Shared Decision Making Aid for Prosthetic Design

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COMIRB Protocol

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I. Hypotheses and Specific Aims:

The overarching hypothesis of this work is that the lack of shared decision making (SDM) for prosthetic design and failure to match patient expectations with a prosthetic design plan result in poor health outcomes for patients with LLA. *Shared decision making* (SDM) is where clinicians and patients share the best available evidence for comparing options in order to achieve informed preferences for making health decisions.[1] A patient's involvement in their health care process is known to affect their satisfaction,[2,3] adherence to care programs,[4] and health outcomes.[5] ***Clinical decision aids* (DAs)** support patients in SDM and making informed health decisions, by providing information on the available options and associated outcomes.[6] DAs are intended to help patients clarify their values associated with the options and potential outcomes, to create a platform for communication with healthcare providers.[6,7] DAs have been shown to improve patient knowledge and realistic expectations for given health options.[1] **This project aims to examine how to better align patient and clinician values and expectations by developing a DA for prosthetic design decision options, to support SDM between patients receiving their first prosthesis and prosthetic care providers.** This proposal will be guided by the International Patient Decision Aids Standards (IPDAS).[6-8]

Aim 1: Qualitatively define the key determinants and decisional needs of new prosthetic patients (n=14) and prosthetic care providers (n=20- 24) during prosthetic design, via semi structured interviews with patient participants and focus groups with prosthetist participants.

Expected Result 1.1: Key determinants and decisional needs for prosthetic design will be defined using content analysis guided by the Ottawa Decision Support framework[9] for patients making health decisions, and the Model for Shared Decision Making in Clinical Practice.[10]

*Expected Result 1.*2: Key stakeholders who contribute directly to prosthetic design decisions (e.g., patients with LLA, prosthetists, physicians, caregivers, close friends or family members) will be identified via purposive sampling, to inform the target end users of a DA prototype.

Aim 2: Synthesize the evidence for prosthetic design decision options to develop a DA prototype.

Expected Result 2.1: Via systematic literature review, a DA prototype will be developed from the evidence on prosthetic design decision options associated with decisional needs identified in *Aim 1*.

Aim 3: Assess the DA prototype's accuracy, comprehensibility, and usability through alpha testing with an ***expert working group*** of patients with LLA and prosthetic care

providers.

Expected Result 3.1: Quantitative results from a Likert scale measurement of the DA prototype's accuracy, comprehensibility and usability will inform revisions to the DA prior to use in a pilot clinical trial.

Expected Result 3.2: Qualitative feedback on the DA prototype's accuracy, comprehensibility, and usability will inform directed iterative revision for the DA prototype and implementation methods for use in a pilot clinical trial.

II. Background and Significance:

This proposal addresses three significant problems with conventional prosthetic design: **1)** suboptimal patient outcomes after LLA; **2)** challenges in the prosthetic design process that limit SDM; and **3)** under-informed expectations for function with a prosthesis for patients and prosthetic care providers.

2.1. High cost and suboptimal patient health and rehabilitation outcomes after LLA

LLA is a high cost, chronic health condition marked by poor health-related outcomes.[11-17] Five-year health care and prosthetic costs after amputation are estimated to be more than triple the lifetime health-care cost of an average person.[16] In spite of the high cost and high resource allocation after LLA, strong evidence demonstrates a decline in functional outcomes, such as physical capacity (strength and balance), and walking ability (velocity and symmetry).[18-20] Psychosocial outcomes (e.g., quality of life, depression) are also lower in people after LLA when compared to general population norms.[11,12,17,21] When physical function and psychosocial outcomes are evaluated in combination, up to half of patients are unable to achieve their pre-amputation levels of mobility and quality of life one year after LLA.[22,23] Thus, successful rehabilitation after LLA is multidimensional, involving many interrelated aspects of health outcomes.[19,24] It is also unclear how health outcomes are affected by patient expectations and patient involvement in prosthetic design decisions.[25,26] **Shared Decision Making (SDM)** is a process of supported patient and clinician communication to identify patient values and inform expectations about potential health options, and has been shown to improve patient satisfaction and adherence to care plans.[1,4,26,27] SDM offers a solution for improving health-related outcomes after LLA through a mechanism of affective-cognitive (knowledge and understanding of options) and behavioral outcomes (adherence to care plans and adoption of health behaviors) **(Figure 1)**.[26] This proposal aims to improve the complex combination of both physical function and psychosocial outcomes of patients with LLA by supporting SDM in the prosthetic design process.

