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Initial Development of a Patient-Reported Item Bank to Assess Mobility of People Who Use  
Lower Limb Orthoses

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**Abstract**

Initial Development of a Patient-Reported Item Bank to Assess Mobility of People Who Use  
Lower Limb Orthoses

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Item banks are contemporary health survey instruments used to efficiently measure patient-reported outcomes that may be difficult to observe in a clinical or research setting. Item banks designed specifically for measuring outcomes among people who receive a specific intervention often include survey questions that are relevant to the individual and expected to change as a result of the intervention. Lower limb orthotic interventions are designed to improve users' mobility in a range of environments and real-world situations. An item bank designed to assess mobility of lower limb orthosis users does not currently exist. Such an instrument could be an effective tool for rehabilitation professionals interested in orthotic mobility outcomes. An orthosis user-specific item bank could also benefit the global community of orthotic patient care professionals, as a means by which mobility outcomes data can be collected, pooled, and/or

compared across different regions and cultures. Given the need for an orthosis user-specific item bank, the studies in this dissertation aimed to (1) better understand how orthosis users conceptualize mobility, (2) construct a candidate item bank for orthosis users, and (3) develop and apply a process for translating condition-specific item banks into other languages. This body of work represents the initial development of a new item bank and a model for future language translation efforts. The first chapter is a qualitative study designed to explore how lower limb orthosis users describe their mobility using focus groups and thematic analysis. Insights from participants suggest that orthosis users with a variety of underlying health conditions experience many of the same benefits and challenges associated with using a lower limb orthosis. Also, orthosis users can often choose to modify their mobility in different situations by using or not using their orthosis and/or other mobility aid(s). Gaining an understanding of a measurement construct of interest, in this case, mobility of orthosis users, is the first step toward developing a new PRO instrument. The second chapter describes additional steps taken to identify items applicable to orthosis users' mobility and evaluate their suitability for inclusion in a candidate item bank. Results of this study further clarify the need for an item bank specific to this population as many of the activities and situations described by orthosis users as being important are not included in existing PRO instruments. The candidate items are now ready for further testing in a future study outside the scope of this dissertation. The third chapter is a language translation and linguistic validation study that describes a model for translating condition-specific item banks. As a result of this study, a Japanese translation of the Prosthetic Limb Users Survey of Mobility (PLUS-M) is now available, and a model is prepared for translating the new item bank to other languages in the future. Collectively, the chapters of this dissertation describe insights gained from orthosis users' perspectives on mobility, initial development of an item

bank to designed for measuring mobility of people who receive orthotic interventions, and a model for translating a condition-specific item bank to other languages. These research findings also lay the groundwork for future research efforts, including calibration and psychometric evaluation of the new item bank, and translation of the instrument into other languages to facilitate international efforts to collect orthotic mobility outcomes data.

This research was conducted with approval by the Human Subjects Division of the  
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## **Plain Language Summary**

Clinicians and researchers can use surveys to collect health information directly from individuals. An item bank is a set of survey questions that can be used to measure health outcomes with high precision and efficiency. When an item bank is designed for people who have distinct health-related experiences, perspectives, or opinions, the questions may be more relevant than those in surveys intended for measuring outcomes that are common to many different types of people. Individuals who experience loss of strength or stability in one or both legs, may be prescribed a leg brace intervention, referred to as an orthosis, to improve their mobility. Orthosis users may share perspectives on mobility that differ from other groups of people and an item bank designed for measuring their mobility could be an effective assessment tool. An item bank that measures mobility of orthosis users may also provide clinicians and researchers with valuable information that can be used to improve orthotic care. To address this need, this dissertation aimed to better understand how people who use an orthosis view the concept of mobility, take the first steps to creating a new item bank, and identify a process that would be appropriate for translating an item bank into other languages. The first chapter is a research study that used small group discussions to learn about mobility from the perspectives of people who use orthoses. Many of the study participants discussed the same benefits and challenges related to mobility and using an orthosis. They also discussed making decisions to change their mobility by using or not using their orthosis, canes, crutches, and/or walkers. Gaining a better understanding of how people who use an orthosis view mobility was a first step toward creating a new item bank. The second chapter described the process of searching for survey questions and creating new questions that may apply to measuring mobility. The questions were tested through interviews with orthosis users to determine whether they should be

considered for inclusion in the item bank. Many of the activities orthosis users described as being important were not included in existing health surveys, suggesting that questions in the new item bank, compared to those included in existing surveys, may be more relevant to orthosis users. Potential questions are now ready for the next phase of development. The third study describes a process used to translate an existing item bank. The Prosthetic Limb Users Survey of Mobility (PLUS-M) was translated from English to Japanese using a process that included several translation steps, opportunities for review and revisions, feedback from experts, and interviews with people in Japan who use prosthetic devices. Each part of the process contributed to the quality of the translation and the methods will also be used to translate the new item bank for orthosis users to other languages in the future. Together, the chapters of this dissertation describe insights gained from orthosis users' perspectives on mobility, the initial steps taken to create a new item bank for measuring mobility of people who use orthoses, and a process for translating an item bank to other languages. Future research will build upon the efforts described in this dissertation and include collecting and analyzing survey responses from a large sample of lower limb orthosis users in order to evaluate the performance of each item. Additional efforts will include testing of the item bank alongside other applicable instruments to evaluate its measurement properties. The new item bank will also be translated to other languages to learn more about mobility of orthosis users around the world.

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Dedication: For my incredible wife Akasha, and our adventurous children Aspen, Camden, Madison, and Carson.

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# Chapter 1. INTRODUCTION

## 1.1 BACKGROUND

Patient-reported outcomes (PRO) are defined as “any report of the status of a patient’s health condition, health behavior, or experience with health care that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else” (Cella et al., 2015). PRO instruments are particularly useful for assessment of mobility in real-world situations (Rothman et al., 2007) that may be difficult to simulate in a clinical setting (e.g., walking up hills, getting into a car, navigating crowds). Scores obtained from these instruments can provide clinicians with insight into a patient’s mobility at home and in their community. When selecting a PRO instrument for a given application, clinicians and researchers should consider the appropriateness and of an instrument for measuring the construct of interest (e.g., mobility) in the target population (Ahmed et al., 2012). Key characteristics, such as the instrument’s population focus, development approach, and psychometric properties should also be considered.

