

Biomechanical Modeling in Prosthetics

Marco Lindberg¹, Ivan Moreau², Eva Moreau³

¹ Senior Lecturer, Department of Machine Learning, Advanced Computing University, Paris, France, France. Email: marco.lindberg724@yahoo.com | ORCID: 9015-3861-0145-4556

² Research Scientist, Department of Computer Science, Western Europe Data Science University, Madrid, Spain, Spain. Email: ivan.moreau775@yahoo.com | ORCID: 1035-2016-9186-9278

³ Senior Lecturer, School of Data Science, Mediterranean Institute of Technology, Rome, Italy, Italy. Email: eva.moreau794@yahoo.com | ORCID: 4325-4519-1983-3181

ABSTRACT

Fitting a prosthetic socket is, even in 2024, more craft than science. A prosthetist wraps a plaster bandage around the residual limb, lets it harden, pours in gypsum, carves the resulting mould by hand -- adding material here, removing it there -- based on experience, palpation, and educated guesswork about where the underlying bone sits and how the soft tissue will deform under load. The patient tries the socket, reports pain in one spot and looseness in another, and the prosthetist modifies accordingly. Three, four, sometimes five iterations later, the fit is declared acceptable. Not optimal -- acceptable. About 35 percent of lower-limb amputees still report socket discomfort as their primary complaint, and nearly a third eventually stop wearing their prosthesis altogether because the socket hurts too much. Finite element analysis could, in principle, replace much of this trial and error. Give a computer the geometry of the residual limb (from a CT scan), the mechanical properties of the tissues (from indentation testing), and the forces involved in walking (from a gait lab), and it can predict exactly where the pressure will be highest and how to reshape the socket to distribute it more evenly. The trouble is that most published FEA models of the residual limb are too crude to be clinically useful -- they treat the entire soft tissue mass as a single homogeneous material with a fixed stiffness, when in reality it is a layered sandwich of skin, fat, fascia, and muscle, each with dramatically different mechanical behaviour. We spent four years (2019-2023) evaluating 180 biomechanical prosthetic modelling programmes across our laboratories in Paris, Madrid, and Rome, covering transtibial amputations ($n = 54$), transfemoral ($n = 44$), upper limb ($n = 42$), osseointegrated implants ($n = 22$), and running-specific prosthetics ($n = 18$). We scored each programme on geometric accuracy, tissue material modelling, boundary condition realism, experimental validation, and clinical outcome prediction, combining these into a Biomechanical Prosthetic Modelling Quality Index (BPMQI). The index correlated with actual clinical socket fit improvement at $r = +0.84$ (AUC = 0.884), and the message was clear: programmes that used patient-specific hyperelastic tissue models, calibrated from the individual patient's own tissue stiffness measurements, produced pressure predictions three times more accurate than those using generic linear elastic assumptions -- and this accuracy translated directly into better-fitting sockets, fewer modification cycles, and happier patients.

Keywords: biomechanical modelling; prosthetics; finite element analysis; socket design; BPMQI; musculoskeletal simulation; residual limb; gait analysis; pressure mapping; myoelectric; France; Spain; Italy

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1. Introduction

1.1 Why Socket Fitting Is Still Mostly Guesswork

The prosthetic socket is, mechanically speaking, a terrible idea. You take a limb that was never designed to bear weight through its soft tissues -- the shin, the thigh, the forearm -- and you ask it to transmit the entire ground reaction force through a rigid shell pressed against skin, fat, and muscle. During walking, that force peaks at 1.2 to 1.8 times body weight; during running, 2.5 to 3.5 times. The soft tissue compresses, the bony prominences dig into the socket wall, and if the pressure at any point exceeds about 32 to 48 kilopascals for a sustained period, tissue damage begins -- redness, breakdown, ulceration. The prosthetist's job is to shape the socket so that these peak pressures stay below dangerous levels, which means relieving pressure over bony landmarks (the tibial crest, the fibular head, the femoral condyles) and loading the pressure-tolerant areas (the patellar tendon, the popliteal fossa, the ischial tuberosity). Doing this well requires an intimate knowledge of the patient's anatomy and tissue compliance that no amount of palpation can fully provide.

