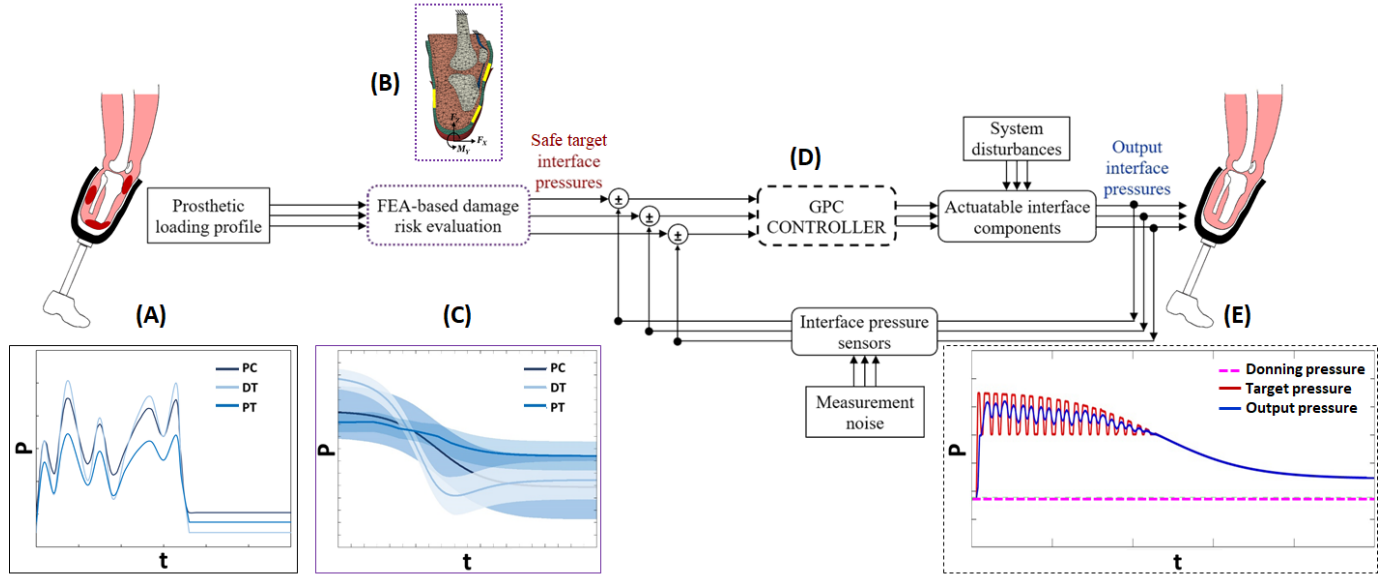


Fig. 2. An illustration of the adaptive prosthetic socket system concept. (A) Input gait loading signal, representative of pressure sensing at the residuum/socket interface for one gait cycle, 0 – 1 second. (B) Sagittal section of a 3D FEA model illustrating loading configuration, boundary conditions and actuator locations. (C) Estimated pressure-time injury risk thresholds, for 0 – 300 minutes, corresponding to the sigmoid strain-time curve [16]. (B) and (C) represent the tissue injury risk evaluation protocol utilizing biomechanical FEA output predictions of localized interfacial pressure-strain relationships to determine control targets for interface actuation. (D) GPC system for maintaining safe tissue strain levels by adaptive actuation of intra-socket liquid bladders. (E) Exemplar control output at the posterior calf location (0 – 300 minutes). P - interfacial pressure, t - time.

The feasibility and performance of the GPC formulation for the proposed interface actuator model was firstly assessed for a standard gait input waveform (Fig. 2A) corresponding to the forces and moments across the socket-tibia-knee joint construct [29]. The durations of stance and swing phases during one gait cycle were determined as 0.72 and 0.48 seconds, respectively, as reported for persons with unilateral transtibial amputation [30]. The input sampling rate was 50 Hz, to preserve at least up to 99% of gait signal power (~ 15 Hz) [31]. The output prediction horizon n_y was chosen as between 30 and 100 minutes, i.e. 120 – 400 sample steps (ss), corresponding to the short loading exposure period after which there is notable decrease in muscle tissue compressive strain endurance [16]. Preliminary work indicated variation of λ in increment steps of one order of magnitude from 10^{-2} to 10^2 across all ROI for optimization. Also, close resemblance was noted in the estimated GPC safe target pressure profiles at the PC and PT actuator locations, with cyclic loading in timeframes under 2 hours. n_u values of 10, 20, and 10 sample steps (i.e. 2.5 min, 5 min, and 2.5 min) were selected for the PT, PC and DT actuator locations, respectively, whereas the n_a values were 20, 30, and 100 sample steps (i.e. 5 min, 7.5 min, and 25 min).

