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A Computational Framework based on Medical Imaging and Random Sampling to Guide Optimal Residual Limb Designs for Individuals with Transfemoral Limb Loss

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Abstract— **The purpose of this study was to understand how the form (i.e., shape and presence of underlying soft tissue) of residual limb tissue influences limb function and comfort for individuals with transfemoral limb loss. Specifically, there exist surgical techniques that are frequently applied to the lower limbs of individuals to reduce an excessive soft tissue envelope. However, the clinical goals are frequently from a cosmetic perspective and are applied most commonly to individuals who are obese and not necessarily those with limb loss. For specific individuals with transfemoral limb loss, there likely exist limb shapes and distributions of underlying soft tissue that more optimally engage with lower-limb prostheses. Based on recent experimental findings, optimizing the limb and its physical connection to lower-limb prostheses, may have equivalent if not greater impact on user outcomes than selection of prosthetic components. This study develops and tests a method for informing optimal designs of the residual limb for individuals with transfemoral amputation. The framework uses patient-specific MRI images of an individual's residual limb, and within a mechanical modeling framework applies Latin hypercube sampling to investigate which portions of the underlying limb tissue most positively affect mechanical objectives associated with limb function and comfort. These theoretical results predicted from this system aimed to inform optimal limb designs were then compared to a currently used surgical method known as medial thighplasty, which was previously applied in one patient, to assess agreement. These simulations showed that the regions of the limb most contributing negatively to the objective function were located at the distal end of the limb and were far from muscle tissue (i.e., were mostly superficial). These findings suggest that limb techniques which seek to produce residual limbs that are most slim at their medial and distal end are beneficial and may lead to improved fit and function of lower-limb prostheses.**

Clinical Relevance—**Prosthetic technology advancement within the last decade has heightened the hopes of individuals with amputation. However, how these devices integrate to their human users is non-trivial and can curtail these advancements. Tools are needed to inform how residual limb itself can be optimized to better integrate with prostheses.**

I. INTRODUCTION

There is an increasing rate of the number of individuals with major lower-limb amputations in the United States and abroad. Every year over 185,000 Americans undergo limb amputations and the number of major amputations is expected to double from 2005 to 2050 [1]. With an increasing growth of major lower-limb amputations, there is an unmet need to improve how lower-limb prostheses are fit to the limbs of these individuals, especially when combined with the advances in prosthetic technology such as power prosthesis and neural interfaces [2][3]. However, the advances in prosthetic technology will mean nothing if patients choose to not wear a prosthetic due to discomfort and poor function of the prosthetic socket. While there are advances in socket technology most of the study in this area pertains to improving prosthetic socket technologies that better engage with the human wearer, such as new shapes, new materials, and new design methods. An alternative strategy is to examine how the human limb may be better suited for prosthetic use. A surgical intervention technique developed that attaches the prosthetic directly to the bone named osseointegration but even this does not solve the problem for all patients [4][5][6]. Recontouring the limb, is another surgical intervention and, recent research suggests that modifications to the limb through recontouring may have a greater influence on the locomotion of individuals with amputations than modifications of the prosthetic sockets alone [7][8]. However, a quantitative tool that helps guide surgeons to what may be the optimal residual limb design would be beneficial.

The purpose of this study was to develop a system that predicts the optimal distribution of soft tissue within the limb of individuals with transfemoral amputation to maximize both comfort and function of their limb during prosthesis use. As a form of validation, we compare how model predictions of the optimal limb design agree with modifications of residual limb shape that are made as a result of a current clinical procedure known as medial thighplasty. We hypothesized that there exist optimal limb designs for individuals with amputation that can maximize comfort and function. We also hypothesized that our model predictions would well agree with the clinical procedure.

II. METHODS

A subject with a transfemoral amputation (female, 75.6kg, 1.64 m, 49 yrs. Age and 35 yrs. post-amputation) underwent a medial thighplasty surgery removing approximately 2.8 kg of tissue from the residual limb. Magnetic resonance imaging

