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Computational Design, Fabrication, and Evaluation of Optimized Patient-Specific Transtibial Prosthetic Sockets

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STUDY PROTOCOL

I. BACKGROUND AND RATIONALE

The overall goal of this study is to further develop, and clinically assess, a computational and data-driven design and manufacturing framework for mechanical interfaces that quantitatively produces transtibial prosthetic sockets in a faster and more cost-effective way compared with conventional processes.

In the United States, 623,000 people live with major lower extremity loss, with that population expected to double by 2050 [1]. The U.S. Department of Veterans Affairs estimates lower extremity amputation (LEA) to account for more than $250 million in direct expenditures each year, not including civilian cases [2]. Complications of prosthetic leg use in persons with LEA often occur at the prosthetic socket, and includes delayed wound healing, recurrent skin ulcerations, and pressure damage to soft tissues [3]–[6]. Such complications can result in limited mobility, which further contributes to conditions such as obesity, musculoskeletal pathologies, and cardiovascular disease [7]–[9]. Conventional prosthetic socket fabrication is an artisanal process requiring substantial human hours, financial cost and patient involvement for evaluation. Computer aided design (CAD) (e.g.[10]–[13]) and computer aided manufacturing (CAM) (e.g.[14]–[24]) methods have been explored as an alternative. However, these tools have not reached full clinical efficacy and do not inform the design in a data-driven sense since the actual design process remains a manual and experience-based procedure [25]. The long-term goal of our research is to develop a fully-quantitative process for prosthetic socket design and production that requires minimal patient involvement and can be delivered at affordable price points.

In pursuit of our long-term goal, our team has recently developed a framework for prosthetic socket design and fabrication [26] that involves: 1) non-invasive imaging to record patient geometry, 2) indentation to assess tissue mechanical properties, 3) data-driven and automated creation of patient-specific designs, 4) patient-specific finite element analysis (FEA) and design evaluation, and 5) 3D printing of the end design for clinical evaluation.

II. OBJECTIVES

The overall goal of this study is to further develop and clinically assess a computational and data-driven design and manufacturing framework for mechanical interfaces that quantitatively produces transtibial prosthetic sockets in a faster and more cost-effective way than conventional processes. Traditionally, prosthetic socket production has been a craft activity, based primarily on the experience of the prosthetist. Even with advances in computer-aided design and computer-aided manufacturing (CAD/CAM), the design process remains manual. The manual nature of the process means it is non-repeatable and currently largely non-data-driven, and quantitative data is either not obtained or insufficiently employed. Furthermore, discomfort, skin problems and pressure ulcer formation remain prevalent. Through the proposed computational modeling framework, a repeatable, data-driven and patient-specific design process is made available which is based on scientific rationale.

Objective/hypothesis: The main hypothesis of this proposal is that a socket, designed using the novel computational design framework, is equivalent to, or better than, a conventional socket (designed by a prosthetist) in terms of: 1) skin contact pressures, 2) gait symmetry, 3) walking metabolic cost, 4) skin irritation levels as assessed by the dermatologist, and 5) comfort as evaluated from a questionnaire. Our hypothesis is supported by the presented pilot data which shows reduced or equivalent skin contact pressures and subject reported comfort levels for several critical anatomical regions.

Specific Aims: 1) Subject-specific biomechanical modeling for N=18 subjects, 2) Computational design and fabrication of sockets for N=18 subjects, and 3) Clinical evaluation of novel sockets for N=18 subjects.

III. STUDY POPULATION

Sample Size

A total of 18 subjects will be recruited for this study. The worst ratio between the mean and standard deviation for pilot contact pressure measurements for static standing was observed for the mid posterior wall, which presented with a mean of 97 kPa, and standard deviation of 8.9 kPa. If two-tailed t-test based analysis is assumed, aiming to detect at least a 10% difference with respect to this mean, with a significance level of 0.05 and a power of 90%, the theoretically required number of test subjects is 12 (power analysis based on the MATLAB *sampsizepwr* function). However, to increase the chances of significant statistics for all measures (with varying signal to noise ratios), while also anticipating potential candidate drop-out, inclusion of N=18 subjects is proposed here.