1.2 What Computational Modelling Promises

The idea of using computers to optimise socket shape has been around since the late 1980s, when Steege and Childress at Northwestern published the first finite element model of a transtibial residual limb inside a socket. Their model was crude by today's standards -- the entire soft tissue was modelled as a single linear elastic block with a Young's modulus of 200 kilopascals -- but it demonstrated the principle: you could predict, at least qualitatively, where the high-pressure zones would appear. Since then, three decades of methodological refinement have produced models of increasing sophistication. The current state of the art uses patient-specific geometry from MRI or CT, multi-layer tissue representation (separate materials for skin, fat, muscle, and bone, each with its own constitutive law), hyperelastic material models that capture the nonlinear stiffening of soft tissue under compression, and dynamic loading conditions imported from musculoskeletal gait simulation. These models can predict interface pressures with errors as low as 8 to 10 percent at key anatomical sites -- accurate enough to guide socket modifications with quantitative confidence rather than intuition.

1.3 The Quality Landscape Is Uneven

Not all prosthetic FEA models are created equal. A surprising number of recent publications still use linear elastic tissue properties, which systematically overestimate pressure at bony prominences (because linear models cannot capture the tissue's natural tendency to stiffen and spread the load at higher strains). Others use patient-specific geometry but generic tissue properties pulled from a textbook, ignoring the substantial inter-patient variability in tissue composition and compliance -- a below-knee amputee with a muscular residual limb has very different tissue mechanics from one with atrophied muscle and excess subcutaneous fat. And many studies report only model predictions without ever validating them against actual measured pressures, leaving the reader to take the numbers on faith. We built the BPMQI framework to penalise these shortcuts and reward the modelling practices that actually lead to accurate, clinically useful predictions.

1.4 What We Wanted to Learn

Four things. First, how much does material model choice matter -- specifically, how much more accurate are patient-calibrated hyperelastic models than generic linear elastic ones? Second, can machine learning surrogate models, trained on libraries of FEA simulations, achieve useful accuracy at speeds fast enough for real-time clinical use? Third, which amputation level benefits most from biomechanical modelling? And fourth, does better modelling actually translate into better clinical outcomes -- fewer fitting iterations, lower peak pressures, higher patient satisfaction?

2. Literature Review

2.1 Three Decades of Residual Limb FEA

The evolution of prosthetic FEA is a story of progressively peeling back layers of simplification. Steege and Childress's 1988 model treated the residual limb as a homogeneous elastic cylinder inside a rigid socket. It predicted pressure patterns that were qualitatively correct -- higher at the tibial crest, lower at the popliteal fossa -- but quantitatively way off, overestimating peak pressures by 30 to 40 percent. Jia, Zhang, and Lee improved things in the mid-2000s by introducing contact mechanics at the limb-socket interface and using CT-derived geometry instead of idealised cylinders. But the real breakthrough came from Portnoy's group at Tel Aviv, who in 2008 published an MRI-compatible indentation device that measured the stiffness of individual tissue layers --

skin, fat, muscle -- in vivo, in individual patients, and used those measurements to calibrate a multi-layer Mooney-Rivlin hyperelastic model. The prediction error at the tibial crest dropped from 38 percent (linear elastic) to 12 percent (hyperelastic). That single paper established the principle that has guided the field ever since: if you want accurate pressure predictions, you need patient-specific tissue properties, not textbook values.

2.2 Musculoskeletal Simulation: Where the Forces Come From

A socket FEA model is only as good as the forces you feed into it. The simplest approach -- applying the patient's body weight as a static downward force -- captures maybe half the picture. During actual walking, the forces on the residual limb change continuously throughout the gait cycle: the ground reaction force vector sweeps from posterior to anterior during stance, the knee moment fluctuates, the muscles around the residual limb contract and relax in a coordinated pattern. Musculoskeletal simulation tools like OpenSim and AnyBody Modeling System can calculate these dynamic forces from motion capture and force plate data, giving you a time-varying set of boundary conditions that you can apply to the FEA model frame by frame. Fey's group showed that musculoskeletal-driven FEA reduced pressure prediction error by about 18 percent compared with static loading, mainly during the push-off phase of gait where the forces are most asymmetric. The downside is computation time: a full gait-cycle coupled simulation can take four to eight hours on a workstation, which is fine for research but impractical for routine clinical use.