A second assessment was carried out to examine the efficacy and performance of GPC for a demonstrative loading sequence of some typical ADL that might be performed by active prosthesis users. These included donning the prosthesis, 30 minutes sitting, 15 minutes standing, 45 minutes walking at a comfortable self-selected pace, and finally sitting again for 30 minutes. For the FEA to determine inputs for this loading scenario, the user was considered to be a person with unilateral transtibial amputation weighing approximately 90 kg [22]. The output prediction horizon n_y was selected between 15 – 30 minutes. Preliminary analysis dictated variation of λ from minimum 0.1 to maximum 10 across all ROI for optimization. n_u values of 20, 20, and 15 sample steps (i.e. 5 min, 5 min, and 3.75 min) were selected for the PT, PC and DT actuator locations, respectively, whereas the n_a values were 30, 25, and 50 sample steps (i.e. 7.5 min, 6.25 min, and 12.5 min).

3. RESULTS

A. Finite Element Analysis

For the three loading cases, the local interfacial pressure estimated at actuator locations ranged from 25.5 – 155.1 kPa, 54.9 – 112.1 kPa and 42.3 – 116.1 kPa, for the DT, PC and PT locations, respectively. Compressive strain in the soft tissues ranged between 40.7 – 81.2%, 56.3 – 85.3% and 47.4 – 72.2%, while the shear strain was between 6.1 – 15.1%, 7.7 – 17.1% and 4.6 – 9%, for the DT, PC and PT locations, respectively. Variations in the pressure and strain estimates were consistent across the loading cases throughout the gait cycle. Fig. 3 shows the predicted distributions of compressive strain on a sagittal plane section view through the tibia, and interfacial pressure for the five gait instances, for one loading case. During heel strike to mid stance, areas of high compressive strain were the lateral femoral epicondyle, fibula head, tibial tuberosity and anterior distal tibia. For heel off and toe off, the strain was concentrated at the patella tendon, the patella and the tibia distal tip. Areas of high interfacial pressure were the tibial tuberosity, anterior distal tibia, proximal posterior calf close to the popliteal fossa and the fibula head during heel strike to mid stance, and the patella, patella tendon, central posterior calf and fibula head during heel off and toe off.

Regression analysis of predicted interfacial pressure-compressive strain relationships, showed a linear relationship ($R^2 = 0.9$) at the PC location, but more complex relationships at the DT and PT locations (Fig. 4), which were described with cubic splines. Moreover, at the DT location, predicted compressive and shear strains were highest around the load-acceptance and push-off gait stages, whereas at the PC and PT locations the strains increased from heel strike to toe off.

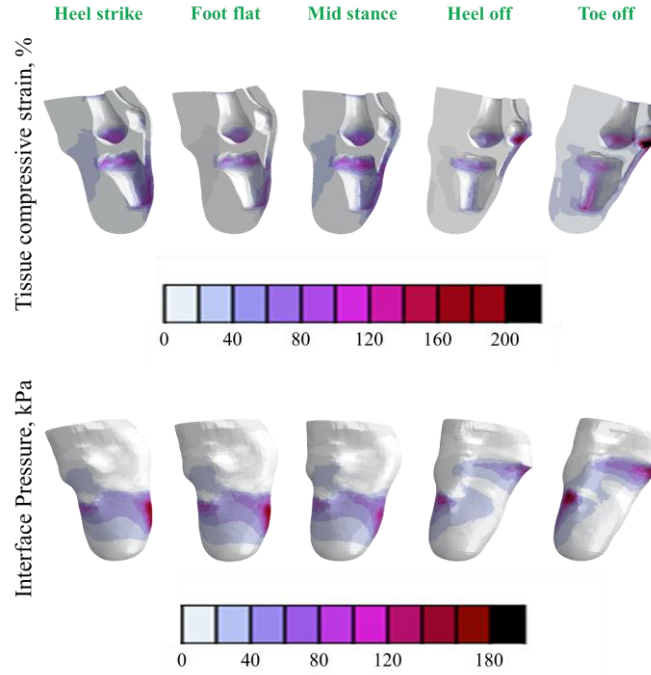


Fig. 3. **TOP:** Sagittal plane section views through the tibia showing the internal residuum compressive strain and, **BOTTOM:** the full field residuum interface pressure estimates during five key stages of stance for one loading case [22].

B. GPC Performance Evaluation

Estimated pressure safety limits to avoid early onset of tissue damage were 54.8 – 51.3 (± 10.8) kPa, 50.8 – 49.1 (± 4) kPa and 68.4 – 57.6 (± 4.1) kPa at the PC, PT and DT regions, respectively, corresponding to the sigmoid strain-time curve [16]. The longer term limits for delayed onset were 27.6 – 24.4 (± 12.5) kPa, 38.6 – 37.1 (± 5.9) kPa and 24.5 – 27.2 (± 7.8) kPa and, at the PC, DT and PT regions, respectively (Fig. 5a, Fig. 6a, Fig. 7a). GPC output profiles and actuation control performance measures for a standard continuous gait waveform at the three ROI are presented in Fig. 5b, Fig. 6b, Fig. 7b, and Table II. Larger values of λ resulted in smaller, slower actuations, and increased control output deviation from the target. For timeframes below 2 hours, control acted to maintain interfacial pressures below the safety threshold at all ROIs. After this time, safe target tracking was maintained at the PC and PT locations, but overshoots of 0.67 – 4.15% were predicted at the DT location.