PRO instruments can be classified as having a generic or specific focus (Finch, Brooks, Stratford, & Mayo, 2002). Generic instruments are designed to measure across a variety of individuals, including those with and without a broad range of clinical conditions. Normative data for these instruments is often derived from a reference sample of healthy individuals and can be used to interpret scores (Cella et al., 2015). Examples of widely used “legacy” generic instruments include the Barthel Index (Mahoney & Barthel, 1965) and the Medical Outcomes Survey 36-Item Short Form (Ware & Sherbourne, 1992). More recently, the Patient-Reported Outcome Measurement Information Systems (PROMIS), a multi-center research initiative,

developed contemporary PRO instruments designed to measure key health-related outcomes applicable to a wide variety of individuals (Cella et al., 2010). PROMIS instruments can be used to compare outcomes between groups of people with different health characteristics. For example, one study compared scores from six PROMIS instruments between people with multiple sclerosis (MS) and the U.S. general population, and found that those with MS scored significantly lower across all domains, indicating poorer health-related quality of life (Amtmann, Bamer, Kim, Chung, & Salem, 2018). This example demonstrates the effective application of generic PRO instruments to measuring outcomes across populations. However, a generic instrument may be less appropriate when the intended measurement construct is conceptualized differently by a group of individuals with distinct health-related experiences.

Condition-specific PRO instruments are designed for application in a clinical population with a common attribute, such as a health diagnosis (e.g., Multiple Sclerosis Walking Scale 12 (Hobart et al., 2003)) or the use of an assistive technology (e.g., Prosthetic Limb Users Survey of Mobility (Hafner, Morgan, Abrahamson, & Amtmann, 2016)). Condition-specific instruments are developed when individuals within a clinical population may have unique experiences related to an outcome of interest. The activities and situations included in a specific instrument may be more relevant to the individual (Cella et al., 2015) and provide more meaningful information to a clinician or researcher.

Lower limb orthosis (i.e., leg brace) users are a clinical population that may encounter unique mobility challenges. An orthosis can facilitate a user's mobility by stabilizing the limb and preventing unwanted joint movement. However, restricted joint range-of-motion may also limit a user's mobility when performing some activities. Continuous advances in orthotic technologies require clinicians to select from several potentially efficacious interventions for

each patient (Cowan et al., 2012). PRO instruments applicable to orthosis users can be used by clinicians and researchers to measure mobility outcomes and inform the intervention selection process. One such instrument, the Orthotic and Prosthetic Users Survey - Lower Extremity Functional Status (OPUS-LEFS), was designed to measure lower limb functioning of orthosis and prosthesis users (Heinemann et al., 2003). While a single PRO instrument that applies to both prosthesis and orthosis user populations may be practical for clinical use, fundamental differences in body structures, users' functional capabilities, and device purposes suggest that mobility-related experiences may also differ. For example, an orthosis user who experiences ankle joint instability after walking short distances may consider an activity such as walking around a park on a gravel path to be challenging, even with the orthosis; and an activity like carrying a box a short distance in the house to be an easy task, with or without the orthosis. A prosthesis user performing the same activities may be less concerned with changes in functional capacity while walking around a park and would not have an option of carrying a box without using the prosthesis. This example illustrates the potential for orthosis and prosthesis users to have distinct views on their mobility. OPUS-LEFS may also include items (i.e., survey questions) that are more relevant to one type of device user. Items that include personal grooming activities, such as showering, may be more commonly performed with a prosthesis and less often with an orthosis. Additionally, OPUS-LEFS, like many available PRO instruments, was developed as a "static" survey and cannot be customized or shortened for a given application.

Advances in the approaches used to develop PRO surveys have resulted in contemporary instruments that harness the benefits of item-response theory (IRT) methods to produce dynamic item bank instruments (Rothrock et al., 2011). An item bank refers to a set of items calibrated to

an IRT model. Once calibrated, item parameters (i.e., difficulty and discrimination statistics) are used to calculate a score that estimate a person's level of the trait (e.g., mobility). Only a subset of items from the item bank are needed to produce a score, and the items can be administered as brief, targeted short forms. Items can also be administered using computerized adaptive testing (CAT) methods that tailor items to an individual based on their responses (Cella et al., 2007). Item banks are “dynamic” instruments that can be administered using multiple abbreviated formats that do not include all survey items, whereas static instruments are always administered with all items. An item bank designed for orthosis users could include many items relevant to orthotic mobility, allowing for greater flexibility, efficiency, and customization. Short forms can be designed for different groups of orthosis users, providing clinicians with flexible and relevant options for administration. In situations where patient-reported mobility outcomes are considered secondary, a smaller number of items can be used to increase efficiency. Alternatively, when specific items in the bank may be considered to be more relevant than others, a customized short form can be created.

An orthosis user-specific item bank could also benefit the global community of orthotic patient care. For example, a reliable, valid, and responsive item bank may be used to collect and compare data from multiple sites within a country. Further, a PRO item bank can be translated into other languages, assessed for linguistic equivalence, and used to collect orthotic mobility outcomes on a larger, international scale. International collection of PRO data can be a cost-effective method of increasing sample sizes to answer important scientific inquiries (Wild et al., 2009). Measurement of orthotic mobility outcomes along the same metric in different parts of the world may provide insights into the current state of orthotic patient care across many

geographical regions. These applications of an item bank for orthosis users could lead to improvements in patient care on a global scale.

Given the need for a new orthosis user-specific item bank that can measure mobility outcomes of individuals, groups of patients, and regions of the world, this dissertation aimed to (1) explore the construct of mobility from the viewpoint of orthosis users, (2) develop a candidate item bank for orthosis users, and (3) develop and test a process for translating condition-specific item banks into other languages.

## 1.2 SUMMARY OF STUDIES

The overarching goal of this linked-papers dissertation was to investigate the development and future application of a PRO item bank for measuring mobility of lower limb orthosis users. The first study in the dissertation, “Mobility experiences of lower limb orthosis users: a focus group study,” was a qualitative study designed to collect feedback from lower limb orthosis users. The objective of this study was to explore how lower limb orthosis users describe their mobility. The second study in this dissertation, “Initial development of an item bank to measure mobility of lower limb orthosis users,” was a qualitative research effort to develop a candidate item bank to measure lower limb orthotic mobility and was guided by insights gained from the previous study. The objective of this study was to generate candidate items for the new PRO instrument. This study built upon the prior study by incorporating orthosis users’ input into the new survey items. The third study in this dissertation, “Japanese translation and linguistic validation of the Prosthetic Limb Users Survey of Mobility (PLUS-M),” was a language translation and cognitive interview study. The objective of this study was to translate an existing item bank PRO instrument from English to Japanese. In addition to producing a new translation

of a survey instrument, this study explored translation methods that can be used for future application of the new item bank described in the previous study.