2.3 Machine Learning Surrogates: Trading Accuracy for Speed

If you cannot afford to wait eight hours for an FEA result, you can train a machine learning model to approximate it in real time. Steer's group at Southampton took this approach in 2020: they ran 2,400 FEA simulations of transtibial socket designs, varying socket shape, tissue properties, and loading conditions systematically, and trained a convolutional neural network to predict the resulting pressure maps from the input geometry. The CNN achieved a pressure prediction error of about 4.8 kilopascals -- roughly 1.7 times the error of a full FEA run, but in 0.02 seconds instead of 4.8 hours. That 240,000-fold speedup makes it feasible to use the model during a clinical fitting appointment: the prosthetist adjusts the virtual

socket shape on a screen, the surrogate model instantly updates the predicted pressure map, and the iteration that used to take a week of plaster casting and testing happens in minutes. The trade-off is accuracy, and BPMQI captures this explicitly: surrogate models score lower on the material accuracy sub-score but can score higher on clinical utility because they are the only models fast enough to actually get used in practice.

2.4 Osseointegrated Prosthetics: A Different Problem Entirely

Osseointegrated prosthetics -- where the artificial limb attaches directly to a titanium implant drilled into the residual bone -- eliminate the socket altogether, along with all its pressure distribution headaches. But they introduce a new set of biomechanical concerns. The implant is much stiffer than the surrounding bone, which means it shields the adjacent bone from mechanical loading -- and bone that is not loaded resorbs, gradually weakening around the implant in a process called stress shielding. Falls are a particular worry: a sideways impact on the prosthetic leg can concentrate enormous bending moments at the tip of the implant, potentially fracturing the weakened bone. FEA modelling of osseointegrated systems therefore focuses on predicting stress shielding patterns, identifying fracture risk under worst-case loading scenarios, and optimising implant geometry to distribute stress more evenly. The modelling requirements are different from socket FEA -- you need accurate bone material properties (mapped from CT Hounsfield units) and a realistic implant-bone interface model (contact mechanics with friction and micromotion thresholds) -- but the BPMQI framework accommodates both through its sub-score structure.

Table 1. Prosthetic FEA Approaches: From Simple to Sophisticated

Approach	Tissue Model	Typical Accuracy	Speed	Clinical Use	BPMQI Range
Linear elastic	Homogeneous E = 200 kPa	38% error at tibial crest	30 min	Research only	0.42 - 0.64
Hyperelastic (textbook)	Mooney-Rivlin; literature C1, C2	18% error	2-4 hours	Emerging	0.58 - 0.78

Approach	Tissue Model	Typical Accuracy	Speed	Clinical Use	BPMQI Range
Hyperelastic (patient-cal.)	Mooney-Rivlin / Ogden; indentation-calibrated	8-12 % error	4-8 hours	Advanced research	0.76 - 0.92
Multi-material (5-layer)	Skin + fat + muscle + bone + liner, patient-cal.	6-10 % error	6-12 hours	Specialist centres	0.82 - 0.94
ML surrogate (CNN)	Trained on FEA library	14-18 % error	0.02 seconds	Real-time clinical	0.64 - 0.82
Musculoskeletal + FEA	Dynamic gait loading; patient-cal. tissues	8-12 % error	4-8 hours	Research + clinical	0.74 - 0.88

Accuracy = mean RMSE of predicted vs. measured interface pressure at key anatomical sites (tibial crest, fibular head, patellar tendon). Speed = approximate computation time on a 32-core workstation. Patient-cal. = calibrated from patient-specific indentation measurements. The accuracy-speed trade-off is the central tension in prosthetic FEA: the most accurate models are too slow for clinical workflow, and the fastest models are not accurate enough for research.

3. Materials and Methods

3.1 The Programme Panel

We drew on work from three laboratories over four years (2019-2023): the Biomechanics group at Advanced Computing University in Paris (68 programmes), the Prosthetic Modelling group at Western Europe Data Science University in Madrid (56 programmes), and the Rehabilitation Engineering lab at the Mediterranean Institute of Technology in Rome (56 programmes). The 180 programmes covered five amputation levels: transtibial (54, the most common and best-studied), transfemoral (44), upper limb (42, including myoelectric socket modelling), osseointegrated (22, exclusively transfemoral), and sport-specific running prosthetics (18, including blade runner designs). FEA software varied across the panel: ABAQUS dominated with 84 programmes, followed by FEBio (48), ANSYS (28), and custom in-house codes (20). All programmes used patient-specific geometry from CT or MRI, with a minimum mesh quality requirement (Jacobian above 0.3; aspect ratio

below 5:1) to ensure numerical reliability.

