Emulation may enable efficient personalization of conventional prosthetic feet

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Summary

Decisions made during the prescription of prosthetic devices are typically based on intuition accumulated from years of trial-and-error across populations of patients. This data is undoubtedly useful in determining which devices are most effective for certain types of patients, but a greater degree of customization in prescriptions would likely be useful. Emulators may enable such customization. We have previously demonstrated such an emulator, but it is not yet clear how a clinician would use such a device to inform a customized prescription. We demonstrate and validate a very simple manual tuning approach. We find that such an approach can be an effective means for tuning a passive prosthetic foot to maximize individuals' satisfaction. This is encouraging evidence that suggests the practical utility of using an emulator to personalize prescription in a clinical setting.

Introduction

The prescription of prosthetic feet is confounded by uncertainty about which device will best suit the patient (Hofstad et al., 2004). Prescription is based primarily on clinical intuition with little opportunity for individualized exploration of different foot designs. A prosthesis emulator provides an opportunity for patients to trial different feet prior to purchase (Caputo et al, 2015), and could enable prescriptions to be more customized to individuals' needs. But it is unclear which methods clinicians should employ to most effectively explore candidate designs. Perhaps the simplest approach would be for the clinician to start with a reasonable guess, and then manually tune device parameters to maximize patient satisfaction. Once arriving at the best values for each parameter, the clinician could then select and fit an off-the-shelf device whose behavior matches the customized parameters or fabricate a custom device.

Methods

We experimentally tested a simple manual tuning procedure with two subjects with unilateral below-knee amputation. They walked at 1.25 m/s on a treadmill while wearing a prosthetic foot emulator (Caputo and Collins, 2014). The ankle torque vs. angle relationship of the emulator was controlled so as to allow the clinician to tune the stiffness of the keel, the orientation of the keel at initial toe contact, and stiffening/softening behavior of the keel. Subjects began the study with a forced exploration trial where they experienced a variety of parameter settings that spanned the entire search space.

The tuning of the different parameters was carried out by a certified prosthetist. The tuning methodology was left up to the prosthetists' discretion. Though the use of the prosthesis emulator was new to the prosthetist, the prosthetist noted that the experience was quite similar to adjusting a conventional microprocessor-controlled prosthetic ankle or knee. Two bouts of optimization were performed. The subject and prosthetist were instructed to work together to determine the best value for each of the settings. Optimization began from an initial condition that was standardized across subjects.

We then validated that the tuned settings in a double-blind validation. We compared the tuned settings to a validation set that consisted of five different conditions. Within the validation set, two of the parameters were held constant while the third varied across the range of possible values. Three validation trials were performed and outcomes were summed across trials. Settings were changed once every fifteen seconds and the patient was instructed to vocalize whether each combination of settings was 'better than', 'worse than', or 'about the same as' the settings that preceded them. The order of appearance of each parameter set was randomized such that each set of parameters appeared once per validation bout.

Results

Optimization and validation outcomes are summarized below in Figure 1. We found that the prosthetist and patient always selected either the best or second-best parameter set. Average tuning times for each subject were 2.1 and 3.5 minutes, respectively.

Discussion

It appears that a certified prosthetist with minimal

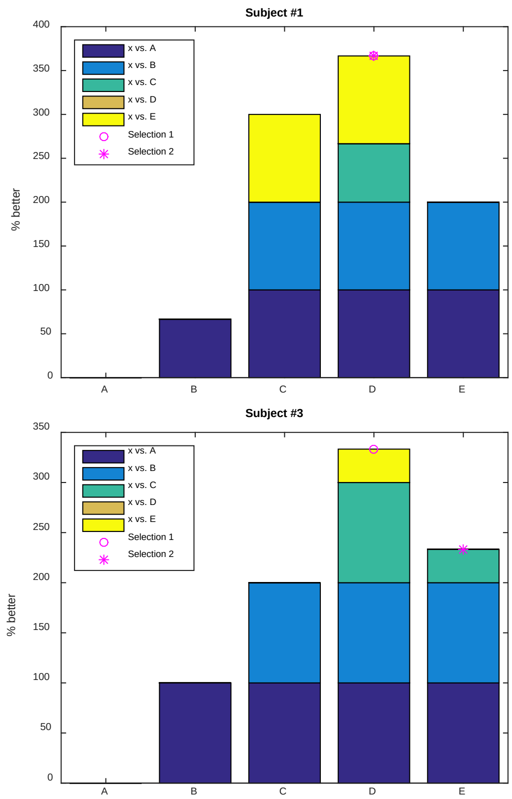

Figure 1: Validation of the settings tuned by the prosthetist. Stacked bar plots indicate the frequency at which each condition was preferred to the alternatives. Conditions A through E refer to variations in the stiffness parameter. All other parameters were held constant during validation. Magenta circles and asterisks indicate the settings that were selected during tuning. Tuning was performed twice to test for consistency.

training in the use of a prosthesis emulator can effectively use such a tool to tune a three-dimensional space of high-level passive prosthetic foot parameters. Tuning was quick and appeared effective. For Subject 3, there was some uncertainty as to whether stiffness D or E was preferred. This uncertainty may have been resolved in an additional tuning trial.

Given the ease and simplicity of the approach, and the relevance of the parameter space to conventional prosthetic feet, the clinical relevance of the approach appears promising. In clinical application, such an approach could help prosthetists select prosthetic devices that more specifically address patients' needs. Neither prosthetist nor patient need to know which make or model of device is being emulated, so this process is unbiased by external factors such as cost.

Throughout pilot testing we observed that the optimization procedure and validation protocol was somewhat sensitive to characteristics of individual subjects. For example, while a discrete change from one parameter value to another may have been clear and significant to one subject, it may have been too subtle for another to discern. In future protocols we will explore methods of adapting the step size and range of parameter values to individual users.

We found that the pairwise comparisons used in validation provided clearer relationships between user preference and parameter values. We suspect that this is due to the relative ease of comparing two experiences presented back-to-back as compared to comparing an experience to an absolute reference.

Whether or not the approach presented here will be effective in other contexts may depend on the parameterization, the outcome(s), and the type of assistive device. For example, we pilot tested a variety of parameterizations and found that subjects performed better with parameterizations that had a lesser degree of coupling between parameters and their effect on outcomes. We optimized for user satisfaction here for ease of measurement and the importance of satisfaction in clinical practice. Such an approach may work well for other outcomes that can be measured quickly and discretely, but other approaches may prove more effective for outcomes which develop more slowly in time.

Automated optimization methods may converge more quickly and enable optimization of larger parameter spaces. However, it is unclear which methods would be best, given the complexity of measuring patient satisfaction. It seems likely that methods which utilize pairwise comparisons will be more effective than those which rely on absolute ratings. Patient fatigue is a major challenge for the design of an effective procedure. Although additional data points are typically useful, the onset of fatigue or discomfort, which was commonly encountered in our pilot testing, can have a strong confounding effect on outcomes.

References

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