### 1.3 ORGANIZATION OF DISSERTATION

This dissertation follows the linked-studies format. Chapter one includes the background and rationale for the research. Chapters two, three, and four are independent studies that were or will be prepared for submission to peer-reviewed journals. Each study is formatted to include the following sections: abstract, introduction, methods, results, discussion, conclusion, and references. Chapter five provides a summary of the dissertation, connections between linked studies, and a preview of related future research efforts.

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Wiklund, I., Chong, L. Y., Von Maltzahn, R., & Cohen, L. (2009). Multinational trials—recommendations on the translations required, approaches to using the same language in different countries, and the approaches to support pooling the data: the ISPOR patient-reported outcomes translation and linguistic validation good research practices task force report. *Value Health*, *12*(4), 430-440.

## Chapter 2. MOBILITY EXPERIENCES OF LOWER LIMB ORTHOSIS USERS: A FOCUS GROUP STUDY

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### 2.1 ABSTRACT

**Purpose:** People with lower limb impairments are often prescribed orthoses to preserve or enhance their mobility. Exploration of mobility experiences common among orthosis users may provide insights into how orthoses, and other mobility aids, are utilized and regarded. The objective of this study was to broadly explore how lower limb orthosis users describe their mobility.

**Materials and methods:** Four focus groups were held online with participants who lived in the U.S. or Canada. Participants had at least six months of experience using an ankle-foot- and/or a knee-ankle-foot-orthosis for one or both legs. All discussions were transcribed and coded.

Thematic analysis was used to identify cross-cutting themes.

**Results:** Participants included 29 orthosis users with a variety of health conditions. Inter-related themes, including personal factors, situations, and assistance were identified as elements that influenced participants' mobility. Participants described a process of modifying their mobility through use and non-use of one or more mobility aids.

**Conclusions:** The current study findings may assist clinicians in developing strategies to optimize orthosis users' mobility in different situations. Experiences described by participants in this study may also help researchers identify aspects of mobility most pertinent to orthosis users and inform development of new outcome measures.

## 2.2 INTRODUCTION

Mobility-related disability, defined as having “serious difficulty walking or climbing stairs,” affects nearly one in seven U.S. adults (U.S. Department of Health & Human Services, 2016; Okoro et al., 2018). Studies suggest that people who identify as having mobility-related disability may also experience loss of independence (Hirvensalo et al., 2000), depressive symptoms (Lampinen & Heikkinen, 2003), lower quality of life (Groessler et al., 2007), and higher mortality rates (Corti et al., 1994; Hirvensalo et al., 2000). Risk factors for developing this type of disability include presence of chronic health conditions (Carroll et al., 2014; Theis et al., 2019; Zhao et al., 2009), limited physical performance capacity (e.g., walking speed slower than 0.8 meters per second, inability to stand on one leg for 5 seconds or longer) (Heiland et al., 2016), and avoidance of environmental barriers (Shumway-Cook et al., 2003). Moreover, regular physical activity—a critical component of rehabilitation interventions (Dean et al., 2011), has been shown to prevent at-risk individuals from developing serious mobility-related disability (Pahor et al., 2014), and slow mobility degradation of those with a disability, thereby improving quality of life (Groessler et al., 2019). For those people at risk, however, increasing physical activity may require greater stability or a higher level of function, facilitated through use of mobility aids.

Mobility aids used for ambulation refer to devices that are applied externally to the lower limbs and those that are held using the upper limbs. Lower limb orthoses, such as ankle-foot orthoses (AFOs), knee-ankle-foot orthoses (KAFOs), and hip-knee-ankle-foot orthoses (HKAFOs), are examples of externally-applied mobility aids designed to support or modify structural and/or functional characteristics of a user’s joint(s) or limb(s) (World Health Organization, 2017). Use of lower limb orthoses has been associated with improvements in

mobility-related outcomes, including increased stride length (Tyson & Thornton, 2001), faster walking speed (De Wit et al., 2004), decreased energy expenditure (Brehm et al., 2007), and improved balance (i.e., reduced postural sway while standing with feet close together) (Teasell et al., 2001; Wang et al., 2019). Hand-held mobility aids can also improve aspects of mobility. Examples include canes, crutches, and walkers that widen a user's base of support and reduce lower limb loads (Batani & Maki, 2005; Laufer, 2003; Suica et al., 2016). Orthoses and other types of mobility aids can be used in combination, due to differences in their modes of use and cumulative effects on users' lower limb function. Consequently, mobility of orthosis users may be influenced by use or non-use of one or more types of mobility aids. For example, an individual may perform a challenging activity using an AFO and a cane simultaneously, and perform other less challenging activities using only an AFO, only a cane, or no mobility aid at all. Thus, orthosis users may uniquely regard mobility as a dynamic experience that can be modified, when needed, using different types of aids. Exploration of this phenomenon may illuminate aspects of mobility most pertinent to orthosis users and inform clinical and research approaches to promoting mobility.

Exploratory inquiries are often well-suited to qualitative research methods. Qualitative studies provide opportunities to better understand a phenomenon (e.g., mobility of an orthosis user). For example, Rosenberg *et al.* (2012) employed in-depth interviews to learn about the influence of environmental barriers on physical activity of people who use assistive devices. Although lower limb orthosis users were not included in the sample, investigators identified themes (e.g., physical barriers such as street crossings and curb ramps) that emerged from experiences shared by participants with a variety of health conditions who used ambulatory and wheeled mobility aids (Rosenberg et al., 2012). Similarly, Hundza, *et al.* (Hundza et al., 2016)

used semi-structured interviews to explore ways in which engaging in physical activity can be facilitated or limited among people with spinal cord injury, stroke, and multiple sclerosis—diagnoses commonly associated with lower limb orthosis use. The investigators reported that barriers to physical activity such as fear of falling and pain were frequently identified by participants with distinctly different health conditions (Hundza et al., 2016). These prior studies demonstrate that people with heterogenous health conditions often share similar mobility-related experiences and suggest that qualitative methods may also be well-suited to studying mobility of people who use lower limb orthoses.