Statistical analysis of the socket clinical evaluation data will focus on the following measurements: 1) local skin contact pressures, 2) metabolic power, 3) gait parameters (symmetry indices for joint angles, positions, torques, and also ground reaction forces), and 4) the socket evaluation questionnaire. For scalar comparisons a paired t-test, with the level of significance set at 0.05, will be used to test for differences between the novel and conventional sockets. For time-series analysis of variance (ANOVA) will be used.

Inclusion and exclusion criteria

18 healthy participants with below-knee amputations will be recruited. Participants will be generally healthy and will have no other musculoskeletal problems or any known cardiovascular, pulmonary or neurological disorders. This study will consider subjects of all sex/gender, race, and/or ethnic orientation, provided that they conform to the inclusion criteria summarized below. We focus on healthy subjects who are unilateral or bilateral transtibial amputees, who are between 18-64 years old, have an activity level of at least K3 (a person with the ability or potential for ambulation with variable cadence, and to traverse most environmental barriers and may have vocational, therapeutic or exercise activity that demands prosthetic use beyond simple locomotion.) and that their amputation took place more than 1 year prior to the start of the study. The latter is to exclude subjects whose limbs will undergo significant changes during the course of the study. Another inclusion criterion relates to the subject's prosthetic sockets. In this study a comparison is made between a subject's conventional sockets (designed by their experiences prosthetist) and our novel (computational modeling derived) sockets. Since we aim to match or improve upon comfortable prosthetic sockets, we will only include subjects whose current conventional sockets are deemed comfortable and of high quality. The quality of a subject's conventional sockets will be judged by the consultant and certified prosthetist involved in this study (Bob Emerson, A Step Ahead Prosthetics). One further inclusion criterion relates the subject's ability to undergo MRI. If subjects are unable to

undergo MRI (e.g. due to claustrophobia or the presence of objects their body that are not MRI Safe) they are excluded from this study.

The American lower limb amputee population consists of subjects with varying etiology, sex, age, and ethnicity. Since clinical evaluation for only N=18 subjects is proposed here it is not practical to attempt to closely match all aspects of variation in the patient population. The key biological feature, relevant to the scientific goals set out for this research, is the biomechanical behavior of soft tissue. The biomechanical behavior, e.g. soft tissue stiffness dictates the response of the tissue to loading and therefore has a direct impact on socket comfort. The biomechanical behavior of soft tissue is known to vary with age, activity level and gender, but little information is known on effects of ethnicity on soft tissue biomechanics or amputee outcomes. Since variation in ethnicity is not expected to effect the study outcomes, subjects from all ethnicities may be eligible. Age and gender are more relevant for soft tissue biomechanics. We will aim to have our subject population reflect the variation in the American amputee population in these respects.

Subject recruitment

Subject recruitment (N=18) will be done via flyers, word of mouth, and by directly contacting subjects who have already worked with existing studies, or who are currently being seen by the consultant certified prosthetist involved in this study. Furthermore, we will actively recruit veterans by advertising the study with the Boston chapter of the U.S. Department of Veteran Affairs. In order to participate in the study, eligible subjects will sign a consent form where pertinent information regarding the study will be provided to them.