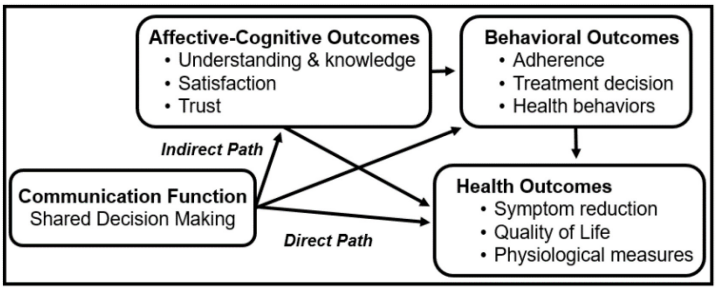

Figure 1. *Conceptual framework linking Shared Decision Making and patient outcomes, adapted from Shay et al.*[21]

2.2. Prosthetic design challenges that limit SDM

One challenge in the prosthetic design process is the variety in patient characteristics that can be difficult to align with abundance of prosthetic design options available to choose from. Prosthetic deisgn options offer a range in technology, appearance,

functional performance, expense, maintenance, method of use, safety, and stability.[28-30] Components of the prosthetic design decision include selecting a prosthetic socket, interface, suspension system, components, and cover (**Table 1**). For example, prosthetic interfaces (e.g., gel, urethane, silicone) between the residual limb and the prosthetic socket may provide increased comfort and protection for bony prominences, however are also associated with increased cost, maintenance, and may be difficult to donn. Additionally, several patient-specific factors may influence prosthetic component selection (**Table 2**); for example, a patient with limited hand dexterity may benefit from a prosthetic suspension system that is easy to donn over a system that requires more upper extremity strength, such as a pin locking gel liner.

However, gel liners may be more ideal for patients with high activity levels, due to the skin protecting features and reduced shear forces on the residual limb. Higher costing prosthetic design options tend to be associated with more advanced appearance, materials, technology, safety features, and greater user satisfaction, yet may be resisted by health-care financers, or be less than ideal in certain environments (maintenance, sweat management, access to electricity for charging, less resistant to water exposure).[28] In order to optimize prosthetic design, prosthetic care providers are challenged with combining the best available evidence around prosthetic design options, their clinical expertise, patient-specific factors, and patient values.[31-33] The most appropriate option for a given patient is often unclear, and matching the optimal prosthetic option to a patient's need and potential remains difficult.[28] The tradeoffs in the prosthetic design decision making process emphasize the need for decision support for both patients and prosthetic care providers.[28,34]

Key Decision: Prosthetic Design	
Decision Components	**Potential Decision Options**
Prosthetic Socket	Total surface bearing, patellar tendon bearing, ischial containment, quadrilateral socket
Prosthetic Interface	Sock, gel, silicone, urethane, foam
Prosthetic Suspension	Suction, pin, lanyard, sleeve, belt
Prosthetic Components	Prosthetic foot, knee
Prosthetic Cover	Foam, protective skin, no cover

Table 1. *Potential Prosthetic Design Subcomponents & Decision Options*

Challenges in the prosthetic design process contribute to a lack of SDM between patients with LLA and their healthcare providers. In the general population, most patients prefer to be active partners in decisions about their healthcare.[26,35] Effective SDM between patients and health care providers is associated with greater patient satisfaction with care processes, adherence to treatment programs, improved self-reported health, and overall informed expectations.[1-4,26] However, patients with LLA assume passive roles in the prosthetic design process due to a lack of knowledge and experience necessary to collaborate in prosthetic decisions.[36] Discussing options and recognizing patient preferences is acknowledged as an important factor in improving prosthetic use and adherence to care plans, even when options are limited.[37] The proposed project aims to improve the exchange of information about prosthetic design options between patients and their prosthetic care providers, in order to align values with prosthetic design decisions.