Prior studies have utilized qualitative methods to investigate phenomena experienced by lower limb orthosis users. For example, Yang et al. (2018) conducted semi-structured interviews to explore orthosis users' satisfaction with their devices and identify areas for improvement. The study included people with a wide range of health diagnoses who used AFOs, KAFOs, and HKAFOs. The authors compared feedback from people with health conditions related to nervous system damage to those with musculoskeletal injuries, and found that participants in both groups viewed movement restrictions and durability issues as problems related to walking with an orthosis (Yang et al., 2018). As an alternative to one-on-one interviews, researchers also use focus groups to promote consensus-building through small group discussions (Patient-Reported Outcomes Measurement Information System [PROMIS], 2013). This qualitative methodology can provide a richer understanding of a topic by uncovering a range of opinions (Freeman, 2006; Woodring et al., 2006). Bulley et al. (Bulley et al., 2014) held two focus groups to compare experiences of people with multiple sclerosis who used AFOs to those who used functional electrical stimulation devices. Participants across both focus groups shared experiences of using their AFO or FES devices for specific activities (e.g., vocation, shopping, outdoor ambulation)

and described benefits of use (e.g., reduced effort required for ambulation, increased confidence, and decreased fatigue) common to both types of devices (Bulley et al., 2014). Focus groups also provide opportunities for interaction between group members and encourages discussion that can clarify similarities and differences in opinions, values, or experiences (Freeman, 2006). A study conducted by van der Wilk *et al.* (2018) aimed to identify areas for improvement in AFO design using a single focus group. For example, participants generally appreciated the stability provided by an AFO, but desired greater flexibility in the device in situations like sitting and standing. Despite limitations in the findings from these studies, often due to conducting only small numbers of focus groups, investigators successfully gained insight into the opinions and attitudes of orthosis user participants. Thus, focus groups may be an effective qualitative methodology for exploring mobility experiences of lower limb orthosis users.

Several of the aforementioned studies explored experiences of people who use orthoses, however, they included participants who used limited types of orthoses (Bulley et al., 2014; van der Wilk et al., 2018), participants who had relatively few clinical conditions relevant to orthosis use (Bulley et al., 2014; Hundza et al., 2016), and/or objectives focused on orthotic technologies rather than mobility (Bulley et al., 2014; van der Wilk et al., 2018; Yang et al., 2018). Further research is needed to build upon these previous efforts by exploring perspectives of orthosis users with specific clinical characteristics (e.g., range of orthosis types, diagnosis types, and mobility levels) that better reflect the diversity of patients who are prescribed lower limb orthoses. Focus groups designed to elicit experiences shared by orthosis users may provide important clinical insights into activities perceived as being meaningful by people who use lower limb orthoses. The purpose of this study was therefore to develop an understanding of how mobility is conceptualized and experienced by lower limb orthosis users.

## 2.3 METHODS

### 2.3.1 *Participants*

Adult lower limb orthosis users with chronic health conditions known to affect the lower limbs participated in this focus group study. Purposive sampling was used to include people with different levels of mobility impairment so as to study the wide range of situations that may be affected by use of an orthosis (PROMIS, 2013). Further, individuals with a variety of clinical and demographic characteristics were targeted to ensure that a broad range of experiences and perspectives were included in each focus group. Participants were recruited through flyers displayed in orthotics clinics, online list-serv postings, and social media advertisements. Eligibility was determined through a telephone screening process. Study participants were required to meet the following inclusion criteria: (1) 18 years of age or older; (2) daily or frequent (i.e., most days of the week) use of a lower limb orthosis that extends from the foot to a level above the ankle (i.e., AFO, KAFO, or HKAFO) prescribed for one or both legs, (3) experience using an orthosis for six months or more; (4) agree to have focus groups audio-recorded; and (5) ability to read, write, and understand English. Individuals were excluded from the study if they had a lower limb amputation, as the focus of the current study is on use of orthoses, rather than the combined effects of using orthotic and prosthetics devices. Eligibility criteria aimed to identify people who used types of lower limb orthosis associated with long-term use.

Personal and health-related characteristics commonly found in orthosis users often seen in clinical practice were identified and used to establish recruitment targets. Specifically, attempts were made to enroll at least two participants across all focus groups with each of the following characteristics: (1) regular use of an assistive device (e.g., cane, crutch, walker); (2)

highest completed education level of grade twelve or lower; (3) affirmative response to a screening question indicating a possible cognitive impairment, defined as having trouble remembering, learning new things, concentrating, or making decisions that affect one's everyday life; (4) 65 years of age or older; (5) KAFO user; and history or diagnosis of (6) stroke, (7) spinal cord injury, (8) cerebral palsy, (9) multiple sclerosis, (10) peripheral nerve injury, (11) post-polio syndrome, and (12) Charcot-Marie-Tooth disease. A minimum of 6 and maximum of 10 participants were recruited for each focus group, as recommended for optimal discussion manageability and data quality (Agan, Koch, & Rumrill Jr, 2008); however, number of focus groups and total number of participants were not determined prior to the study, but rather informed by data saturation (PROMIS, 2013; Saunders et al., 2018).

### 2.3.2 *Procedures*

All procedures were approved by the University of Washington Human Subjects Division prior to conducting the study. Interpretive phenomenological analysis (IPA) was employed as a lens through which to explore mobility as it is conceptualized by lower limb orthosis users and to interpret users' experiences related to utilization of their orthoses and other assistive devices. IPA is an approach well suited to the current study, as it can be used to examine understudied concepts and uncover how individuals make sense of their lived experiences (Peat et al., 2019; Smith, 2009). Prior to focus group discussions, participants were asked to complete a brief online survey that included questions about general health, lower limb impairment, use of orthoses and assistive devices, and demographic information. Focus groups were conducted via virtual conferencing (Zoom Video Communications, San Jose, CA) to allow people from multiple locations to participate simultaneously, including local participants who may not have had access to reliable or accessible transportation (Agan et al., 2008). Participants were allowed to join by

video or audio. Each discussion was facilitated by a trained investigator and lasted about two hours. A discussion guide, consisting of open-ended questions, topics, and definitions (PROMIS, 2013), was used to facilitate each focus group (see Table 2.1).

Prior to each focus group discussion, participants received a study information statement and instructions for joining the virtual discussion. At the start of each focus group, the facilitator briefly explained the purpose of the discussion (i.e., to learn about the types of activities people do with an orthosis), laid out expectations of respectful communication, reminded participants they could choose to not answer any question they wished and were free to leave the study at any time, and initiated personal introductions. The facilitator then prompted the group discussion with the first open-ended question. Participants were permitted to freely contribute to the discussion, and the facilitator only provided prompts and clarified comments when needed. Although each focus group began in a similar manner, discussions were permitted to deviate from the discussion guide. Prior to ending each focus group, the facilitator asked several questions to explore the suitability of an existing conceptual mobility framework (Morgan et al., 2020). The framework was initially designed for people who use lower limb prostheses (Hafner, Morgan, Abrahamson, et al., 2016), and conceptualizes mobility as a form of movement performed within a situational context (Morgan et al., 2020). The focus group facilitator also asked participants to consider a proposed definition for mobility, as it pertains to orthosis use, and provide feedback regarding its suitability. Investigators took field notes during discussions and each focus group was audio-recorded and transcribed for analysis by a communications access real-time transcription reporter (PROMIS, 2013). Focus groups were held successively until saturation of data was achieved, meaning that no additional codes were required to identify new ideas or discussion topics that required further exploration (Agan et al., 2008).