For the simulations of GPC for a loading sequence of typical ADL, peak actuation magnitudes and rates were predicted where the largest changes in target pressure occurred, during transitions from sitting to standing and walking to sitting actions for the PC and PT locations, and during transitions from standing to walking and walking to sitting actions for the DT location (Fig. 5c, Fig.

6c, Fig. 7c).

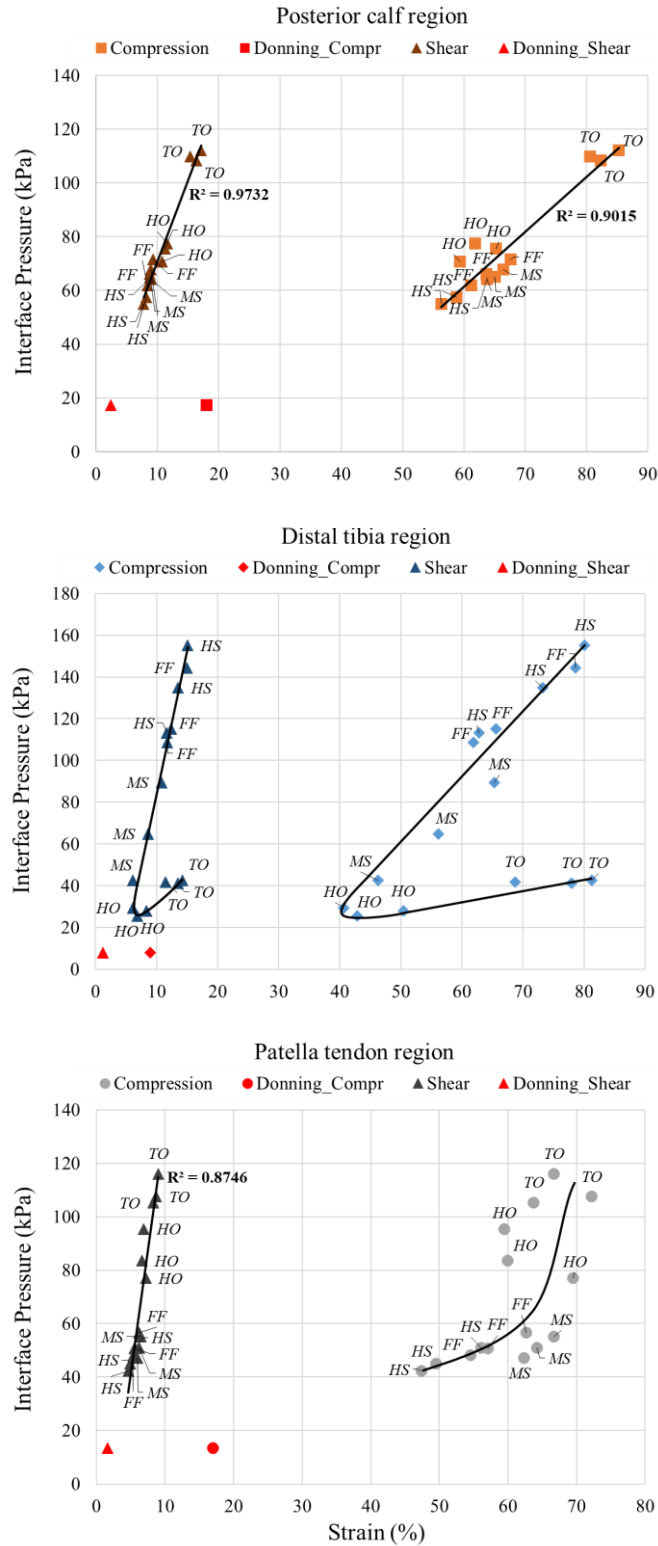


Fig. 4. Interface pressure vs. residuum tissue strain relationships at the posterior calf, distal tibia and patella tendon locations, showing combined results for all the three loading cases applied. HS - Heel Strike, FF - Foot Flat, MS - Mid Stance, HO - Heel Off, TO - Toe Off