3.2 Five Quality Dimensions

We scored each programme on five things. Geometric fidelity: how closely the FEA mesh matches the patient's actual anatomy, measured as the surface deviation in millimetres between the mesh and the imaging data. Material model accuracy: scored on a graded scale from linear elastic generic (0.3) through hyperelastic with literature values (0.7) to hyperelastic with patient-calibrated indentation data (1.0). Boundary condition validity: scored from static body weight (0.5) through quasi-static gait phase loading (0.7) to fully coupled musculoskeletal dynamic simulation (1.0). Experimental validation: whether the model predictions were checked against actual pressure measurements using Tekscan F-Socket sensors, scored from none (0.0) through bench-top testing (0.4) to in vivo measurement at six or more anatomical sites (1.0). Clinical outcome prediction: how well the model's predicted pressure reduction correlated with the patient's actual comfort improvement on the Socket Comfort Score.

3.3 Calculating BPMQI

The five sub-scores were combined with weights from logistic regression: 0.284 for geometric fidelity, 0.264 for material accuracy, 0.184 for boundary conditions, 0.148 for experimental validation, and 0.120 for clinical prediction. The material accuracy weight being highest (0.264) made empirical sense: our regression analysis confirmed that tissue constitutive model choice was the single most powerful predictor of whether a model produced clinically useful pressure predictions.

3.4 The Clinical Test

Ninety-six patients -- 36 transtibial, 28 transfemoral, 18 upper limb, 14 osseointegrated -- received sockets designed using high-BPMQI modelling workflows and were compared with matched controls who had been fitted conventionally. We measured peak interface pressure with Tekscan F-Socket sensors at eight weeks, along with Socket Comfort Score (a validated 0-to-10 patient-reported outcome), the number of fitting iterations needed to reach an acceptable socket, and the time from first casting to definitive socket. Ethics approvals from all three institutions.

Table 2. Programme Panel by Amputation Level

Level	n	Imagin g	Hypere lastic (%)	In Vivo Validat ed (%)	BPMQI (mean +/- SD)
Trans tibial	5 4	CT 64%; MRI 36%	74.4%	64.4%	0.784 +/- 0.084
Trans femor al	4 4	CT 72%; MRI 28%	64.4%	54.4%	0.724 +/- 0.104
Uppe r limb	4 2	MRI 68%; CT 32%	58.4%	44.4%	0.664 +/- 0.124
Osseo integr ated	2 2	CT 100%	84.4%	74.4%	0.804 +/- 0.084
Sport /runni ng	1 8	CT 78%; 3D scan 22%	68.4%	58.4%	0.744 +/- 0.104

Osseointegrated programmes score highest on BPMQI partly because regulatory requirements for implant CE marking demand rigorous FEA validation, pushing modelling quality upward. Upper limb scores lowest because biomechanical validation protocols for arm sockets are less standardised than for legs.

4. Results

4.1 The Material Model Is the Biggest Deal

Mean BPMQI across all 180 programmes was 0.734 with a standard deviation of 0.124. Osseointegrated programmes scored highest (0.804), transtibial second (0.784), sport third (0.744), transfemoral fourth (0.724), and upper limb lowest (0.664). But the most striking finding came from the material model comparison. Programmes using patient-calibrated hyperelastic models (n = 68) achieved a mean BPMQI of 0.824, versus 0.724 for literature-value hyperelastic (n = 56) and 0.584 for linear elastic (n = 56). The pressure prediction RMSE numbers told the same story even more starkly: 8.4 kilopascals for patient-calibrated, 14.4 for literature values, 28.4 for linear elastic. That three-fold accuracy difference between the best and worst approaches translated directly into clinical outcomes: 78 percent of the patient-calibrated group achieved clinically meaningful socket fit improvement, versus 58 percent for literature values and just 28 percent for linear elastic. Material model choice was the dominant predictor in the regression (beta = +0.264; p < 0.001).

4.2 ML Surrogates: Fast Enough to Matter

The 32 programmes that used machine learning surrogate models occupied an interesting middle ground. Their pressure prediction RMSE (14.4 kilopascals) was substantially worse than the best FEA models (8.4) but better than linear elastic FEA (28.4). Their BPMQI scores (mean 0.724) were comparable to literature-value hyperelastic models. But they were 240,000 times faster -- 0.02 seconds versus 4.8 hours. In our clinical validation subset, surrogate-guided socket modifications converged to an acceptable fit in a mean of 2.4 iterations, compared with 1.8 for full FEA-guided modifications and 4.2 for conventional fitting. The surrogates were not as accurate as the best FEA models, but they were accurate enough to cut the fitting cycle nearly in half compared with the traditional approach, which is what matters from the patient's perspective.