2.3. Under-informed patient and prosthetic care provider expectations

Both patient and prosthetic care provider expectations around anticipated function with a prosthesis are under-informed.[36,38,39] Patients with LLA do not know what to expect from their first prosthesis, and their expectations for returning to pre-amputation levels of

function after LLA are often unrealistically high.[38,39] The tendency for patients to believe that parts of a prosthesis determine their ability to walk rather than their own physical ability is a prevalent concern among prosthetic care providers.[39] Prosthetic care providers also express difficulty predicting patient health outcomes with a prosthesis, further contributing to the ambuiguity of both patient and clincian expectations for prosthetic rehabilitation.[39] The lack of informed expectations may potentially link to reported low levels of patient satisfaction for function with a prosthesis,[40,41] and prosthetic non-use rates by patients as high as 15%.[42] Thus, managing unrealistic patient expectations in the prosthetic design process is a difficult endeavour and often viewed negatively in prosthetic care.[39] In other populations, patient expectations for a given outcome are associated with success in rehabilitation, adherence to care plans, and improved functional recovery.[5,43-45] In a review on patient expectations after a surgical intervention, patients whose functional expectations were fulfilled had higher gains in satisfaction and physical quality of life.[45-47] In contrast, patients with unrealistic expectations for a given outcome after a health event may become discouraged and fail to meet their maximum potential.[48] In order to achieve patient satisfaction with prosthetic care, a patient's expectations for a prosthesis must align with their experience.[41] *We hypothesize that the failure to match patient expectations with a prosthetic design plan result in poor health-related outcomes for patients with LLA.* The proposed project aims to inform realistic patient expectations during the prosthetic design process, to improve health-related outcomes after LLA.

III. Preliminary Studies/Progress Report:

Existing research has identified that **DA** address problems in conventional healthcare by: **1)** improving patient health outcomes by providing high quality information on the available prosthetic design options and associated outcomes; **2)** supporting patients and care providers in identifying and discussing values associated with healthcare options and reducing decisional conflict; and **3)** aligning patient and care provider goals and values to inform expectations for healthcare options.

3.1. Decision Quality: DA to improve LLA health outcomes

The relationship between patient health outcomes after LLA and SDM has yet to be explored.[26] A potential mechanism for improving health-related outcomes after LLA is through SDM by means of improving patient knowledge and understanding of prosthetic design options.[26] DAs are designed to support patients and healthcare providers in SDM by providing high quality information on available decision options,[6] and have been shown to improve patient knowledge of options by as much as 20%.[1,49,50] Through the development and use of an innovative DA for prosthetic design, patients with LLA will gain new access to knowledge (high quality evidence) necessary to participate in decision making for their prosthesis. Upon completion, this proposal will be positioned to examine patient knowledge of prosthetic design options in concordance with patient health outcomes.

3.2. Quality of Decision Making: Increase SDM and reduce decisional conflict in prosthetic design

The proposed study will introduce SDM to the prosthetic design process using a novel DA to promote discussion of prosthetic design options, thus reducing decisional conflict. SDM has been shown to help patients make informed decisions that are in line with their

goals and values,[51,52] and can be valuable for situations where evidence is insufficient or when personal preferences heavily influence the decision.[53] Furthermore, the use of DAs has been shown to increase the likelihood of discussing potential decisions, patient participation, and decrease decisional conflict by up to 10%.[1,50] Given the problem of limited patient participation in prosthetic design decisions, this proposal offers a solution for improving the quality of decision making in the prosthetic design process by supporting SDM between prosthetic care providers and patients. This proposal will also explore methods for implementing the use of a DA and identify areas for training on SDM in the prosthetic design process.

3.3. Decision Quality: Align patient and prosthetic care provider values to inform expectations

The proposed study will create and test a DA that improves values-treatment concordance for prosthetic design decisions in order to create realistic expectations for selected prosthetic options. This is important, as it will translate directly to clinical practice by helping patients construct and communicate personal values associated with the different options. A crucial aspect of the proposed study is the solution for uninformed patient and prosthetist expectations by means of a DA, to create a platform for aligning both patient and provider values (the benefits or risks that matter most) around the potential options, thus creating more realistic expectations for the outcome of each option.[54] DAs have been shown to improve the congruency between the decision and patients' values by as much as 51%, and improve realistic expectations of option outcomes by as much as 82%.[1,50] The proposed study will create a DA that is a new and innovative approach to improving values-treatment concordance for prosthetic design decisions, in order to create realistic expectations for selected prosthetic options.