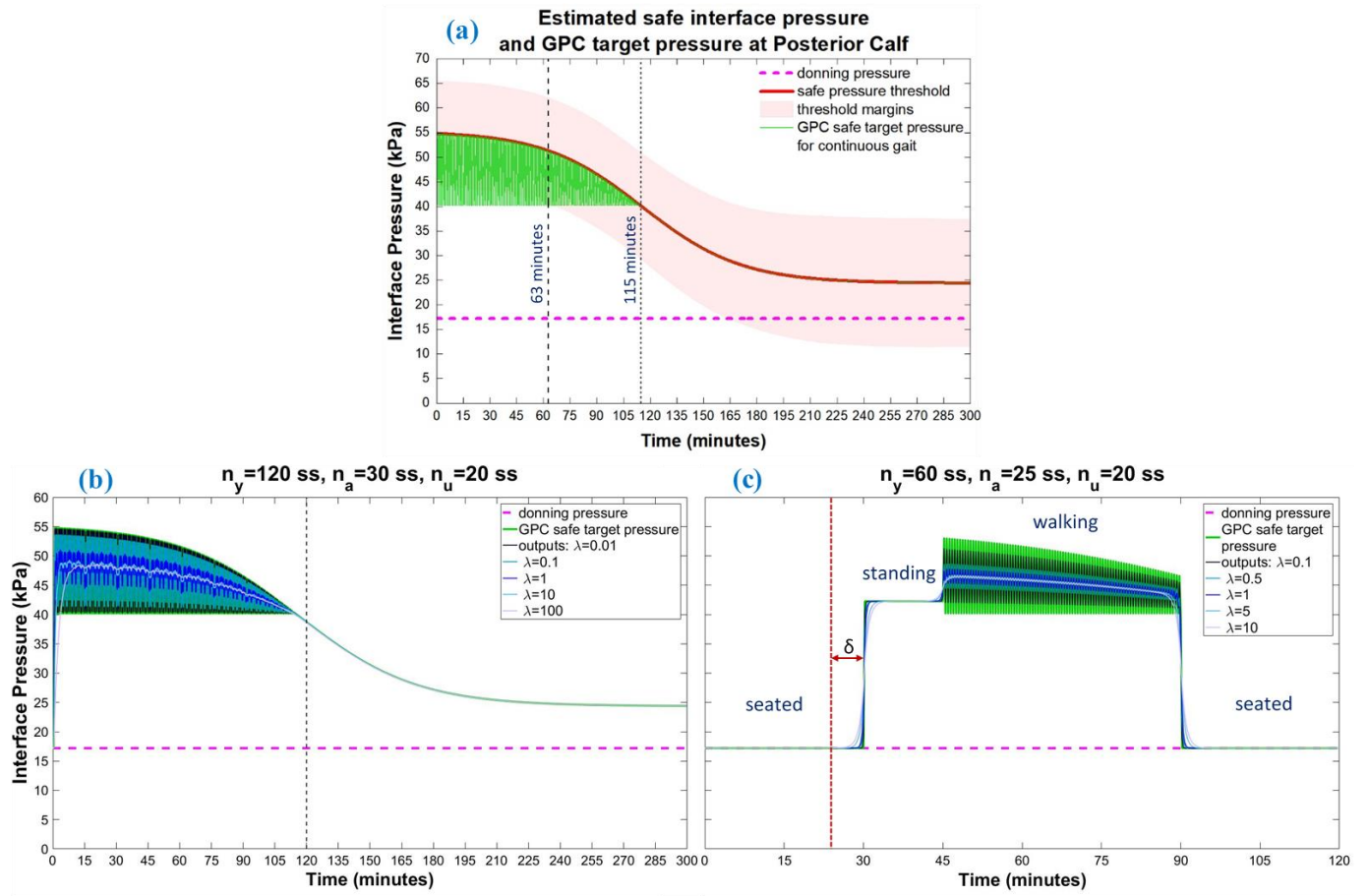


Fig. 5. TOP: (a) Estimated interface pressure safety threshold, and GPC safe target pressure plots for a standard continuous ambulation waveform at the posterior calf location. BOTTOM: GPC performance for a liquid bladder actuator for different values of the control weighting constant, λ , for (b) a standard continuous ambulation waveform, and (c) a demonstrative loading sequence of typical ADL, $\delta = 6.25$ minutes and denotes the minimum delay, n_a , that may be required between loading input measurements and controlled actuation in practical application. ss - sample steps.

TABLE II

SUMMARY OF SIMULATED GPC OUTPUT PERFORMANCE FOR A LIQUID BLADDER ACTUATOR BY RESIDUUM LOCATION FOR A STANDARD CONTINUOUS GAIT WAVEFORM, AND A DEMONSTRATIVE LOADING SEQUENCE OF TYPICAL ADL. BLUE SHADING INDICATES RESULTS WITHIN PREFERRED ACTUATION RATE RANGE.