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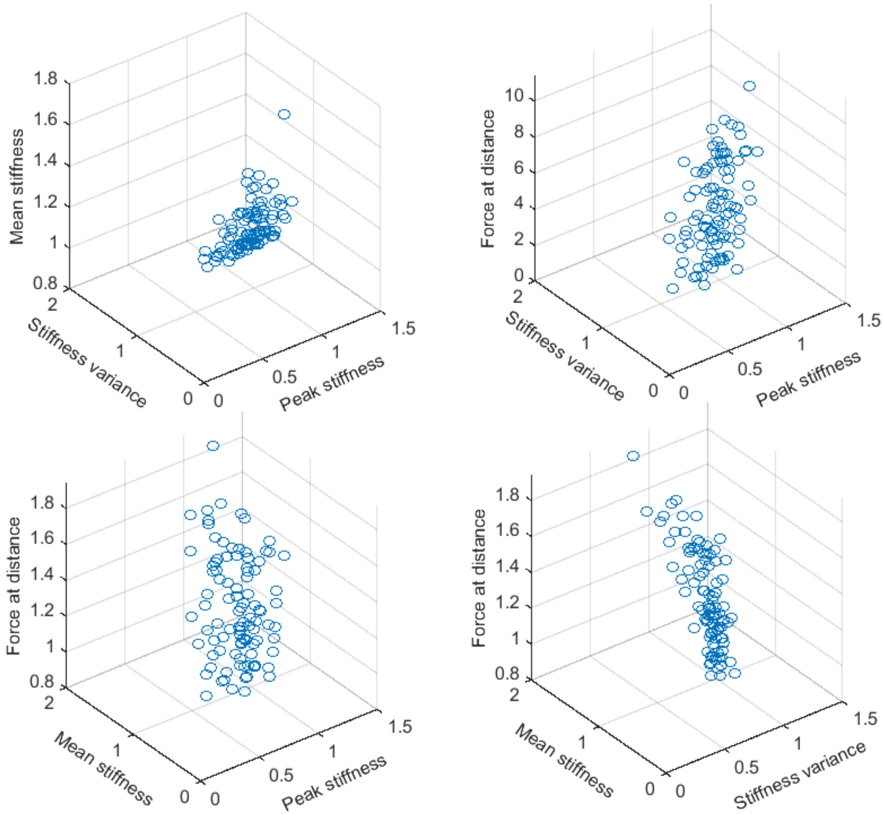

Figure 1: *Plots showing point clouds comparing individual objective function scores for all of the randomly sampled models. These data show there are significant spread and directionality across all individual objectives. For all individual objectives, reducing the normalized value would be optimal.*

(MRI) was performed on the patient pre- and post-surgery. Using those scans, three-dimensional (3D) leg models were generated using SolidWorks and then imported into Abaqus. Using Abaqus, a 3D model of a transfemoral residual limb was generated from MRI medical images taken from one subject. The model consisted of a femur, muscle tissue envelope and an adipose tissue and skin tissue envelop. Then using latin hypercube sampling, elements were removed, and we assessed how that removal influences multiple mechanical objectives pertaining to limb function and comfort including (detailed below). One hundred random samples were collected in which groups of different elements were removed. For each sample, simulations performed that applied a uniform pressure to the outside of the limb, representing weight-bearing and prosthesis donning, while the displacement of the elements on proximal surface of the limb were constrained.

In order to understand the influence, the removal of the individual elements had on the mechanical properties of the limb, we developed a set of mathematical formulas to provide a single objective value to gauge the performance of the limb. Performance objectives pertaining to limb function and comfort were developed. For each model and simulation, a total objective function was evaluated that included four objectives, average nodal stiffness, nodal stiffness variance and peak nodal stiffness (along the surface elements of the limb), as well as an aggregate proximal reaction force (of the constrained elements on the proximal surface of the limb) measure that was weighted by the distance of the reaction force relative to the femur. These individual objectives were normalized based on an initial simulation that was run using an unaltered limb model before any points are removed, so that they occupied the same relative portions of the total cost function. The "optimal" limb was evaluated as one that increased the average nodal stiffness and the proximal reaction forces closest to the residual femur (i.e., both to improve limb "function") as well as reduced nodal stiffness variance and reduced peak nodal stiffness (i.e., both to improve limb "comfort"). These individual objectives were viewed in isolation and combination (Fig. 1) to determine how much these objectives covaried across the randomly-sampled limb designs.

After calculating the total objective value function, a total histogram (Fig. 2) provided the scores for removal based on an "aggressive", "moderate", and "conservative" approach during surgery. Aggressive was defined as 90% of the points removed, moderate as 75% removed, and conservative as 50% removed (as sampled from the histogram in Fig. 2).