IV. Research Methods

A. Outcome Measure(s):

A.1. Aim 1: Qualitative Scoping Outcome Measures

Semi-structured interviews with participants with LLA will be conducted by a trained qualitative interviewer using video web conferencing with audio recording. Video conferencing will provide the benefits of in-person interviews (e.g., developing rapport, increasing accuracy, adding validity) while reducing participant travel burden.[55] One-on-one semi-structured interviews with participants with LLA provide the opportunity for the interviewer/interviewee to diverge and pursue an idea or response in more detail (i.e., discussion of personal values associated with prosthesis design).[56,57] Therefore, one-on-one semi-structured interviews provide the greatest potential for collecting high-quality data contributing to the decisional needs of prosthesis users. Interview guides will be informed by peer reviewed literature on prosthetic design, the Shared Decision Making Model for Clinical Practice,[10] and the Ottawa Decision Support Framework[9] and contain broad, open-ended questions to explore perspectives on prosthetic decision making.

Focus groups are advantageous when the best information is likely to come from group interaction,[58] and will be conducted with prosthetist participants by a trained qualitative interviewer using video web conferencing with audio recording. Given the professional nature of the decision and environment in which prosthetic design decisions take place, the collaborative group approach within a focus groups will likely provide

optimal high quality, rich data around the decisional needs of prosthetists.

In addition to qualitative data collection, descriptive data will be collected from all recruited participants (prosthetists and patients with LLA), including demographics, the Control Preferences Scale[59] (a measurement of preferences regarding participation in healthcare decisions), and the eHealth Literacy Scale[60] (a measurement of perceived ability to find and use traditional, scientific, media, and computer health information), in order to inform future methods for implementation of the DA.

A.2. Aim 2: Systematic Review and Synthesis of the Evidence Outcome Measures

The quality of the studies will be evaluated using the Cochrane Criteria List for Methodological Quality Assessment.[61] Finally, evidence will be summarized and interpreted, to guide the development of the DA. Results will be reviewed via focus groups by the ***expert working group***, to confirm accuracy and credibility.[6]

*A.3. Aim 3: Alpha Testing with the **Expert Working Group** Outcome Measures*

The DA will be presented to the ***expert working group,*** and feedback on the accuracy, comprehensibility, and usability of the DA prototype will be collected. This study will use descriptive statistics for evaluating accuracy, comprehensibility, and usability of the DA. **Accuracy** of the DA will be determined by the percentage of ***expert working group*** members who perceive the presented risks and benefits in the DA to align with the scientific evidence available on the prosthetic design decision outcomes.[50] **Comprehensibility** of the DA will be classified as the degree to which the DA content covers information necessary for making an informed decision about prosthetic design, and will be evaluated using a Likert scale for each component of the DA.[6,62,63] **Usability** will be qualified as the extent to which the information presented in the DA is clear, understandable, and effective, and will be evaluated using a Likert scale for each component of the DA.[63] Additional feedback on the accuracy, comprehensibility, and usability of the DA prototype will be collected by means of short individual semi-structured interviews after each round of alpha testing.

B. Description of Population to be Enrolled:

*B.1. Aim 1-3: Assemble an **expert working group***

A separate ***expert working group*** will be assembled for consultation throughout all aims of the proposed work, and for alpha testing in *Aim 3*. In order to check the credibility of results and ensure all appropriate topics necessary for prosthetic design decision making are included in an initial DA prototype, focus groups will be conducted with the expert working group to review and confirm the results from *Aims 1 and 2*. In order to alpha test the DA prototype in *Aim 3*, quantitative data and semi-structured individual interviews will be conducted with the expert working group.

The ***expert working group*** will consist of at least 5 and up to 12 people with LLA actively receiving prosthetic care, and at least 5 and up to 12 prosthetic care providers with greater than 5 years of experience. Individuals will be invited to join the ***expert working group*** based on expertise, and representation of key stakeholders relevant to the prosthetic design process identified in *Aim 1* (e.g., certified prosthetists, therapists, physicians, and other caregivers).[64] Patient expert group members will be identified through the University of Colorado Health Amputee Support Group, through the Amputee Coalition of America, and through Amputee List Serve (AMP-L). Healthcare provider expert group members will be identified through local and professional clinic partners and the Orthotics and Prosthetics List Serve. The group will be referred to for checking credibility of results, in the development and refining process of the DA, and alpha testing

of the DA.