IV. STUDY DESIGN

A cohort of 18 subjects will be recruited for this study. MRI data will be recorded for all subjects. Through image segmentation geometrically accurate 3D finite element analysis (FEA) models will be constructed. Further, non-invasive indentation testing will be performed which, through combination with inverse FEA, provides accurate subject-specific mechanical properties for all subjects. The resulting predictive FEA models will then be used in a novel, data-driven, and automated computational design framework for prosthetic sockets, to design prosthetic sockets for all subjects. The framework optimizes the socket designs, as assessed by skin contact pressures and internal tissue strain, through iterative adjustment of the virtual tests sockets. Final designs are subsequently 3D printed. To evaluate the prosthetic sockets with each of the subjects each subject will do a standing and walking exercise using their conventional sockets or the novel sockets. Meanwhile skin contact forces, walking metabolic cost, and gait symmetry are recorded. After the exercises, skin irritation will be assessed by a dermatologist, and socket comfort is assessed using a questionnaire. Together this data provides a quantitative and qualitative evaluation and comparison of the novel and conventional sockets.

V. Methods

The overall goal of this study is to further develop, and clinically assess, a computational and data-driven design and manufacturing framework for mechanical interfaces that quantitatively produces transtibial prosthetic sockets in a faster and more cost-effective way compared with conventional processes.

In pursuit of our long-term goal, our team has recently developed a framework for prosthetic socket design and fabrication that involves: 1) non-invasive imaging to record patient geometry, 2) indentation to assess tissue mechanical properties, 3) data-driven and automated creation of patient-specific designs, 4) patient-specific finite element analysis and design evaluation, and 5) 3D printing of the end design for clinical evaluation. This study aims to advance these approaches, and clinically assess the overall design process for N=18 transtibial amputees. Socket evaluations are conducted during standing and walking activities. For these evaluations, skin-socket interface pressures are recorded using sensors located at the skin-socket interface. During the walking evaluation, motion capture is used additionally to allow for gait analysis. Furthermore, metabolic cost is measured by indirect calorimetry using an open circuit respirometry system. These experiments are repeated for each patient's conventional socket for comparison. In addition to these quantitative evaluations, each study participant completes a socket evaluation questionnaire, and a certified dermatologist writes a report documenting skin conditions subsequent to each socket test.

The main hypothesis of this proposal is that the novel quantitative socket is equivalent to, or better than, a conventional socket in terms of: 1) skin contact pressures, 2) gait symmetry, 3) walking metabolic cost, 4) skin irritation levels as assessed by the dermatologist, and 5) comfort as evaluated from a questionnaire. Furthermore, we hypothesize that equivalence or improved socket performance can be achieved for all N=18 subjects using a single computational design framework, i.e. that we can formulate the computational design framework such that it can automatically design these sockets for all subjects without requiring algorithm adjustments from one subject to the next.

In order to address the hypothesis that the novel sockets can perform equivalently to, or better than, conventional sockets (designed by a qualified prosthetist) we propose an experimental evaluation using N=18 subjects. Static standing and walking exercises will be performed. During the standing and walking exercise skin contact pressures will be recorded. During walking skin contact pressure, metabolic cost, and motion capture data will be recorded. Finally, a custom socket evaluation questionnaire will be used to assess the level of socket comfort experienced by the subject.

This study consists of three phases:

1) Data collection

2) Socket design

3) Socket evaluation

Participant involvement is required for phase 1 and 3 which occur in two separate sessions.

Session 1 (phase 1): Data collection

In the first session, each amputee participant will be scheduled to visit the Biomechatronics Group in The MIT Media Laboratory and our imaging center (the MIT McGovern Institute). The main purpose of this session is to quantitatively measure the stiffness of the residual limb and map out the anatomy of the residual limb, for N=18 subjects, by using Magnetic Resonance Imaging (MRI), 3D scanner, ultrasound scanner, and a stiffness-measuring device on the amputee. Mechanical property investigation may also take place during imaging, e.g. during MRI by using MRI compatible indentor systems. Subjects are scanned using a 3T MRI system (Siemens Magnetom 3 Tesla, Siemens Medical Systems, Erlangen, Germany). The structural and geometrical data derived from MRI (e.g. using segmentation) provides the input for computational model development (used in the socket design process). Morphological data (such as height, weight, limb length and circumference) of the participant will also be recorded.