III. RESULTS

A heatmap was created to assess how individually-sampled regions of the limb contributed to the overall objective function, which attempted to maximize limb comfort and function (Fig. 3). These images highlight the distribution and depth of the sampled points relative to the muscle tissue envelope and show little overlap between sampled regions. The highest (i.e., least optimal) objective

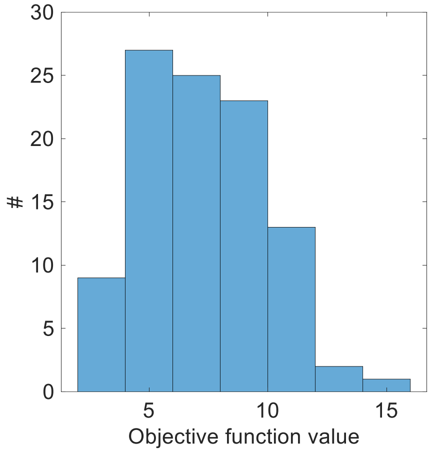

Figure 2: *Histogram of objective function values across all randomly sampled limbs. In our system, reducing the objective function was more optimal.*

function scores (shown in orange Fig.3) occurred mostly in regions of the limb that contained the largest volume of adipose tissue (i.e., the distal, medial and posterior regions). While most of the higher scores are located distally, there were also large scores that existed proximally. Most of these samples still occurred in the medial region of the limb. The lowest scoring value appears to be located close to the muscle tissue in the middle portion of the limb. The largest value is located away from the muscle and is a more proximal element that had been removed during the sampling. Most of the scores fall between four and ten (Fig. 2).

Using the histogram of the objective function values (Fig. 2) and the heat map of the models (Fig. 3) new limb visualizations were created (Fig. 4) to represent different surgical approaches. An “aggressive” approach was determined to be when the top 90% of the scored elements could be removed, a moderate approach was when the top 75% of the scored elements could be removed, and a conservative approach was when the top 50% of the scored elements could be removed. Examining these representations of the data, the areas that suggest removal with an “aggressive” surgery type could include areas located more proximal on the limb as well as the areas near the muscle tissue in addition to areas at mid-length of the limb and the distal end of the limb. When examining the conservative model, it is suggested that points at the bottom of the limb are removed and points along the surface of the limb away from muscle tissue. The aggressive model also suggests more points be removed from the medial side of the limb while the moderate and conservative do not show those points. Although the areas containing the most adipose tissue are shared throughout the models, there is still an increase in the number of points being suggested for removal in these areas based on a more aggressive approach.

IV. DISCUSSION

Determining an optimal limb based on random sampling

Based on the number of elements removed it shows that some areas could be examined more precisely and that perhaps more models are needed to get a clearer picture of the entire limb. Examining elements based on depth gives an interesting take away message that elements located away from the muscle are likely to score higher and thusly give more issues for the patient than elements close to the muscle, suggesting that an overall slimming of the limb would be optimal. When examining the entire model, higher scoring (i.e., “bad”) points are at the ends of the limb and not in the middle. This means that tissue at the end of the limb could be causing more issues than in the middle of the limb.

Incorporating surgical preferences and agreement between model and clinical procedure

Considering the most conservative data it appears that most points occur away from the muscle tissue, implying an overall slimming of the limb will improve scores and help the patient. There were also many points near the bottom of the limb, which had a large portion of excess adipose tissue. This shows that elements removed from that area would also improve scores, the main take away from the conservative model is that