	Actuator location	Peak Actuation Pressure Magnitude (kPa)					Peak Actuation Rate (kPa/s)				
		0.01	0.1	1	10	100	0.01	0.1	1	10	100
Continuous Gait	λ	0.01	0.1	1	10	100	0.01	0.1	1	10	100
	PC	14.29	12.16	5.12	0.95	0.40	0.95	0.81	0.34	0.06	0.03
	PT	5.42	4.28	1.68	0.38	0.33	0.36	0.29	0.11	0.03	0.02
	DT	43.4	44.5	65.6	134.7	300.0	4.01	3.71	1.51	0.51	0.20
ADL Loading Sequence	λ	0.1	0.5	1	5	10	0.1	0.5	1	5	10
	PC	21.19	14.48	11.21	5.57	4.02	1.41	0.97	0.75	0.37	0.27
	PT	29.39	20.08	15.55	7.59	5.43	1.96	1.34	1.04	0.51	0.36
	DT	34.76	23.74	18.38	8.95	6.39	2.32	1.58	1.23	0.60	0.43
	Actuator location	Maximum Error (%)					Maximum Overshoot (%)				
		0.01	0.1	1	10	100	0.01	0.1	1	10	100
Continuous Gait	λ	0.01	0.1	1	10	100	0	0	0	0	0
	PC	-	-	-	-	-	0	0	0	0	0
	PT	-	-	-	-	-	0	0	0	0	0
	DT	-	-	-	-	-	0	0	0	0.67	4.15
ADL Loading Sequence	λ	0.1	0.5	1	5	10	0.1	0.5	1	5	10
	PC	11	31	40	58	63	0	0	0	0	0
	PT	20	54	71	101	109	0	0	0	0	0
	DT	33	91	119	170	184	0	0	0	0	0