Session 2 (phase 3): Socket evaluation.

During a second session the sockets (designed based on the image and mechanical property data) are evaluated (at the MIT Media Lab's Biomechatronics department). In this session both the conventional and novel socket systems will be tested. For all subjects the order of testing (conventional or novel first) is randomized. Subjects are first asked to sit on a chair and expose their residual limb surface for force sensor placement. Recently we established a new inter-socket skin contact pressure assessment system based on flexible pressure and force sensors (A201, 111N, FlexiForce®, TekScan, Boston, MA, USA, and also F-Socket, TekScan, Boston, MA, USA). Data for an array of force sensors can be simultaneously recorded during static standing or dynamic walking exercises. Evaluating loads at select anatomical regions are of interest, these sites include: 1) the medial crest, 2) the fibular head, 3) the tibial crest, and 4) the Mid posterior wall. Sensors are secured to the skin using a thin adhesive tape (12.7 mm wide, 0.0625 mm thick, Scotch Magic®, 3M, USA) which can be removed with minimal discomfort. After sensor placement a liner is rolled over the skin and sensors. The conventional sockets are evaluated with the subject's own liner and suspension system. For evaluation with the novel socket, subjects are fitted with a custom liner (e.g. through Ottobock Healthcare Gmbh) or standard commercially available liners (such as the Silosheath Double cushion 3-mm liner, Silipos Holding LLC, Niagara Falls, N.Y, USA). A commercially available sleeve is used for suspension (such as BK Suspension sleeve, Silipos Holding LLC, Niagara Falls, N.Y, USA). Next the compliant socket and rigid outer socket are donned on. For the novel sockets the outer socket is first attached to the subject's conventional foot-ankle system, and alignment is optimized by a certified prosthetists (present during all socket fitting and evaluation procedures) consulted for this study (Bob Emerson, A Step Ahead Prosthetics). Once subjects have been fitted with the sockets the standing, followed by the walking exercise is conducted. For the walking exercise not only force but also metabolic cost and motion capture data are recorded. The metabolic analysis will provide an assessment of the energy expenditure while wearing either a conventional or the novel socket (discomfort may result in a less efficient or asymmetric gait causing increased energy use). For metabolic cost analysis, subjects are equipped with a breath-by-breath portable telemetric system (Model K4b^2, COSMED, Rome, Italy). Subjects are also equipped with 46 reflective markers (15 mm diameter) for motion capture (following the Helen Hayes marker model). For the standing evaluation subjects are asked to stand still in an upright position for 5 minutes while skin contact force (or pressure) data and resting state metabolic data is acquired.

For the walking evaluation subjects are asked to walk at 1.4 m/s for 10 minutes on an instrumented treadmill (Bertec, Columbus, OH) while ground reaction forces are recorded, as well as 3D marker locations and the metabolic data. The marker locations are recorded at a sampling rate of 100 Hz by a 12 infrared camera motion capture system (model: T40s, Vicon Motion Systems Ltd, Oxford, UK). The locations of these markers is chosen to track joint motion.

The treadmill system used for the walking exercise is equipped with parallel bars to prevent any injury to the subject if he were to lose balance and fall. A safely harness attached to the ceiling will also be utilized if the subject makes that request. In addition, a member of the laboratory staff will also accompany the study participant to catch him/her in the event of a fall, if necessary. The participant may ask to rest or to terminate their participation in the study at any time. The socket evaluation session (walking and standing evaluations) should take no more than 4 hours to complete.

The kinematic and force plate data can be combined with inverse dynamics analysis to compute joint angles and moment profiles. Furthermore, analysis between data for the left and right limb and for the conventional and novel socket allows for comparison of symmetry measures. Symmetry indices will be derived for: 1) ankle, knee, and hip joint angle, position, torque time profiles, and 2) the vertical ground reaction forces. The metabolic measurements for standing will be

subtracted from the metabolic rate of walking trials in order to obtain the net metabolic cost of walking.