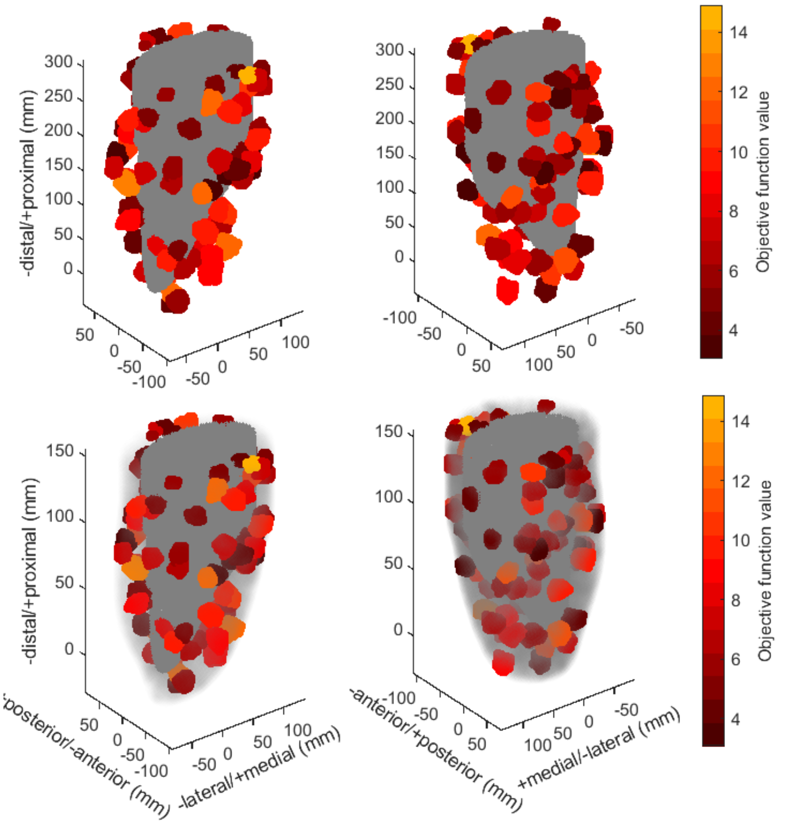

Figure 3: *Models showing total objective scores and randomly removed points with (bottom row) and without (top row) the existing soft tissue envelope in the anterior (left column) and posterior (right column) views.*

excess adipose tissue removal will improve scoring. The aggressive and moderate models show more points near the muscle tissue and more points in the middle of the limb. This shows that the removal of those points can improve scores but that other factors need to be considered before removal, as would be expected from an aggressive approach. Finally, (although not shown) our model predictions of the optimal locations to remove limb soft tissue well agree (~80% agreement) with those removed in this patient by a clinical limb recontouring procedure.

Limitations and future considerations

These data suggest that a more dense sampling of the limb tissue would be beneficial to give further insight into the influence of the entire limb tissue. Selecting viable regions for limb sampling based on clinical experience would also be beneficial and possible using this approach. Adding more complexity to the models such as a knowledge of vascularity would lead to a more useful system and be incorporated with additional terms in the objective function or constraining the sampling space.

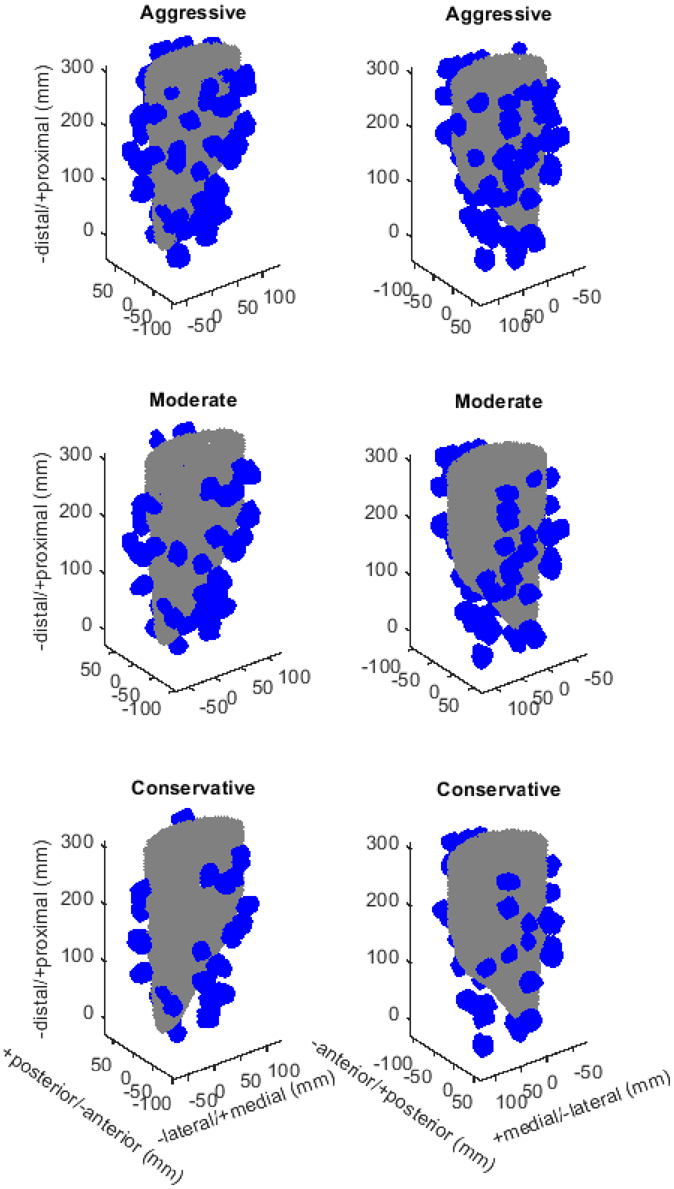

Figure 4: *Models showing nodes that could be removed based on aggressive, moderate, or conservative surgical preference in anterior (left) and posterior (right) views.*

V. CONCLUSION

The results of our study suggests that reducing soft tissue through surgical recontouring can positively influence the fit and function of a residual limb, and that this process can be quantitively informed through mechanical modeling and random sampling techniques. Such strategies may allow patients to take advantage of conventional and new prosthetic technologies.

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