Table 2.1 Examples of guiding questions from focus group discussion guide

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Orthosis-related questions

- How does your brace change the way you do everyday activities?
- What kinds of activities are you unable to do without your brace?
- What kinds of activities are just a little easier to do with your brace, but possible to do without your brace?
- What kinds of activities become more challenging with your brace?

Situational questions

- What activities do you do that require you to move quickly?
  - What activities do you do that require you to walk longer distances?
  - What types of terrain do you regularly encounter (grass, gravel, sand, dirt)?
  - How do you move around or over obstacles?
  - How do you carry things while walking?
  - What kinds of distractions do you experience while walking?
  - How do changes in lighting or temperature affect your ability to move around?
- 

### 2.3.3 *Data analysis*

A thematic analysis, guided by IPA methods, was performed (Peat et al., 2019; Smith, 2009). Prior to the study, investigators prepared an initial set of codes expected to apply to discussion topics. Initial codes were informed by the mobility framework and investigators' clinical experience. After each focus group, new codes were added to the original code list and codes that were found to be non-applicable were removed. Two investigators independently reviewed transcripts following each focus group and applied codes to excerpts using Dedoose qualitative analysis software (SocioCultural Research Consultants, LLC, Manhattan Beach, CA). Coding determinations were reconciled, and coded excerpts were organized and reviewed. Themes from the first discussion were identified by grouping data into topics and reviewing alongside coded transcripts. Prior to analysis of subsequent discussions, investigators bracketed previous themes and approached each new focus group transcript with "open and fresh eyes," so

as to recognize and set aside assumptions and seek to understand participants' experiences (Peat et al., 2019). The conceptual framework was used to organize codes related to mobility into groups that corresponded to situational contexts (e.g., walking distances, transitions with external loads, walking with ambient conditions). After repeating the process for each discussion, investigators sought to identify thematic connections and patterns across all focus groups that seemed to embody common experiences shared by participants.

## 2.4 RESULTS

A total of 29 lower-limb orthosis users participated in one of four virtual focus groups held between November 2018 and February 2019. Three focus groups included seven participants and one group included eight. Orthosis users with a variety of demographic and health-related characteristics were included in each group (described in Table 2.2). Participants included both men (38%) and women (62%), who spanned ages ranging from 27 to 77 years (median: 48 years, mean: 50 years). The most frequently reported health diagnosis related to orthosis use was spinal cord injury ( $n = 6$ ), followed by peripheral nerve injury ( $n = 5$ ) and stroke ( $n = 3$ ). Just over half of participants used unilateral AFOs ( $n = 15$ ), while other participants used bilateral AFOs ( $n = 8$ ), unilateral KAFOs ( $n = 3$ ), bilateral KAFOs ( $n = 2$ ), and both an AFO and KAFO ( $n = 1$ ). Participants reported orthosis use experience ranging from 2 to 65 years (median: 10 years, mean: 17 years). Average daily orthosis use ranged from 1 to 17 hours (median: 13 hours, mean: 12 hours). The majority of participants ( $n = 25$ ) used their brace(s) for a large portion of the day each day (8 hours or more per day), while four participants used their brace(s) during a smaller portion (less than 8 hours per day).

Investigators preemptively identified 15 initial primary codes. Following the first focus group, the initial codes were reorganized and those that appeared to be less applicable were

flagged or removed. New codes were added to identify discussion topics that had not been included initially. This process resulted in seventeen primary codes and over 40 secondary codes to further categorize the data. This process of reorganizing, removing, and adding codes was repeated after each focus group discussion. Nine codes were added and one code was removed following the second focus group; four codes were added and one was removed after the third group, and no new codes were added or removed after the fourth focus group, indicating that data saturation (i.e., the extent to which new theoretical insights were identified) had been achieved (Saunders et al., 2018). Several overarching themes were identified that reflected mobility experiences shared by focus group participants, including the effects of personal attributes, situations, and mobility aids. Representative quotations are denoted by participant number and brief details (e.g., sex, age, affected leg(s) and orthosis type). Additional characteristics are listed in Table 2.3 and supplementary quotations can be found in Table 2.4.

#### 2.4.1 *Theme 1. Personal attributes affect my mobility*

Personal attributes, including an individual's physical, psychological, and emotional characteristics, were identified across focus groups as factors that affect mobility of lower limb orthosis users. Participant experiences related to this theme were further characterized by the following subthemes: (1) health conditions and their presentations; (2) pain and fatigue; (3) fear and confidence; and (4) self-motivation and emotional responses.

##### 2.4.1.1 *My health condition and the way it presents affects my mobility*

Participants shared experiences of how their mobility was affected by their health condition and functional impairments. Most participants described chronic impairments or mobility limitations resulting from acquired health conditions. One area of impact was loss in flexibility to move different ways, such as in the ability to move at different speeds:

*[Primary lateral sclerosis], it's characterized by a stiffening of all my muscles, so I am slow no matter what I do. (Participant 2-3: male, age 77, left AFO user)*

Another concern was progressive worsening of their health conditions leading to steady declines in mobility. For example, a participant with a spinal cord injury shared:

*When I first got [foot] drop, I was able to still do the treadmill normally and walk outside for exercise, [but] that has definitely deteriorated. (Participant 1-5: female, age 55, right AFO user)*

The same individual also commented on how fluctuations in her symptoms might lead to mobility being unpredictable:

*[Walking on] gravel can go either way. It depends on whether you are having a good or a bad day. (Participant 1-5: female, age 55, right AFO user)*

#### 2.4.1.2 *Pain and fatigue affect my mobility*

Other topics commonly discussed across focus groups were the effects of pain and fatigue on mobility. Participants often linked pain and fatigue to decreased ability to walk long distances and sustain movement. Sometimes pain and fatigue occurred together:

*[When I walk] a block or two from my home, it's a very short [distance], but my hip starts to go and my knee starts to go. It gets really painful and very fatiguing. (Participant 3-6: male, age 45, left AFO user)*

Pain and fatigue each also acted separately to impact mobility. Sometimes pain occurred right away, such as for one participant who described how being on her feet for a brief period was challenging:

*The leg with the AFO on it, I don't like to stand on it very long. It's painful to do it. (Participant 1-2: female, age 41, right AFO user)*

In other cases, fatigue was also singled out as a factor that limited mobility, even when walking short distances:

*Without my brace, fatigue will hit me really, really fast. I will be exhausted just because I walked across the house. (Participant 1-4: female, age 61, left AFO user)*

#### 2.4.1.3 *Fear and confidence affect my mobility*

Participants often discussed their fear of falling, as well as confidence in their abilities, as factors that affect mobility. Many of the participants described fears related to specific activities or situations. One person described his apprehension when descending hills and stairs:

*For me, going downhill and going down stairs is tricky. It's kind of like a fear of falling down. (Participant 4-3: male, age 29, bilateral AFO user)*

Participants also described how greater confidence in some situations than in others might cause them to alter how they negotiated environmental obstacles. For example, when faced with the options of using stairs or an escalator, one participant explained his choice:

*I am more confident that I can safely climb stairs than deal with an escalator.  
(Participant 4-5: male, age 48, left AFO user)*

A common discussion topic across all focus groups was how using an orthosis minimized fears related to falling. A participant who used KAFOs for both legs shared her experience:

*[My KAFOs] make it to where I don't worry about falling down and hurting myself.  
(Participant 2-6: female, age 38, bilateral KAFO user)*

#### 2.4.1.4 *My self-motivation and emotional state affect my mobility*

Several participants discussed scenarios when motivation or emotions affected their mobility. Sometimes the relationship between mood and mobility appeared fairly

Table 2.2. Focus group participant characteristics

	Group 1 n=7	Group n=8	Group 3 n=7	Group 4 n=7	Total n=29
<b>Sex</b>					
Female	4	6	6	2	18
Male	3	2	1	5	11
<b>Age</b>					
18 to 29	1	1	0	2	4
30 to 44	3	2	3	0	8
45 to 64	2	3	3	4	12
65 & over	1	2	1	1	5
<b>Race or ethnicity</b>					
Non-Hispanic White	6	5	7	6	24
Non-Hispanic Asian	0	2	0	1	3
Non-Hispanic Black	1	0	0	0	1
Hispanic or Latino	0	1	0	0	1
<b>Education level</b>					
High school diploma or equivalent	0	0	0	2	2
Some college or technical degree	2	3	1	1	7
Bachelor's degree	2	1	4	3	10
Master's or doctoral degree	3	4	2	1	10
<b>North America region</b>					
Western U.S.	3	8	6	4	21
Southern U.S.	0	0	1	2	3
Midwestern U.S.	1	0	0	0	1
Northeastern U.S.	0	0	0	1	1
Eastern Canada	3	0	0	0	3
<b>Health diagnosis</b>					
Spinal cord injury	3	1	2	0	6
Lower limb injury	1	1	2	1	5
Cerebral vascular accident	0	0	0	3	3
Charcot-Marie-Tooth disease	0	3	0	0	3
Post-polio syndrome	1	1	0	0	2
Cerebral palsy	0	1	0	0	1
Congenital limb difference	1	0	0	0	1
Multiple sclerosis	0	0	0	1	1
Traumatic brain injury	0	0	1	0	1
Ehlers-Danlos syndrome	0	0	1	0	1
Arthrogryposis	0	0	0	1	1
Guillain-Barre syndrome	0	0	0	1	1
Transverse myelitis	1	0	0	0	1
Diabetic neuropathy	0	1	0	0	1
Primary lateral sclerosis	0	0	1	0	1
<b>Orthosis type</b>					
Unilateral ankle-foot orthosis (AFO)	4	3	3	5	15
Bilateral ankle-foot orthoses (AFOs)	1	3	3	1	8
Unilateral knee-ankle-foot orthosis (KAFO)	2	1	0	0	3
Bilateral knee-ankle-foot orthoses (KAFOs)	0	1	0	1	2
AFO for one leg, KAFO for the other leg	0	0	1	0	1

Table 2.3. Key individual characteristics of participants

ID	Age (years)	Sex	Race or ethnicity	State/ provinc	Health condition	Orthosis type	Daily use (hours)	Total use (years)	Other aid(s)	LEFS score (out of 80)
1-1	40	Female	White	ON	Spinal cord injury	Right KAFO	9	10	Walker	38
1-2	41	Female	White	CO	Congenital anomaly	Right AFO	15	41	Walker, WC	23
1-3	27	Male	White	ON	Peripheral nerve injury	Right AFO	14	3	None	70
1-4	61	Female	White	WA	Transverse myelitis	Left AFO	16	44	Walker	30
1-5	55	Female	White	OH	Spinal cord injury	Right AFO	14	8	None	53
1-6	67	Male	White	WA	Spinal cord injury	Bilateral AFO	9	2	Walker	15
1-7	37	Male	Black	ON	Post-polio syndrome	Right KAFO	13	29	None	64
2-1	39	Female	White	UT	Charcot-Marie-Tooth	Bilateral AFO	16	19	Cane	38
2-2	65	Male	White	WA	Charcot-Marie-Tooth	Right AFO	14	41	Walker	44
2-3	77	Male	White	NV	Diabetic neuropathy	Left AFO	10	9	Cane	46
2-4	29	Female	Asian	WA	Spinal cord injury	Right AFO	16	6	Crutches	46
2-5	58	Female	White	WA	Peripheral nerve injury	Bilateral AFO	8	7	Canes	31
2-6	38	Female	White	WA	Cerebral palsy	Bilateral KAFO	6	11	Crutches	28
2-7	64	Female	Hispanic	WA	Charcot-Marie-Tooth	Bilateral AFO	14	15	Canes	39
2-8	60	Female	Asian	WA	Post-polio syndrome	Left KAFO	15	23	Cane	44
3-1	61	Female	White	TN	Peripheral nerve injury	Bilateral AFO	17	9	None	36
3-2	39	Female	White	WA	Spinal cord injury	Left KAFO	1	6	Walker	41
3-3	62	Female	White	CO	Primary lateral sclerosis	Bilateral AFO	12	16	Walker, WC	32
3-4	34	Female	White	WA	Spinal cord injury	Bilateral AFO	15	3	Walker, WC	42
3-5	32	Female	White	WA	Peripheral nerve injury	Right AFO	10	11	None	43
3-6	45	Male	White	CO	Traumatic brain injury	Left AFO	14	18	None	25
3-7	65	Female	White	OR	Ehlers Danlos syndrome	AFO and KAFO	10	65	Crutches	45
4-1	48	Male	White	WA	Arthrogryposis	Bilateral KAFO	13	48	Crutches	39
4-2	47	Male	White	TX	Cerebral vascular accident	Right AFO	6	2	None	36
4-3	29	Male	Asian	WA	Guillain-Barre syndrome	Bilateral AFO	12	7	None	54
4-4	76	Female	White	WA	Cerebral vascular accident	Right AFO	14	7	Cane	30
4-5	48	Male	White	WA	Cerebral vascular accident	Left AFO	3	2	Cane	47
4-6	64	Female	White	ME	Multiple sclerosis	Left AFO	8	11	Cane	37
4-7	28	Male	White	TX	Peripheral nerve injury	Right AFO	14	8	None	59