After the standing and walking exercises subjects will be requested to take off the socket and liner to expose their residual limb skin surface. The consultant dermatologist (Dr. Tan) will then inspect the skin and report on skin irritation. The dermatologist will also talk to the subjects on comfort and instruct them to fill out the developed socket evaluation questionnaire. Questions will also relate to points where contact pressure measurements will be made, thus enabling direct comparison of local comfort assessment to pressure findings. Subjects fill out their answers by drawing a line at a desired level for each of the questions. This method allows for post-processing based conversion of the input to numerical data (i.e. 0-100 %) and lacks biases associated with constrained integer number input (e.g. favoring of even/odd numbers).

Data & Safety Monitoring Plan

All sensor (e.g. force/pressure) data is recorded using data acquisition units (e.g. Arduino Uno, Arduino LLC) connected to dedicated laptop computers. The motion capture data (VICON system) and treadmill data (speed and force plates) are recorded using a dedicated desktop computer. The metabolic cost analysis are recorded on a dedicated data acquisition unit (COSMED) and are subsequently uploaded to a laptop computer.

We will record video (in digital format) for each subject walking for analysis and development purposes. Videos in digital format will be archived in a password protected secure server located at the MIT Media Laboratory. Access to video material will be limited to authorized investigators associated with this study. Video will remain archived in the data server for future reference. Upon subject request, videos can be deleted from server once study is completed.

Benefits

There are no immediate benefits for participating in this study. The prosthetic sockets produced will be prototypes and would not be immediately available.

It is expected that knowledge generated in this study will benefit society. The processes developed for producing 3D printed sockets during this research will be used to understand how to most effectively attach (mechanical) devices to humans. This understanding will aid the development of advanced prostheses, orthoses and other augmentation/rehabilitation technologies.

Risks

Following the inclusion criteria (which include MRI safety) there should be no elevated risk associated with the MRI acquisitions. Other risks and discomforts are minimal as they are those incurred by standing still for 5 minutes, and walking on a treadmill for 10 minutes, both while using either a conventional socket and the 3D printed socket.

There will be a "spotter" standing next to the treadmill and close to the amputee while standing or walking in our facilities. We will give subjects periodic rest/water breaks. Any other necessary assistance to make the subjects comfortable will be provided. If during the standing or walking exercise the subject experiences discomfort such that he/she wishes to terminate the test he/she can decide to do so at any time. To minimize these uncomfortable situations, we will have a certified prosthetist and a dermatologist around during the fitting process during the socket evaluation.

The dermatologist (Dr. Tan) involved in the study will be present during socket evaluation and will judge skin irritation as a function of socket discomfort. Actual harm is unlikely but the researchers,

dermatologist, and prosthetist are present to judge any potential harm. Feedback from the subject can be obtained promptly by researchers present, prosthetist, and/or the dermatologist present. The MIT ethical board (COUHES) will be informed of any adverse circumstances. No follow-up will be made as the procedure poses minimal risk of injury.

Informed Consent

Informed consent will be obtained. The informed consent process will be conducted prior to the initial visit by qualified and approved study personnel. Retention is based upon the decision of each participant to continue with research enrollment. Participants may discontinue at any time without consequence.

VI. DATA ANALYSIS

Personal identifiers

All data and files particular to a subject will be anonymized (subjects will be assigned a code for naming files e.g. subject1_month_day_year) and stored on password protected computers to which only the members of the research group have access.

Data storage

The data will be stored on a password protected computer server in the MIT Biomechatronics Group, Media Laboratory, E-14 room 274. Access to this server is secured by a password. Only authorized investigators associated with the study will have access to data.

Treatment of data after study completion

The data will remain in the MIT Media Laboratory secure server for future processing. Upon subject request, digital videos can deleted from the data server once study is completed.

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