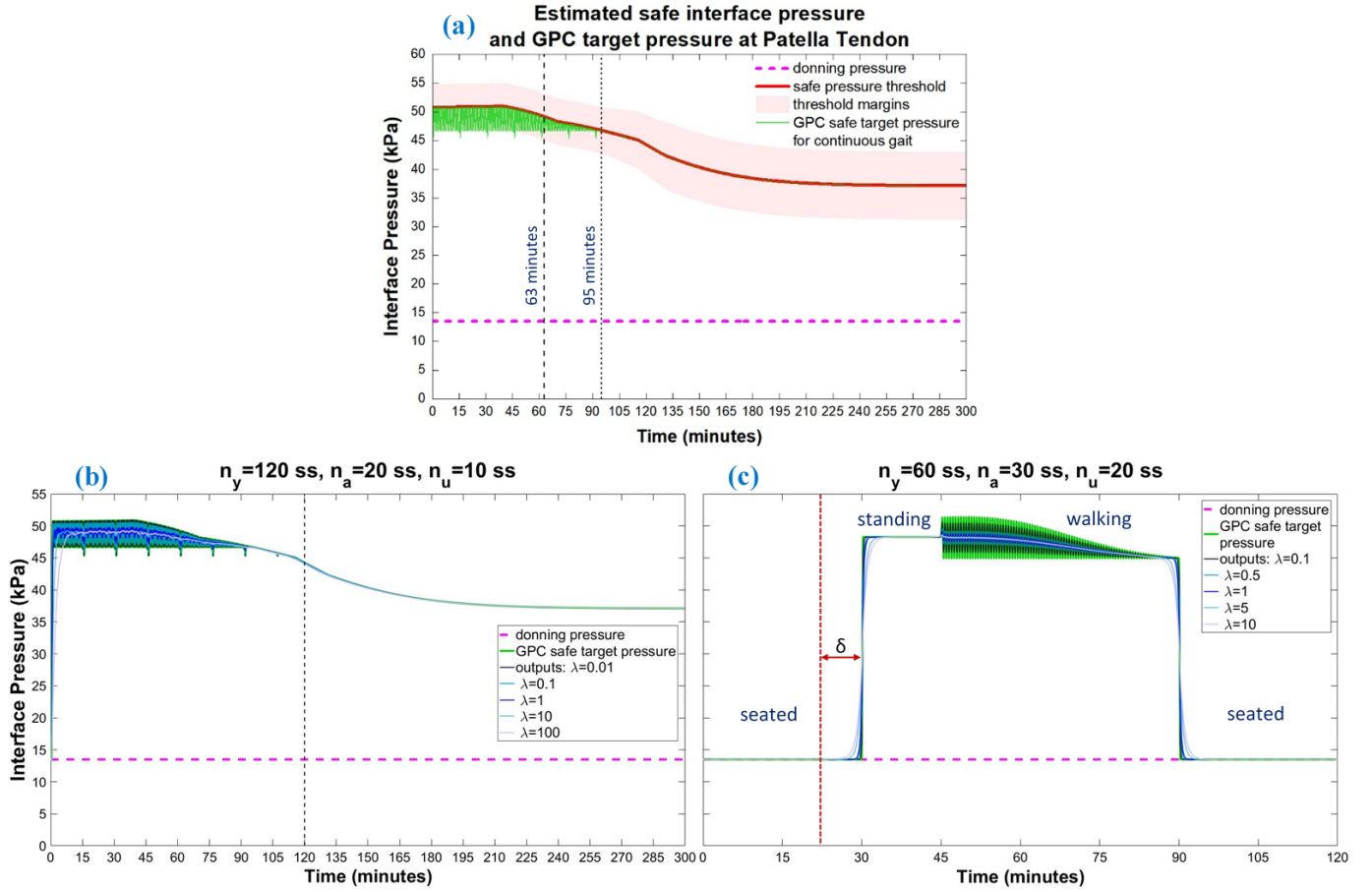


Fig. 6. TOP: (a) Estimated interface pressure safety threshold, and GPC safe target pressure plots for a standard continuous ambulation waveform at the patella tendon location. BOTTOM: GPC performance for a liquid bladder actuator for different values of the control weighting constant, λ , for (b) a standard continuous ambulation waveform, and (c) a demonstrative loading sequence of typical ADL, $\delta = 7.5$ minutes and denotes the minimum delay, n_d , that may be required between loading input measurements and controlled actuation in practical application. ss - sample steps.

4. DISCUSSION

This study presents development of a framework for an adaptive transtibial prosthetic socket that enables active interface actuation to modulate tissue strain within estimated safe levels. Local interfacial pressure and compressive strain estimates throughout the gait cycle were observed to be comparable to related studies [21]: the distal anterior and proximal posterior parts of the residual limb were predicted to be loaded around heel strike and unloaded around toe off, as a result of socket flexion and extension moments. The opposite loading trend was predicted at the proximal anterior and distal posterior locations (Fig. 3). Peak soft tissue compressive strains were estimated as 81.2%, 85.3% and 72.2% at the DT, PC and PT regions, respectively, consistent with maxima reported in similar FEA studies [32]. Furthermore, peak shear strain of 15.1% was predicted at the distal tibia, comparable to other published predictions [33]. These results provide some corroboration to the model predictions, though there will of course be considerable inter-person variability in these measures, as well as recognized inconsistency in FEA predictions across studies attributed to differences in model structures and levels of sophistication, material properties, loading regimes, and the methods applied for evaluating model outputs [34].

Numerous previous studies have quantified prosthesis-limb normal interfacial pressures and shear stresses in efforts to optimize lower limb prosthetic socket design for user comfort and the quality of socket fit. An important finding of the current study is that relatively low interfacial pressures, 27 – 55 kPa, can result in large local internal compressive strains, above 50% (Fig. 4) indicating theoretical DTI risk for weight-bearing periods longer than 1 hr [16]. This observation is particularly important for prosthetic socket fitting for users with peripheral neuro-deficiency due to vascular diseases, who may lack adequate sensorial alert to onset of tissue damage. Other studies have also shown that interfacial pressures alone are misleading for determining susceptibility to DTI, owing to inter-person variability and distinct geometry of bones and soft tissue layers, and tissue properties [35], and high interfacial pressures may not necessarily correspond to high internal tissue strain. Portnoy *et al.* [18] reported 65 kPa pressure against 73% compressive strain for one participant, and 92 kPa against <35% strain for another. A different study investigating

impact of permanent wheelchair use reported peak pressure of 18 ± 3 kPa under the gluteus ischial tuberosity against peak strain of $74 \pm 7\%$ in the gluteus muscle [36].