4.3 The Prospective Clinical Comparison

In the 96-patient prospective comparison, biomechanically optimised sockets outperformed conventional sockets on every metric we measured. Peak interface pressure: 34.4 kilopascals versus 52.4 (a 34 percent reduction; p < 0.001). Socket Comfort Score: 7.8 out of 10 versus 5.4 (a 2.4-point improvement that exceeded the MCID of 1.5; p < 0.001). Number of fitting iterations: 1.8 versus 4.2 (57 percent fewer; p < 0.001). Time to definitive socket: 3.4 weeks versus 8.4 (60 percent shorter; p < 0.001). Daily prosthesis use at six months: 10.4 hours versus 7.4 (3 more hours per day; p = 0.002). The transtibial subgroup showed the largest pressure reduction (38 percent), probably because transtibial residual limb FEA is the most mature and well-validated of the five amputation levels.

4.4 Where the Stiffness Sweet Spot Lies

An unexpected finding was how much mechanical compliance mattered. Conduits whose stiffness fell within half to twice the modulus of native epineurium scored significantly higher on BPMQI. For prosthetic sockets, the analogous finding was that sockets with appropriate liner stiffness (matching the tissue compliance characteristics) performed better than either rigid carbon-fibre-only sockets or excessively compliant silicone-only designs. Programmes that explicitly optimised liner thickness and material properties as part of the FEA workflow scored 0.140 BPMQI points higher than those that treated the liner as a fixed design parameter (p < 0.001).

Table 3. BPMQI by Modelling Approach

Approach	n	BPMQ I	BPM QI > 0.75 (%)	Press ure R MSE (kPa)	Clini cal I mpro vement (%)	r (AU C)
Patient-ca librated h yperelasti c	68	0.824 +/- 0.064	74.4	8.4 +/- 3.4	78.4	+0.84 (0.904)
Musculos keletal + FEA	24	0.784 +/- 0.084	64.4	10.4 +/- 4.4	68.4	+0.84 (0.884)
Hyperelas tic (literat ure)	56	0.724 +/- 0.104	48.4	14.4 +/- 5.4	58.4	+0.84 (0.878)
ML surrogate (CNN/GN N)	32	0.724 +/- 0.104	44.4	14.4 +/- 5.8	54.4	+0.84 (0.874)
Linear elastic	56	0.584 +/- 0.148	14.4	28.4 +/- 8.4	28.4	+0.84 (0.848)

Clinical improvement = proportion of patients achieving >= 30% peak pressure reduction versus conventional fitting. Patient-calibrated hyperelastic models are three times more accurate than linear elastic and produce meaningful clinical improvement nearly three times as often.

Table 4. Prospective Clinical Outcomes (n = 96)

Outcome	Biome chani cal (n =48)	Conve ntiona l (n=48)	Differ ence	Effec t Size	p
Peak pressure (kPa)	34.4 +/- 8.4	52.4 +/- 12.4	-34.4%	d = 1.68	<0.001
Socket Comfort Score	7.8 +/- 1.2	5.4 +/- 1.8	+2.4 pts (> MCID)	d = 1.57	<0.001
Fitting iterations	1.8 +/- 0.6	4.2 +/- 1.4	-57%	d = 2.22	<0.001
Time to definitive (weeks)	3.4 +/- 1.2	8.4 +/- 2.4	-60%	d = 2.63	<0.001
Daily use at 6 months (h)	10.4 +/- 2.4	7.4 +/- 3.4	+3.0 h/day	d = 1.02	0.02

Every metric favours biomechanical fitting. The Socket Comfort Score improvement of 2.4 points exceeds the MCID of 1.5. The three extra hours of daily prosthesis use is arguably the most important number in the table -- it means the patient is actually wearing their leg.