B.2. Aim 1: Qualitative Study Participants and Sampling Plan

Participants (estimated up to 14 patients, within 1 year from lower limb amputation, receiving their first prosthesis and up to 24 prosthetic care providers) will be recruited through well-established clinical partners representing diverse prosthetic practice environments (including the Denver VA Medical Center and private prosthetics practices), located in Albuquerque, NM, Tucson, AZ, and Denver, CO, and clinics throughout the US. Patient participants will also be recruited through the Amputee Coalition of America, and through Amputee List Serve (AMP-L). Standard to qualitative research methods, purposive sampling will be employed to ensure maximum variation of socio-demographic and clinical characteristics, and to ensure inclusion of all key stakeholders in the prosthetic design process.[65] Prosthetic care providers will be sampled based on a diverse representation of professional experience and involvement in the prosthetic design process, including prosthetists, therapists, physicians, and associated care providers. Patient participants will be sampled based on diverse representation of above- and below-knee amputation, age, sex, etiology, and availability to participate in a 1-hour, semi-structured interview. The patient sample is expected to reflect a distribution of amputation levels and etiologies similar to population-level estimates: ~54% vascular and ~45% traumatic etiology.[66] Patients will be recruited early in their rehabilitation process, for insight into the decisional needs for their first prosthesis and initial care planning. Recruitment will target 14 patients and 24 prosthetic care providers with the goal of achieving thematic saturation, the point where no additional properties of themes emerge from qualitative analysis.[67-69] If thematic saturation has not been attained, enrollment will continue beyond the targets for each group.

C. Study Design and Research Methods

C.1. Overview of Approach

The goal of this proposal is to develop and conduct alpha testing of a DA for prosthetic design decisions. The aims in this proposal are guided by IPDAS for developing patient decision aids **(Figure 2)**.[63]

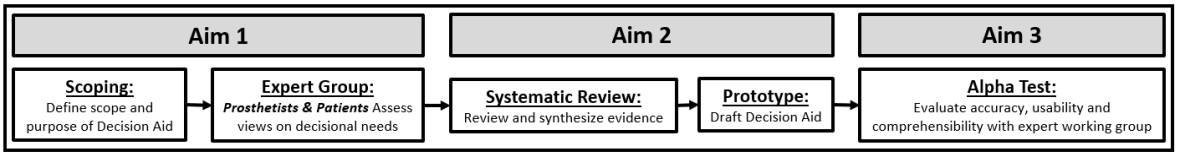

Figure 2: *Steps for development of a DA, adapted from the International Patient Decision Aids guidelines, Coulter et al.*[63]

Steps will include **Aim 1)** qualitatively define the scope and purpose of the DA**; Aim 2)** review and synthesize the available evidence to inform the development of a prosthetic design DA prototype; and **Aim 3)** alpha testing for accuracy, comprehensibility, and usability of the DA, with an expert group of patients and prosthetic care providers. **Aims 1** and **2** are an exploratory sequential mixed methods study design for developing the DA, a commonly used study design for instrument development.[70] **Aim 3** is a convergent parallel mixed method design for alpha testing of the DA. **(Figure 3)**

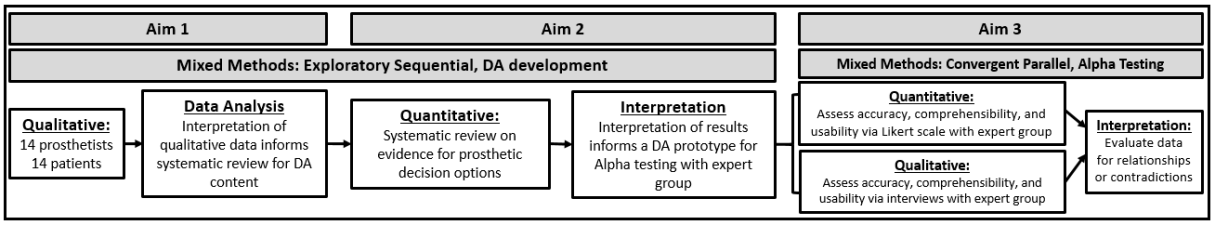

Figure 3: *Study design overview*

C.2. Aim 1: Define the Scope and Purpose of the DA

The objective of *Aim 1* is to qualitatively define the scope and purpose of the DA, by exploring the key determinants for prosthetic design decisions, and decisional needs of both patients and prosthetic care providers during prosthetic design.[63,71] This aim will clarify 1) all components of prosthetic design decisions that will be included in the DA prototype, 2) the key determinants that contribute to decision making, 3) the target end users of the DA, and 4) the necessary content to be included in the DA that will help inform the decision.