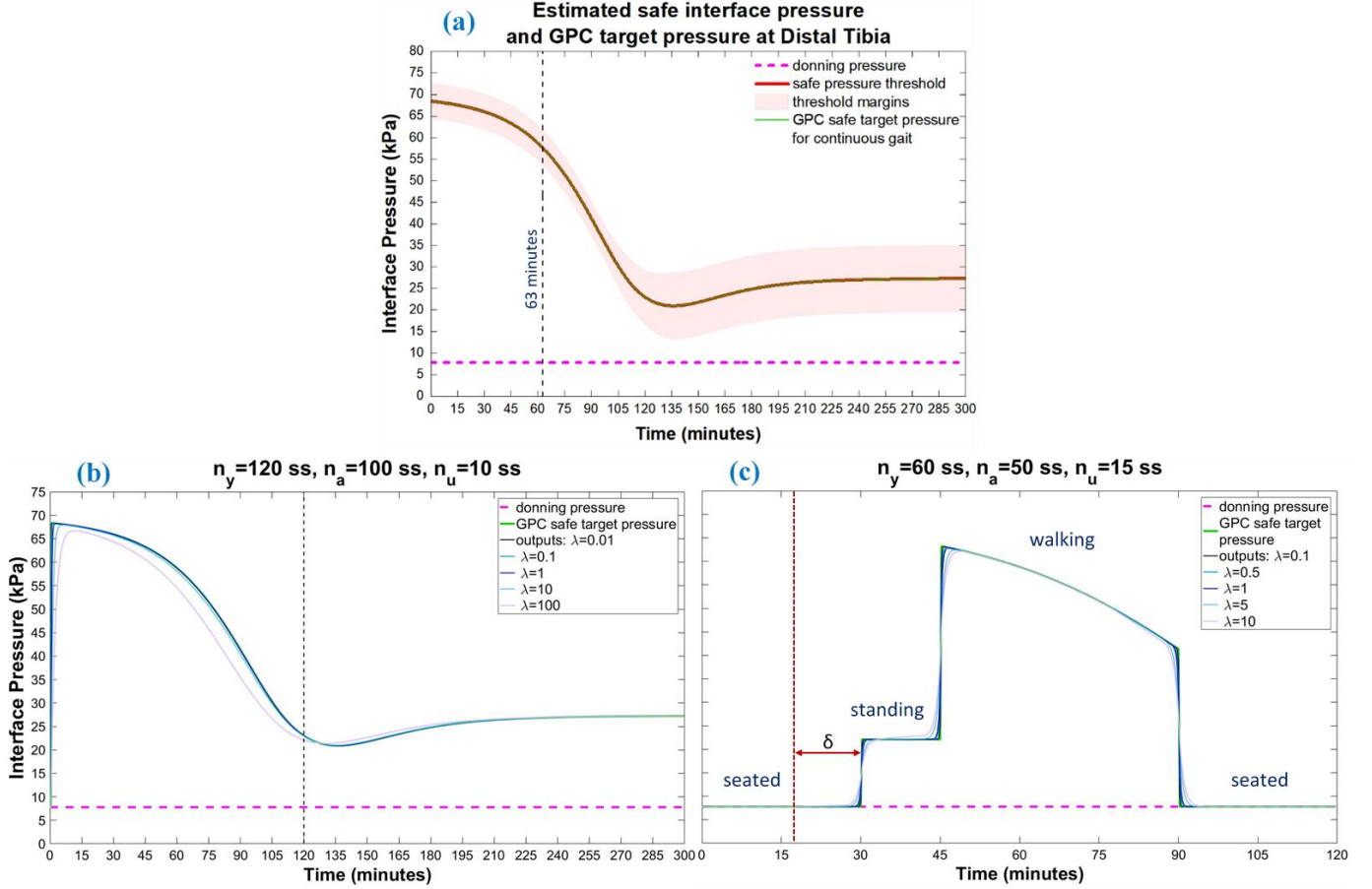


Fig. 7. TOP: (a) Estimated interface pressure safety threshold, and GPC safe target pressure plots for a standard continuous ambulation waveform at the distal tibia location. **BOTTOM: GPC** performance for a liquid bladder actuator for different values of the control weighting constant, λ , for **(b)** a standard continuous ambulation waveform, and **(c)** a demonstrative loading sequence of typical ADL, $\delta = 12.5$ minutes and denotes the minimum delay, n_a , that may be required between loading input measurements and controlled actuation in practical application. ss - sample steps.

In the present study, GPC control was simulated with a cost function optimization to minimize residuum tissue injury risk with a liquid bladder actuator. For the three actuator locations considered, interface actuation maintained pressure within the estimated safety thresholds, and above the nominal levels predicted upon socket donning alone, which was used as prediction of ensuring prosthesis suspension during swing (Fig. 5 – Fig. 7). According to related studies evaluating user outcomes for the elevated vacuum socket suspension system, over 72% of users reported preferred variations in vacuum of 3.4 – 6.8 kPa ($\approx 1 - 2$ inHg) during ambulation [37]. Consequently, in the current study, estimates of preferred actuation performance for continuous walking were indicated as up to 0.34 kPa/s, 0.36 kPa/s and 1.51 kPa/s for the PC, PT and DT locations, respectively, with a maximum overshoot of 0.67% at DT, and similarly, 1.41 kPa/s, 1.34 kPa/s and 1.58 kPa/s with no overshoot, for the loading sequence of typical ADL (Table II). Additionally, during continuous walking, cyclic control action observed at the PC (Fig. 5b) and PT locations (Fig. 6b) for timeframes under 2 hours may be beneficial for enhancing blood flow to the residuum tissues [38].

This study provides local interfacial pressure-time safety threshold estimates for the three actuator locations, generated based on an existing strain injury threshold [16]. Though external validity of these interfacial pressure thresholds is limited owing to different input data and conditions between the two studies, they offer some novel representative approximations for assessing injury risk of residuum tissues as a result of in-socket loading. Some comparable studies on self-adjusting sockets involving actuatable magneto-rheological fluid socket inserts [12], an air-cuff liner [10], and intra-socket fluid bladders [13] reported improved performance compared to conventional sockets [39] with regards to measured peak interfacial pressure – 70 kPa, 57 kPa and 72 kPa versus 170 kPa, 83 kPa and 79 kPa, at the patella tendon, central posterior calf and distal residuum regions, respectively. The results of the current study indicate that although self-adjusting sockets may show reduced pressures compared to standard sockets, additional measures may be necessary to sufficiently eliminate the risk of DTI in residuum tissues under long-term loading (Fig. 5a, Fig. 6a, Fig. 7a).