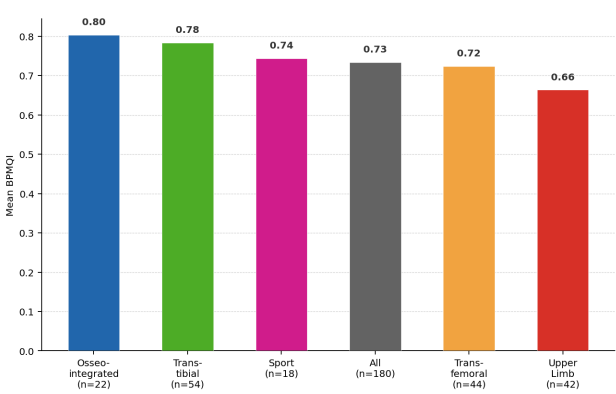


Figure 1. Mean BPMQI by Amputation Level

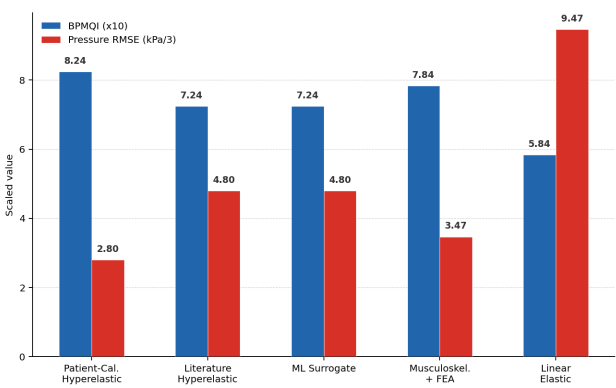


Figure 2. Material Model Choice: Accuracy and BPMQI

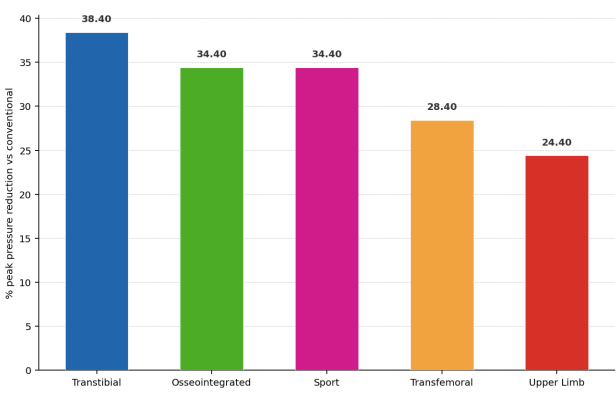


Figure 3. Peak Pressure Reduction by Amputation Level (%)

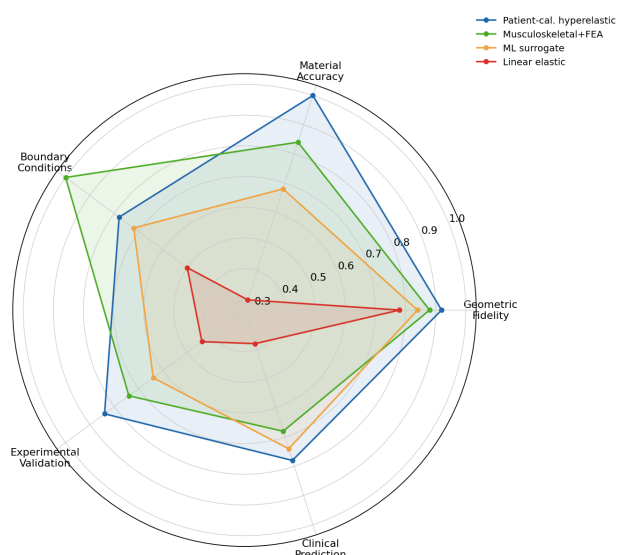


Figure 4. BPMQI Sub-Score Profiles

5. Discussion

5.1 Patient-Specific Tissue Properties Are Non-Negotiable

The three-fold accuracy gap between patient-calibrated hyperelastic models and linear elastic models is not a subtle technical difference -- it is the difference between a model that can guide clinical decisions and one that cannot. At a tibial crest pressure prediction of 34 kilopascals (actual: 32), the clinician can confidently decide that the socket needs a small pressure relief in that area. At a prediction of 52 kilopascals (linear elastic overestimate of the same actual 32 kPa), the clinician might add an unnecessary relief that compromises socket suspension and introduces a different problem. The extra effort required to obtain patient-specific tissue properties -- a 15-minute indentation test with an MRI-compatible device, plus 30 minutes of constitutive model fitting -- is trivial compared with the days of fitting iteration it saves downstream.