C.3. Aim 2: Review the Evidence for Prosthetic Design Decision Options to Develop a DA Prototype.

The purpose of **Aim 2** will be to develop a DA prototype for new prosthetic users over two steps: 1) systematic review of the evidence on the prosthetic design decision options identified in **Aim 1** and their associated risks and benefits; and 2) development of a DA prototype.[63,71]

C.3.1. Aim 2: Systematic Review and Synthesis of the Evidence on Prosthetic Design Decision Options

A comprehensive systematic literature review will be conducted on the relevant data and evidence associated with the available options, as they relate to the key components of prosthetic design decisions and the decisional needs defined in *Aim 1*.[63] The review will appraise the available evidence on the risks and benefits of the possible choices associated with each component of prosthetic design, and summarize the results in a final document.[63] The systematic review will follow the Cochrane Handbook and PRISMA Guidelines for Systematic Reviews.[61,72]

C.3.2. Aim 2: Developing a DA Prototype

The development of the DA proposed in this study will follow the IPDAS guidelines for decision aid development.[6,8] Based on this guideline, the DA will include high quality evidence on the options in sufficient detail for each decision associated with prosthetic design, potential outcome probabilities, clarity for identifying patient values associated with each option, and guidance on deliberation and communication.[8] Use of plain language will be implemented and checked by the ***expert working group***, for comprehensiveness for all literacy levels.[8] Format of the decision aid will be established (i.e., paper article, video, web-based).[63,71] For accessibility in multiple environments (long distance vs. local, internet access vs. no technology access), a minimum of two formats will be considered.[71]

*C.4. Aim 3: Assess the Accuracy, Comprehensibility, and Usability of the DA Through Alpha Testing with the **Expert Working Group** of Patients and Associated Healthcare Providers.*

The objective of this aim is to assess the accuracy, comprehensibility, and usability of

the DA through alpha testing with an ***expert working group*** established in *Aim 1*. The DA will be presented to the ***expert working group,*** and feedback on the accuracy, comprehensibility, and usability of the DA prototype will be collected. Evaluating the accuracy, comprehensibility, and usability of the DA with potential end-users will ensure that 1) the DA contains high quality accurate information, 2) the DA presents material that is valuable to the decision making process for prosthetic design, and 3) the DA is logical and understandable to the target end users, and can be feasibly and rapidly adopted in practice.[1,63,70,73] Both qualitative and quantitative data will be collected and analyzed separately, to create a more complete understanding of the DA's accuracy, comprehensibility, and usability.[70] The alpha testing will inform iterative modifications to the DA in future prototypes, and will produce findings that will determine whether the DA should be recommended for pilot testing in the clinic setting.[74]

D. Description, Risks and Justification of Procedures and Data Collection Tools:

The risks associated with the semi-structured interviews are minimal. Additionally, the quantitative measures to be used (e.g., questionnaires) are low-risk and considered to be safe. These minimal and low-risks include the risk of misinterpretation of discussion and questionnaires, potentially resulting in negative or unproductive thoughts by the patient or prosthetist. Additionally, one purpose of the semi-structured interviews is to uncover any unforeseen consequences of the information included in DA (e.g., patient anxiety about prosthetic decisions, recovery) and to address these risks. It is also important to note that patients and therapists already discuss prosthetics and prognosis as part of standard care, however currently these discussions are woefully under-informed by evidence. Finally, rare, unknown, or unforeseeable (unexpected) risks may also occur.

As with all clinical research studies, there is the general risk of breach of confidentiality or data security. To minimize this risk, only the minimal necessary data will be collected, and procedures to maintain confidentiality will be followed.

Little research has been conducted to promote shared decision making as a method for improving patient outcomes for people with LLA. This study will initiate work on developing a DA prototype to identify the potential for efficacy and implementation in clinical practice. The patient and clinician participants have potential to benefit immediately from the educational experience surrounding interaction with research team who are highly interested in addressing functional limitations and disability following non-traumatic lower-limb amputation. In addition, the results of the study will indicate whether larger efforts (i.e., Phase II trial) are indicated to test implementation of such intervention as a key element of standard prosthetic design decisions following LLA.