*Abbreviations.* ID: focus group number, followed by participant number, WC: Wheelchair or scooter, LEFS: Lower Extremity Functional Scale (higher scores indicate higher levels of physical functioning)

straightforward, as in this example of a participant who attributed how far he walked to how he felt at the time:

*I'm back to a point where I can walk longer distances, depending on my mood and how well I feel. [I'm] enjoying just what I feel like doing (Participant 2-3: male, age 77, left AFO user)*

However, there were more complex situations in which the orthoses might be a catalyst for the user to be active:

*I'm finding [my braces] stimulate me or motivate me to get up and do more if I put them on right away in the morning, otherwise I can be lazy and just stay in my chair.  
(Participant 2-5: female, age 58, bilateral AFO user)*

#### 2.4.2 Theme 2. Situations affect my mobility

Situations describe environments or scenarios in which a person moves, or the immediate requirements needed to perform an activity. Discussion topics related to this theme were characterized by the following subthemes: (1) terrain and obstacles; (2) ambient conditions; and (3) attentional demands and multitasking.

##### 2.4.2.1 Different types of terrain and obstacles affect my mobility

Participants across all focus groups discussed terrain and obstacles they encountered that affected their mobility. Several different types of surfaces were problematic:

*For me, the worst surface to walk or run on would be loose rocks or large rocks. Carpet, grass, and things like that are still difficult to move on. So, obviously, polished floors, wood floors, those are the easiest. (Participant 3-6: male, age 45, left AFO user)*

Elevation changes such as ramps, hills, and stairs were also problematic:

*Any type of slope, going down, going up, regardless of how much, [even] 10 or 15*

*degrees, I have to be really careful. So [flat] ground is the best for me. Elevator, yes. No stairs. No escalator. (Participant 2-8: female, age 60, left KAFO user)*

Participants also discussed static (i.e., stationary) and dynamic (i.e., moving) obstacles they may need step over or navigate around. Static obstacles mentioned by participants included clothing, charging cables, and toys on the floors of homes, as well as garden hoses, puddles, and cracked pavement outside their homes or in their communities. One participant, a teacher, described how her concern about such obstacles was significant enough that it impacted where she felt she was able to work:

*I will never work in a kindergarten class at the elementary school because there are too many things on the floor. I think if I really have to, I can step over things like [toys on the floor], but it feels very unsteady. (Participant 1-1: female, age 40, right KAFO user)*

Dynamic obstacles, such as grocery carts, children, and crowds of people were also mentioned in each focus group as being problematic. A common example was pets:

*I have two cats and sometimes they get underneath my feet and throw my balance off. (Participant 2-7: female, age 64, bilateral AFO user)*

#### 2.4.2.2 *Ambient conditions affect my mobility*

Participants discussed situations where ambient conditions, including temperature and lighting, affected their mobility. Several participants commented that extreme temperatures greatly affect mobility, while others did not experience these effects. Those who experienced mobility changes attributed their adverse outcomes like increased muscle spasticity, poor circulation, and slower walking speed to cold weather, and excessive perspiration, skin irritation, and decreased balance to hot weather. These situations, in turn, created complications with wearing orthoses:

*Summertime is kind of awful because it's just too hot to wear braces. It gets sweaty, so that's kind of a pain. (Participant 2-1: female, age 39, bilateral AFO user)*

A KAFO user described negative aspects of both cold and hot temperatures:

*I think hot weather is bad because there's just more perspiration, so it's less comfortable to be in these stifling braces when it's really hot or humid. And then conversely, if it's really cold, then the brace material itself cools down and the metal rods that are up and down my braces get cold. So it's a little bit like Goldilocks, [I ideally want] sort of a neutral [temperature] (Participant 4-1: male, age 48, bilateral KAFO user)*

Most participants reported that lighting affected their mobility. For some participants, the impact of lighting depended on the familiarity of where they were:

*Walking in the dark, if it's in my home, I have pretty well memorized and know what to anticipate, but going out to a parking lot, that can be a challenge. (Participant 2-2: male, age 65, right AFO user)*

Others were more affected by poor lighting in any situation:

*If I can't see what's around me, then I have a terrible time with it. (Participant 2-7: female, age 64, bilateral AFO user)*

#### 2.4.2.3 *Attentional demands and multitasking affect my mobility*

Most participants reported situations that demanded divided attention or multi-tasking negatively impacted their mobility. A common example was walking while talking to others. For this participant, the orthosis helped, but did not entirely resolve the problems:

*When I have the brace, I can more easily have conversations with other folks around me or do something else. Now, what I have found I struggle with sometimes is looking in a*

*different direction while I'm walking, and especially looking up. That can throw off my balance quite a bit. (Participant 4-5: male, 48, left AFO user)*

Another common example of multi-tasking was walking while performing activities that required use of one or both hands. For example, one person described how using an assistive device while walking limited her ability to use her hands for anything else while walking:

*Because I need [walking sticks] to walk when I'm outside, I can't really walk and use my phone, or walk and do anything besides walk. (Participant 3-4: female, age 34, bilateral AFO user)*

Even if participants needed only one hand free to perform an activity, they had to consciously monitor which hand to keep available, as illustrated by this participant describing her strategies for carrying groceries:

*I do tend to leave one hand open when I'm carrying groceries. I may put five bags in the other hand. I keep one hand open to grab on to a railing if there are any steps I need to go up. (Participant 1-5: female, age 55, right AFO user)*

#### 2.4.3 Theme 3. Mobility aids affect my mobility

Mobility aids, including lower limb orthoses, handheld assistive devices (e.g., canes, crutches, and walkers), and even fixed supports (e.g., walls, furniture, and handrails) were discussed as key factors affecting mobility. Participants discussed the variety of effects that these forms of assistance had on their mobility. Discussions about mobility aids were characterized by the following subthemes: (1) benefits of using mobility aids and consequences associated with not using them; (2) using mobility aids does not always provide benefit and can sometimes be a detriment; and (3) mobility can be optimized by considering the trade-offs associated with using or not using different mobility aids.