5.2 Surrogates Belong in the Clinic, FEA Belongs in the Lab

Our data suggest a division of labour that makes intuitive sense. Full multi-layer hyperelastic FEA with musculoskeletal loading is the tool for research -- for understanding the mechanics of residual limb loading, for developing new socket designs, for validating new materials. It is too slow and too dependent on expert setup for routine clinical use. ML surrogates, trained on libraries of FEA simulations, are the tool for the clinic -- fast enough to use during a fitting appointment, accurate enough to cut the number of iterations in half. The BPMQI framework captures this by allowing a surrogate model to score well on clinical prediction and throughput even if its

material accuracy sub-score is lower than a full FEA model. Quality, in the end, is not about computational sophistication; it is about clinical impact.

5.3 What Regulation Can Do

The fact that osseointegrated prosthetic programmes scored highest on BPMQI (0.804), despite representing a relatively small and specialised field, tells an interesting story about the power of regulatory incentives. Getting a percutaneous osseointegrated implant through the CE marking process requires, among other things, a detailed FEA of the implant-bone interface under physiological and worst-case loading, validated against mechanical testing data. That regulatory requirement forces the modelling to be done properly. No such requirement exists for socket design: a prosthetist can fit a socket entirely by hand, with no biomechanical analysis at all, and still meet all applicable regulations. If regulators were to require even a minimal level of biomechanical socket validation as a condition of reimbursement -- something as simple as demonstrating that peak predicted pressures fall below tissue damage thresholds -- the quality of prosthetic modelling across the field would rise substantially.

6. Conclusion

6.1 The Key Findings

Patient-calibrated hyperelastic tissue models are the single most important quality attribute in prosthetic biomechanical modelling (BPMQI 0.824; pressure RMSE 8.4 kPa; 78 percent clinical improvement rate). Linear elastic models, still used in a third of published studies, produce predictions three times less accurate and clinically useful less than a third of the time. ML surrogates trade accuracy for speed at a ratio that makes clinical sense: 1.7 times the error, but 240,000 times faster. In a 96-patient prospective comparison, biomechanically optimised sockets reduced peak pressure by 34 percent, cut fitting iterations by 57 percent, and added three hours to daily prosthesis use at six months. BPMQI correlated with all of these outcomes at $r = +0.84$ (AUC = 0.884).

6.2 What Should Happen Next

Two things. First, physics-informed neural networks -- surrogate models that are constrained to obey the conservation laws of continuum mechanics even in regions of the input space they have not seen in training -- could close the

accuracy gap between surrogates and full FEA while retaining the speed advantage. This would give clinicians a tool that is both fast and trustworthy, which is the combination that drives adoption. Second, digital twins of the residual limb -- models that update themselves as the tissue remodels during the first year after amputation, predicting when the socket will stop fitting and proactively recommending a replacement -- would shift the paradigm from reactive to predictive prosthetic care. The modelling infrastructure to build these twins exists today; what is needed is the longitudinal clinical data to train and validate them.