For the sequence of typical ADL, the GPC formulation based on future targets enabled smooth transitions between actions, avoiding large instantaneous pressure changes. Control outputs were below estimated pressure thresholds and errors did not represent poor control action, but rather could be applied as criteria for selecting control parameters for multi-modal prosthetic device usage for transitioning between different locomotion modes. For real implementation, explicit programming of a minimum delay equivalent to n_a between current interfacial pressure measurements and controlled actuation would be essential to enable timely detection of imminent control target changes based on user movements (Fig. 5c, Fig. 6c, Fig. 7c).

This study indicates that GPC can be applied to give satisfactory interface actuation performance and minimize tissue damage risk for an adaptive prosthetic socket with multiple in-socket actuators, in several scenarios. Control parameters can be selected which would be predicted to meet operational requirements and avoid deviations into high tissue damage risk, for an exemplar liquid bladder actuator model.

Limitations

The present FEA study involved quasi-static loading at several gait stages, an analysis simplification justified by the slow walking cases of interest. Also, only a limited set of prosthetic loading cases were applied, taken from published literature. Further studies involving full dynamic analysis, additional prosthetic loading scenarios and characterization of effects of different walking speeds could generate more robust surrogate models for DTI risk evaluation, and ideally the load cases would match the individual from whom the modelling geometry was obtained. Moreover, the study only considered three anatomical regions of the transtibial residuum for in-socket actuation. Additional actuator locations and combinations should be evaluated to assess possible requirement of a more complex control structure [40]. Furthermore, the FE analysis in the present study was based on a single model. In a proposed practical application of this study, conducting person-specific, image-based FEA for each candidate patient would be prohibitively expensive. Instead, such a control framework might be tuned using simpler models [41] based on linear ultrasound measurements [42] of soft tissue coverage thickness over bone at key residuum regions, ultrasound elastography [43] or indenter measurements of skeletal tissue compliance [44], and population-driven techniques assessing effects of different residuum morphologies and geometries on biomechanical measurements [19]. Extrapolation of the predictions obtained in the current study is further limited by several model simplifications and assumptions. The present model is somewhat simple. More advanced models might be compared, considering the effects of different tissue continuum material models, multi-layered models with distinct tissue layers or discrete muscle sets, residuum interface boundary conditions considering the influence of temperature and humidity, and personalised tissue structures and mechanical properties. This is of particular importance because the tissue injury prediction process considers strain [45], and such studies would be useful for defining more detailed pressure-strain data capturing individual variability in tissue biomechanical response to loading.

The current study is a theoretical analysis of GPC feasibility, and practical implementation may be different. GPC applies unbiased predictions in the steady state, and to improve accuracy for a physical implementation low-pass filters may be required to adequately handle additional impact of prosthetic alignment and other biomechanical gait effects, and measurement noise. This may enhance disturbance rejection by reducing input signal sensitivity to high frequency noise, and improving output prediction accuracy by eliminating bias due to past random changes [27]. Also, the control optimization parameters and constraints applied here may differ for a practical implementation due to system losses and gait effects. The study demonstrates that interface actuation performance measures can be manipulated within the GPC formulation to achieve various control objectives, and trade-offs between them. Studies considering end-user feedback are required to assist in prioritizing actuation performance metrics based on comfort levels, and to perform multi-objective optimization to identify minimal values for actuation rates and pressure changes. Design validation entailing prototyping with embedded actuators, including electroactive polymers (EAPs) for example, and interface sensors is required to robustly test the described socket concept. Development studies could be extended to further evaluate GPC performance measures for variation of actuator sites, multi-modal capacity for transitioning between different locomotion modes, or within multi-level control strategies with gait recognition, for establishing a pathway to clinical adoption.

5. CONCLUSION

This study presents a framework for controlling a self-adjusting transtibial prosthetic socket based on minimizing an estimated residuum soft tissue injury risk. The study establishes the use of FEA to generate socket adjustment control training data for DTI risk assessment. It further demonstrates the feasibility of the GPC formulation for adaptive interface actuation control minimizing tissue injury risk in several scenarios, and the influence of a cost function optimization on actuation performance of intra-socket actuators. The presented platform could be useful for extending recent efforts in adjustable lower limb prosthetic sockets.

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CONFLICT OF INTEREST AND ETHICAL APPROVAL

None of the authors has any conflict of interest to declare.

Ethics permission obtained through the University of Southampton secondary data ethics approval, references ERGO#29927 and ERGO#41476.

DATA AVAILABILITY

Supporting data will be made openly available upon acceptance of a peer-reviewed version, at the University of Southampton repository.

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