E. Potential Scientific Problems:

Due to the pilot design of the proposed study, and to maximize successful use of DA, we have selected optimal champion clinic partners for our initial *Aim 1* qualitative exploration and for the ***expert working group***. Participant selection will be, in part, based on their willingness participate in feedback on incorporating novel measures into practice, which may introduce limitations in generalizability and bias around future DA implementation in other clinics. Therefore, data collection and recruited participants will be a convenience sample, which may introduce limitations in generalizability and bias around future DA testing in other clinics.

F. Data Analysis Plan:

F.1. Aim 1: Qualitative Data Analysis

Transcripts from the semi-structured interviews and focus groups will be analyzed with ATLAS.ti 7.0 software using qualitative directed content analysis.[75,76] Qualitative directed content analysis is a process where existing theory guides the discussion and interpretation of the research findings, providing focus for the research question, to produce a final identification of themes, patterns, or categories.[75] Pre-determined codes will be based on steps of SDM defined by the Shared Decision Making Model for Clinical Practice,[10] and on existing theory of decisional needs, as described by the Ottawa Decision Support Framework.[9] In order to maintain inter-coder reliability, two members of the research team (one clinician and one non-clinician, to manage potential biases) will independently review and code the transcripts, and reconcile results. Codes will be modified or added as needed; any new material that does not fit with existing codes will be discussed to further extend or refine the existing decisional needs.[75] In the circumstance of any disagreements, a third team member will consult. Codes will then be grouped into themes to identify the primary components of prosthetic design decisions, determine the key determinants for each decision, and identify the decisional needs of both patients and prosthetic care providers. To maintain unbiased results and trustworthiness of the findings, coding rules and an audit process will be used.[76] Credibility of results will be ensured by conducting focus groups to share and evaluate the final themes with an established ***expert working group*** of prosthetic care providers and patients with LLA (described below). In order to develop a DA prototype in **Aim 2**, this aim will clarify the primary decisions and identify the key decisional needs (e.g., knowledge needs of patients and healthcare providers, associated values). Results from this aim will be foundational for defining current SDM practices in prosthetic design, identifying areas of need for decision support, identifying end users of the DA, and informing a SDM training and implementation strategy in future pilot work.

F.2. Aim 2: Systematic Review Analysis

The systematic review will follow the Cochrane Handbook and PRISMA Guidelines for Systematic Reviews.[61,72] Two study reviewers will identify relevant work from multiple resources (e.g., MEDLINE, EMBASE). Key search terms and inclusion criteria will be established prior to searching for identifying relevant work (e.g., pertaining to LLA participants, inclusion of outcomes of interest, key words reflective of the decisional needs identified in *Aim 1*). The quality of the studies will be evaluated using the Cochrane Criteria List for Methodological Quality Assessment.[61] Finally, evidence will be summarized and interpreted, to guide the development of the DA. Results will be reviewed via focus groups by the ***expert working group***, to confirm accuracy and credibility.[6]

*F.3. Aim 3: Alpha Testing and Iterative Modification With the **Expert Working Group***

The DA will be presented to the ***expert working group,*** and feedback on the accuracy, comprehensibility, and usability of the DA prototype will be collected. All quantitative data will be collected through Research Electronic Data Capture (REDCap) and analyzed with R, version 3.5.1. This study will use descriptive statistics for evaluating accuracy, comprehensibility, and usability of the DA. Based on thresholds in published testing of accuracy, comprehensibility, and usability of existing DAs, 80% will be the threshold for each component of the prosthetic design decision included in the DA. If accuracy, comprehensibility, and usability score less than 80%, the DA will be revised and an additional round of alpha testing will be conducted. Iterative revisions to the DA and rounds of alpha testing will continue until all outcomes measure 80% or greater.