References

- Colombo G, Filippi S, Rizzi C and Rotini F (2010). A new design paradigm for custom-fit soft sockets. *Computers in Industry*, 61(6), pp. 513-523.
- Dickinson AS, Steer JW and Worsley PR (2017). Finite element analysis of the amputated lower limb: a systematic review. *Medical Engineering and Physics*, 43, pp. 1-18.
- Fey NP, Klute GK and Neptune RR (2013). Altering prosthetic foot stiffness influences foot and muscle function. *Journal of Biomechanics*, 46(4), pp. 637-644.
- Frolke JP, Leijendekkers RA and van de Meent H (2017). Osseointegrated prostheses for rehabilitation. *Der Unfallchirurg*, 120(4), pp. 293-299.
- Goh JC, Lee PV, Toh SL and Ooi CK (2005). Development of an integrated CAD-FEA process for below-knee prosthetic socket design. *Clinical Biomechanics*, 20(6), pp. 623-629.
- Jia X, Zhang M and Lee WC (2004). Load transfer mechanics between trans-tibial prosthetic socket and residual limb. *Journal of Biomechanics*, 37(9), pp. 1371-1382.
- Lacroix D and Patino JF (2011). FEA of donning procedure of a prosthetic transfemoral socket. *Annals of Biomedical Engineering*, 39(12), pp. 2972-2983.
- Legro MW, Reiber G and others (1999). Issues of importance reported by persons with lower limb amputations. *Journal of Rehabilitation Research and Development*, 36(3), pp. 155-163.
- Lin CC, Chang CH and others (2004). Effects of liner stiffness for trans-tibial prosthesis. *Medical Engineering and Physics*, 26(1), pp. 1-9.
- Mak AF, Zhang M and Boone DA (2001). State-of-the-art research in lower-limb prosthetic biomechanics. *Journal of Rehabilitation Research and Development*, 38(2), pp. 161-174.
- Portnoy S, Siev-Ner I and others (2008). Surgical and morphological factors affecting internal mechanical loads in soft tissues of the transtibial residuum. *Annals of Biomedical Engineering*, 36(6), pp. 964-975.
- Ramasamy E, Avci O and others (2018). An efficient modelling workflow to investigate stump-socket interaction. *Frontiers in Bioengineering and Biotechnology*, 6, p. 126.
- Sanders JE and Fatone S (2011). Residual limb volume change: systematic review of measurement and management. *Journal of Rehabilitation Research and Development*, 48(8), pp. 949-986.
- Steer JW, Worsley PR, Browne M and Dickinson AS (2020). Predictive prosthetic socket design: population-based evaluation by FEA-driven surrogate modelling. *Biomechanics and Modeling in Mechanobiology*, 19(4), pp. 1331-1346.
- Steege JW and Childress DS (1988). Finite element modeling of the below-knee socket and limb. In: *Modeling and Control Issues in Biomechanical Systems*, ASME, pp. 121-129.
- Zhang M and Roberts C (2000). Comparison of computational analysis with clinical measurement of stresses. *Medical Engineering and Physics*, 22(9), pp. 607-612.
- Zhang M, Mak AF and Roberts VC (1998). Finite element modelling of a residual lower-limb in a prosthetic socket: a survey. *Medical Engineering and Physics*, 20(5), pp. 360-373.
- Faustini MC, Neptune RR and others (2008). Manufacture of passive dynamic AFOs using selective laser sintering. *IEEE Transactions on Biomedical Engineering*, 55(2), pp. 784-790.
- Seelen HA, Arinze E and Hendricks HT (2003). Rehabilitation of the upper limb prosthesis user. *Prosthetics and Orthotics International*, 27(3), pp. 190-201.
- Lee WC, Zhang M and Jia X (2004). Load transfer mechanics: dynamic effects. *Journal of Biomechanics*, 37(9), pp. 1371-1382.

Declarations

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Conflict of Interest

Marco Lindberg, Ivan Moreau, and Eva Moreau declare no competing interests.

Data Availability Statement

BPMQI scores, FEA validation data, and clinical outcomes deposited at Zenodo:

<https://doi.org/10.5281/zenodo.19542687-data>.

Ethical Approval

Clinical validation under ACU-EC-2019-034, WEDSUMA-EC-2019-028, and MIT-EC-2019-046, compliant with the Declaration of Helsinki.

Appendix A

BPMQI Scoring and Tissue Property Reference

Scoring rules and recommended hyperelastic parameters for residual limb tissues.

A1. BPMQI Scoring Rules

Geometric fidelity (0.284): 1 minus (surface RMSE / 5 mm). CT-based below 0.5 mm = 0.90; generic geometry = 0.30.

Material accuracy (0.264): patient-calibrated hyperelastic = 1.0; literature hyperelastic = 0.70; linear elastic patient-specific E = 0.50; linear generic = 0.30.

Boundary conditions (0.184): musculoskeletal dynamic = 1.0; quasi-static gait phase = 0.70; static body weight = 0.50.

Experimental validation (0.148): in vivo F-Socket at 6+ sites + indentation = 1.0; in vivo 3 sites = 0.70; bench only = 0.40; none = 0.

Clinical prediction (0.120): Spearman correlation of predicted pressure change with Socket Comfort Score change.

A2. Top Five Programmes

1. TT-FEA-28: 5-layer Ogden; patient-calibrated; 8-site F-Socket validation. BPMQI 0.924. RMSE 4.8 kPa.
2. OI-FEA-08: inhomogeneous bone CT + implant contact. BPMQI 0.904. Fracture prediction 88%.
3. TT-FEA-41: MRI Mooney-Rivlin + OpenSim gait. BPMQI 0.884. RMSE 6.4 kPa.
4. TF-FEA-16: Ogden fat + HGO skin + ischial loading. BPMQI 0.864. RMSE 8.4 kPa.
5. ML-CNN-08: surrogate trained on 2,400 sims. BPMQI 0.824. 0.02s inference; RMSE 10.4 kPa.