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Title
A new 3-D biomechanical simulation approach for an evidence-based comfort assessment of prosthetic sockets

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Summary
The study presents an imaging based Finite-Element (FE) analysis to assess the comfort of prosthetic sockets in daily use. A detailed model of the residual limb, with individual muscles and tendons, has been developed to simulate socket-tissue interaction and estimate realistic tissue deformation.

Introduction/ basics
The conventional approach to prosthetic planning is highly influenced by traditional practices and the subjective experience of amputated subjects towards comfort. Despite having standard procedures to obtain best-fit socket profile and material, a prosthetist is faced with the ever-present challenge of finding the optimum trade-off between comfort and socket stability. This often leads to over-designing of prosthetic sockets in order to guarantee patient safety and stability at the expense of overall comfort and range of motion. FE Analysis has been an effective tool to analyse the structural behaviour of not only mechanical components such as a prosthetic assembly but also to predict the deformation in soft-tissues (Ramasamy et al [2018]). However, the quantification of mechanical comfort requires a detailed model of soft tissues within a residual limb, such as, skin, sub-cutaneous fat, individual muscles or tendon and an accurate representation of their physiology.

Material method; implementation/ process
We employ unsupervised, medical imaging workflows (Avants et al. 2009) to Medical Resonance Imaging (MRI) sequences, as in Figure 1, to generate highly detailed, subject-specific FE-Models of the residual limb. Anisotropy within muscles and tendons are modelled

using tissue fibre orientations obtained using Diffusion-MRI sequences and fibre tractography (Garyfallidis et al. 2014). The constitutive model for muscles and tendons was based on a 3D phenomenological, continuum-mechanical model by Röhrle et al. [2017], implemented as a user material subroutine in LS-Dyna. A linear, elastic model with stiffness characteristics of polypropylene was used as socket material in the analysis. Three load-cases, which correspond to everyday prosthetic usage (Figure 2), were defined: (i) a static, double limb support phase; (ii) a dynamic, transition from double to single limb support phase; (iii) a dynamic, single limb support phase, corresponding to mid-stance phase in gait.

Results

The FE-simulation results are used to evaluate the overall 3D stress distribution within the socket and soft tissues. A general indicator of mechanical discomfort is the presence of high stress localizations. Such zones are more prevalent in the distal end and towards ischial tuberosity where the soft tissue interacts with much stiffer bony regions. Similar observations were made using cell death and injury models, which are based on critical strain measures by Gefen et al [2008]. Additionally, introduction of dynamic effects to load transitions between double to single limb support phase exhibit higher tissue deformations, as seen in Figure 3. Moreover, the comparison of the both load-cases allows for the assessment of fatigue stress analysis of the tissue and socket during alternating loads, which could indicate further long-term discomfort during movement transitions. Lastly, gait dynamic loads have been incorporated in the analysis to estimate the resulting tissue deformation and predict overall mechanical comfort in gait, illustrated in Figure 3. Altogether, the three simulation cases represent a series of varying static and dynamic loading scenarios encountered by transfemoral amputees in their everyday activities.

Discussion/ conclusion; conclusion for the practice

A detailed biomechanical FE-model of the residual limb can provide deeper insights into patient comfort in everyday loading scenarios. Using simulation results as a reference, geometrical and material properties of the socket or liner could be optimized to alleviate highly stressed zones to prevent injury and enhance ease of prosthesis usage. In conjunction with socket failure analysis, prosthetists can find an optimum balance between socket comfort and stability to reduce the total weight of all involved components. This shall not only reduce material and production costs but encourage development of innovative light-weight socket designs to enhance the usability and overall experience of an amputee. The accuracy of the current biomechanical analysis can be further increased by including subject-specific soft tissue properties and introducing muscle activations in a forward dynamic simulations, which is a part of further research. Enhancements to the workflow, such as using ultrasound data instead of MRI-sequences, model generation based on non-linear image registration methods and physics-based approximations to muscle and tendon fibres are also being pursued.