Additional feedback on the accuracy, comprehensibility, and usability of the DA

prototype will be collected by means of short individual semi-structured interviews after each round of alpha testing. Results from the qualitative feedback on the DA prototype will inform revisions to the prototype for additional rounds of alpha testing, and inform an implementation plan for future clinical use of the DA, including training on SDM in prosthetic care. Thematic analysis will be used to analyze results from the *Aim 3* qualitative interviews.[65] An initial coding team of 3 researchers will develop the code book for each group of interviews (patients and prosthetic care providers), and once agreement is established (estimated 3-6 interviews), remaining transcripts will be coded by two primary coders. The coding team will include both clinical and non-clinical members to minimize potential bias (e.g., prosthetist, occupational therapist, and non-clinical research assistant). All transcripts will be coded and analyzed via open coding using Atlas.ti software. Methods for maintaining trustworthiness and credibility will reflect those listed in **Aim 1**.

Finally, in the convergent mixed methods design, qualitative and quantitative data from **Aim 3** will be individually analyzed and then consolidated to explain any unanswered questions or unexpected findings in the alpha testing of the DA. Common concepts will be integrated and compared to identify and describe feasibility and acceptability results, using data consolidation and merging.[70] Data connection methods will be used to maximize strengths and minimize weaknesses of both qualitative and quantitative results.[70] Results from the analysis will further improve and tailor the DA to fit the need of both patients and prosthetic care providers, and inform study procedures and implementation methods for pilot testing in a clinical beta testing trial. Modifications will be made to the DA in an iterative process (at least two rounds of testing and modification with the ***expert working group***, or until greater than 80% DA accuracy, comprehensibility, and usability is achieved) to ensure that the DA is optimal for clinical implementation.[6] An audit trail will be maintained through the modification process, for reporting feedback and how this feedback was incorporated into the design.[8]

G. Summarize Knowledge to be Gained:

This study focuses on a prevalent and understudied population of people with LLA. Due to high heterogeneity and limited evidence on what factors are important in prosthetic design decisions, the outcomes following LLA are poor. With little to no additional risk, this exploratory sequential trial has high potential to develop a method intended to improve SDM for prosthetic design and to advance the quality and reduce the overall health consequences (and costs) for patients with LLA.

An abundance of prosthetic design options are available, ranging in appearance, functional performance, expense, maintenance, and method of use.[28,30] However, matching prosthetic design options with a patient's values, expectations, and functional potential remains a challenge, and this can affect patient outcomes.[28,34] For example, patients with LLA report having expectations for returning to normal after receiving their prosthesis,[38] yet up to 50% are unable to achieve ambulation necessary for activities of daily living one year after amputation,[23,77] and patient satisfaction with their prosthetic care remains low.[40,41] These outcomes suggest that prosthetic design decisions may not align with patient values or expectations for function, highlighting the need to incorporate patient preferences in the prosthetic design process.[37]

Currently, clinician and patient expectations for function with a prosthesis are underinformed.[28,39] Prosthetic care providers report difficulty estimating patient outcomes after LLA, managing patient expectations, and interpreting existing evidence around prosthetic design options, and instead rely on past experiences for subjective prosthetic design decisions.[28,39] Thus, up to 30% of patients may be using prosthetic components designated for a functional level lower than their current functional capacity.[78] Additionally, providing rationale for prosthetic design decisions remains challenging for prosthetic care providers,[28] limiting shared patient-provider involvement in weighing outcomes associated with the potential prosthetic options. On the other hand, patients report unmet expectations between their goals and the capabilities of a prosthesis,[36,38] and general uncertainty throughout the rehabilitation process.[38] Although patients express a desire to be more involved in the prosthetic design process, their involvement in prosthetic decision making is minimal.[36-38] Patient involvement in prosthetic design decision making and their expectations of function with a prosthesis may have an important influence on functional recovery, however this relationship remains unclear.[25,26]

The development of a novel DA for prosthetic design will address the challenge of matching patient expectations with prosthetic design. The DA is an innovative tool designed to support patients and healthcare providers in SDM and making informed health decisions, by providing information on the available options and associated outcomes.[6] DAs are intended to help patients clarify their values associated with the options and potential outcomes, to create a platform for communication with healthcare providers.[6,7] DAs have been shown to improve patient knowledge and realistic expectations for given health options.[1] This proposed study will be guided by the International Patient Decision Aids Standards (IPDAS)[63] to develop a DA to enable shared decision making and translation of evidence to the point of care.

Two key deliverables of this proposed study will be a final DA prototype for beta testing in a clinical pilot trial to examine efficacy and implementation of the DA for prosthetic design, and an implementation plan for rolling out the DA in clinical practice. The future clinical trial will be planned in the final quarter of the proposed study period.

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