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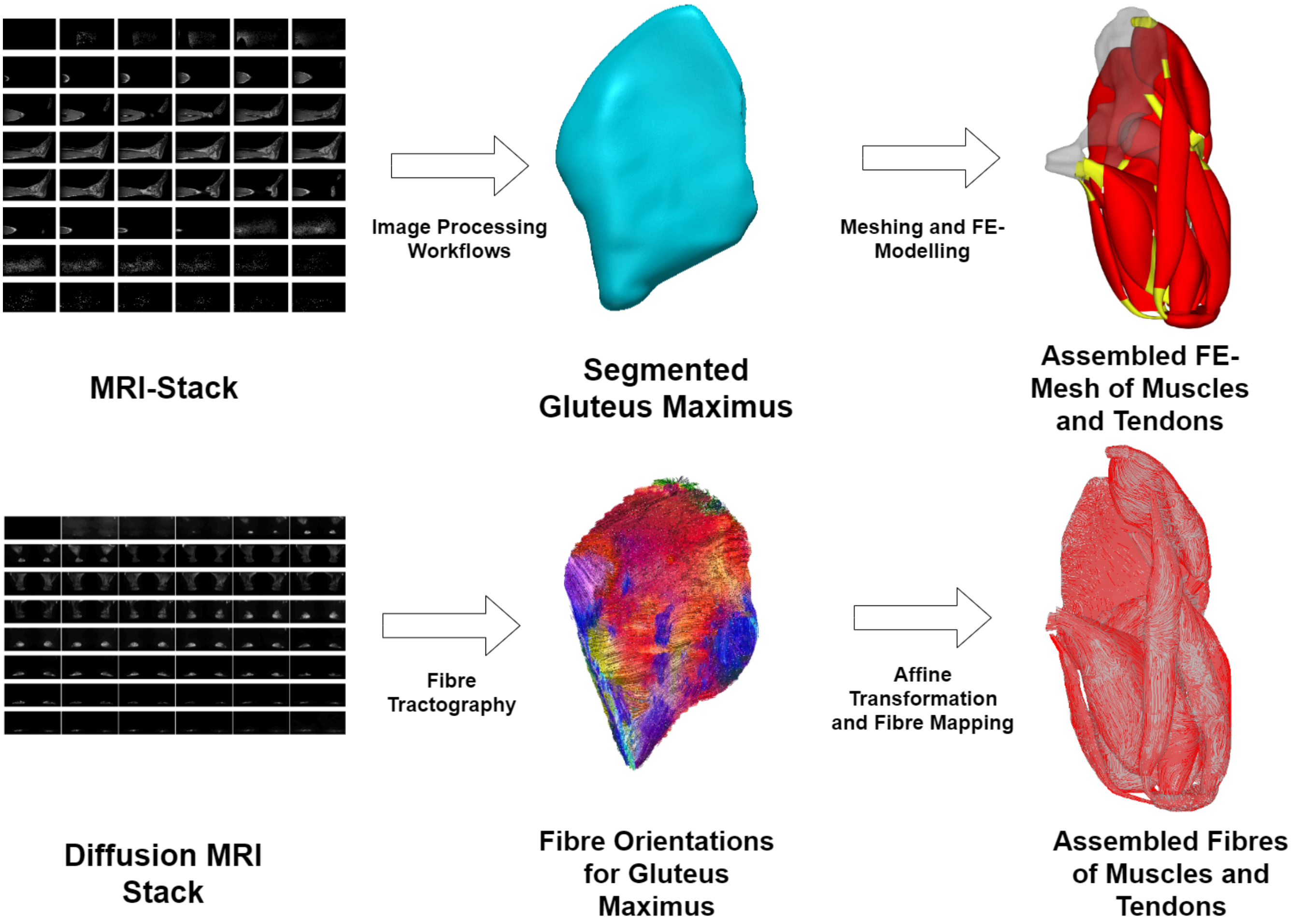

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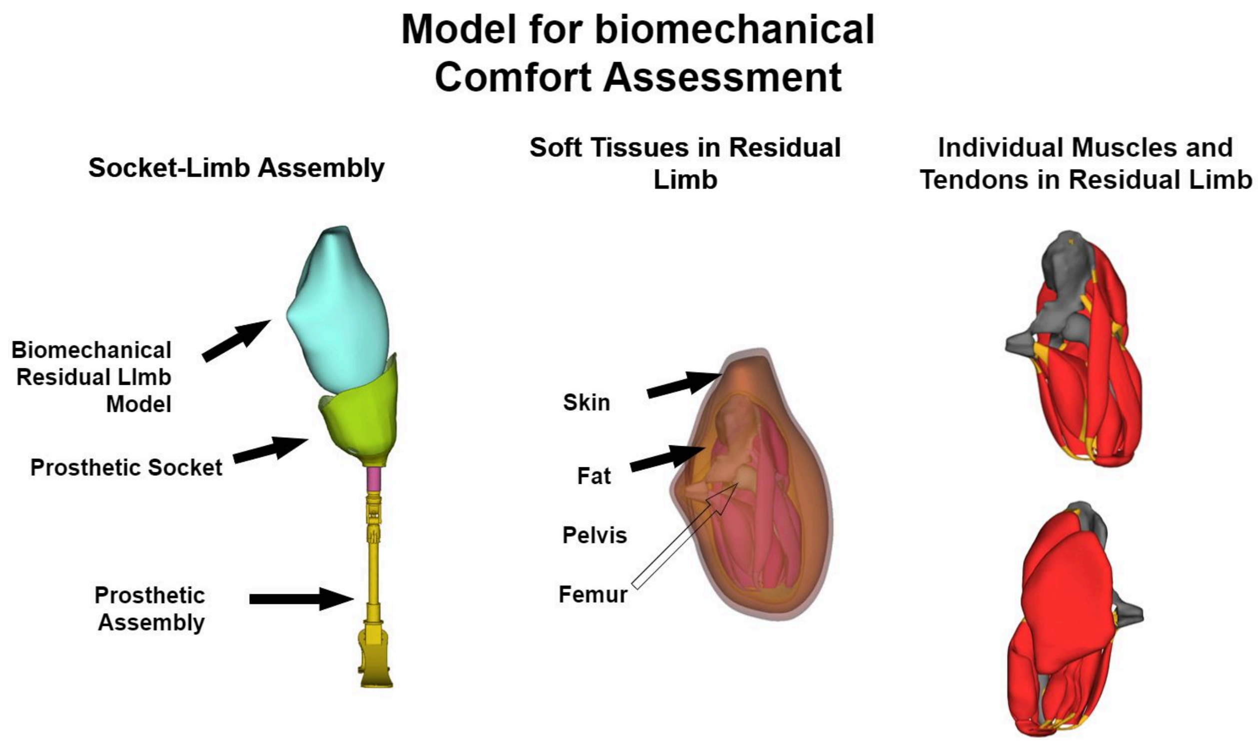

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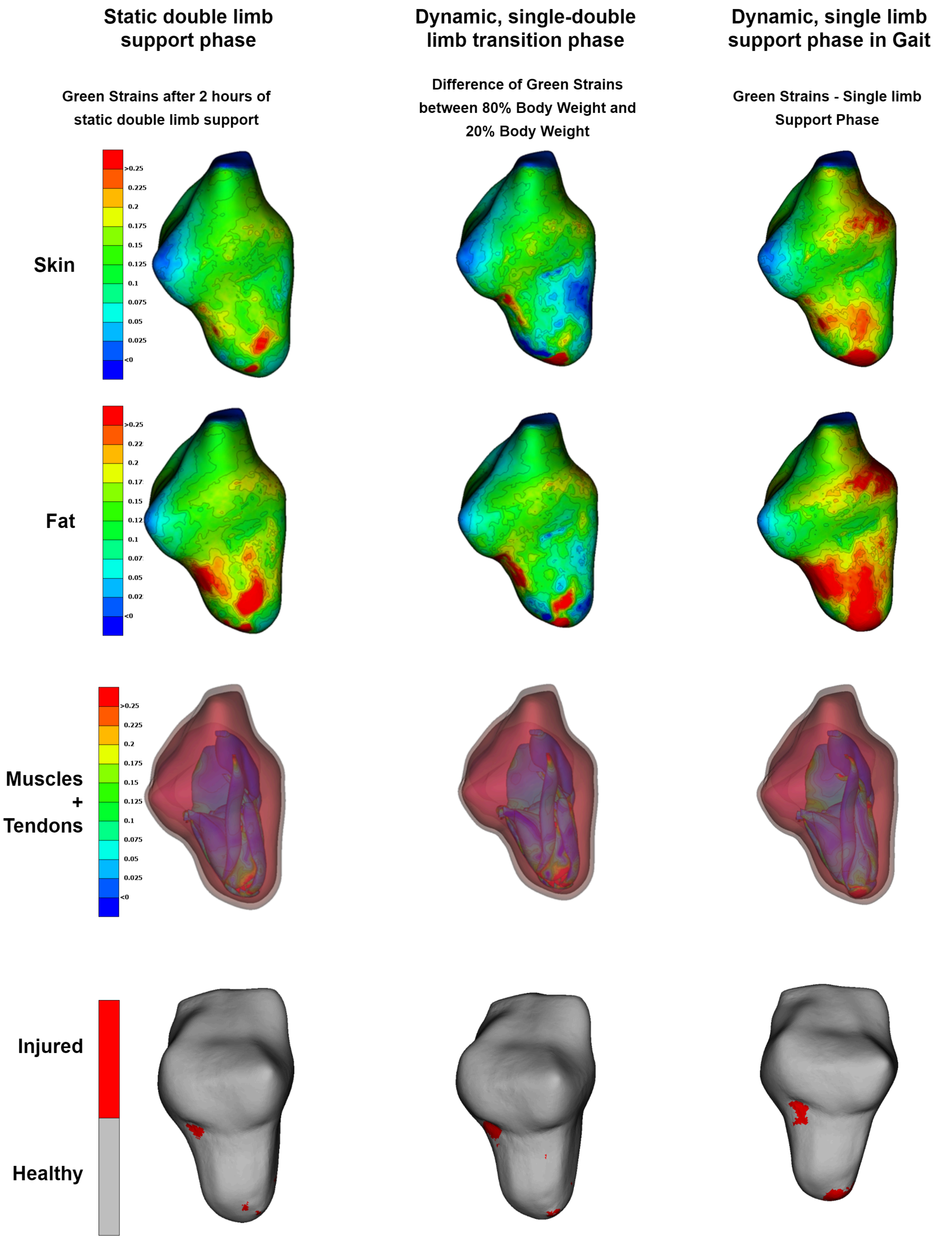

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