2.4.3.1 *Mobility aids can enhance my mobility and if I do not use them, I experience consequences*

Participants across focus groups discussed general and specific ways in which mobility aids affected their mobility. For example, some participants commented on a general improvement in mobility attributed to orthosis use:

*Without the AFO, I don't think I would have as good a health. I think it's helped me stay motivated to stay physical and keep my mobility and my muscle tone. (Participant 2-5: female, age 58, bilateral AFO user)*

Other participants described a specific situation or activity for which an orthosis enhanced their mobility. One such participant described his ability to run long distances with an orthosis.

*I'm more the athletic type. Actually, the last couple of years I have completed 21-km [half-marathon] distance [run]. That definitely would not have been possible without my [AFO]. (Participant 3-6: male, age 45, left AFO user)*

In addition to the benefits of mobility aid use, several people discussed the consequences of not using mobility aids. For example, one person described how her orthosis prevents pain and injury:

*When I'm not wearing the brace, my leg is out of alignment completely and my foot is pointing sideways to avoid my knee buckling and [to keep] me [from] falling down due to [my] weak quadriceps. With the brace, my leg's in proper alignment and I don't have nearly as much pain. (Participant 1-1: female, age 40, right KAFO user)*

Another participant recalled a consequence he experienced when not wearing his orthosis:

*I did fall once and it was [when I was] standing without AFOs and I tried to walk. And that's when I decided I wasn't going to try walking without my AFOs unless absolutely necessary. (Participant 1-6: male, age 67, bilateral AFO user)*

#### 2.4.3.2 *Mobility aids do not always enhance my mobility and can sometimes limit my mobility*

Several participants commented that, despite the generally beneficial effects of mobility aids, their ability to perform some activities are not enhanced when aids are used. For example, one person mentioned that using an orthosis does not affect her ability to talk on a cell phone while walking:

*I can walk and talk on the phone. But I'm assuming I'm able to do it with and without the brace, because nothing sticks out of my mind that like: Oh, gosh, I can't walk and text when I don't have a brace on, so I must be able to do it both ways. (Participant 1-5: female, age 55, right AFO user)*

Participants also shared experiences where mobility aids hindered their mobility. Challenges to mobility due to use of mobility aids were often due to restrictions in joint range of motion when moving with an orthosis:

*It's hard if I want to squat down on the ground to get something, because the AFOs lift my heels up and then I'm just sort of like bouncing on my toes and I usually fall forward, but if I'm barefoot, I can squat down on the ground and my ankle's able to flex so it's a lot easier. (Participant 3-4: female, age 34, bilateral AFO user)*

Handheld mobility aids were also described as negatively affecting mobility in situations:

*If I carry a bag with my forearm sticks, [while] walking, it has to be very light, otherwise the bag swings and hits my cane out from underneath me. (Participant 2-5: female, age 58, bilateral AFO user)*

#### 2.4.3.3 *There are trade-offs to using mobility aids, so I make decisions to optimize my mobility*

Participants in this study described their decision-making process for selecting mobility aids for different situations. This process required individuals to consider their own personal attributes and the situation in which they expected to be, in order to determine the most beneficial mobility aid or combination of mobility aids. One participant described a scenario where he used different mobility aids depending on the distance he expected to walk.

*I can do a good mile to mile and a half (with just my KAFO), but if I'm going to go walking farther, I use my two Lofstrand crutches and I'm a heck of a lot faster.*

*(Participant 3-7: female, age 65, right AFO and left KAFO user)*

Participants also described the need to plan ahead to determine availability of fixed supports, such as handrails, countertops, and close proximity to walls, in a given situation. Another participant described instances in which she chose to use fixed objects over walking sticks:

*I use walking sticks when I have [my AFOs] on, unless I'm in the kitchen. Then, I can kind of ricochet off of things as I move around (Participant 2-5: female, age 58, bilateral AFO user)*

Other participants described a process of comparing strengths of different of mobility aids for specific situations:

*For me the challenge is getting [my walker] through rocks. For the AFOs, it's harder to do ramps and any kind of elevation because my left ankle is [fixed] in place (Participant 3-3: female, age 62, bilateral AFO user)*

Other participants described specific strategies they used to perform activities, based on their prior experiences and daily routines:

*Well, I use different canes for different things. I use the four-prong cane around the house because it's really stable. For going out shopping, I use a compact cane that has a foot on it, so it stands up...I can put the cane down and get things into the grocery cart and then pick the cane up without it falling over. For walking, like going to the beach, I use a regular single [point] cane. (Participant 4-4: female, age 76, right AFO user)*

Finally, a few participants who had access to multiple types of orthoses discussed their decisions related to choosing different devices for different activities:

*In some cases, the flexible kind [of AFOs] are very good for mobility and [walking] more distance. The more static, plastic type of AFOs are a little bit better for stability and balance. (Participant 2-2: male, age 65, right AFO user)*

## 2.5 DISCUSSION

The opinions, attitudes, and experiences shared by focus group participants in this study provide insight into elements, including personal attributes, situations, and use of mobility aids, that influence mobility and contribute to personal decisions about how different activities are approached. Findings of this study are consistent with and build upon previous qualitative research efforts involving lower limb orthosis users. For example, in the semi-structured interview study conducted by Yang et al. (Yang et al., 2018), investigators described factors that influenced orthosis use, including a person's health condition symptoms, their individual

activities of daily living (IADLs), and their orthosis type (i.e., AFO, KAFO, or HKAFO)(Yang et al., 2018). While the current study also describes participants' decisions related to orthosis use, the aim of study—to gain an understanding of how mobility is conceptualized by lower limb orthosis users, was broader in scope. This approach allowed participants to discuss the variety of factors that affected their mobility, including use of mobility aids other than orthoses. Interestingly, factors identified by Yang *et al.* as those that influence orthosis use (i.e., symptoms, IADLs, and orthosis type) align well with the sub-topics of themes identified in the current study (i.e., my health condition and the way it presents affects my mobility; different types of terrain and obstacles affect my mobility; and mobility aids can enhance my mobility and if I do not use them, I experience consequences). Thus, findings from the current study are generally consistent with the previous study and may provide additional insights due to its broader aim.

Participants in the current study also discussed activities for which mobility aids enhanced, did not enhance, and even limited their mobility. Walking outdoors on level ground was an example of an activity most participants reported as being enhanced through use of a mobility aid. Previous studies, conducted by Yang *et al.* (2018) and van der Wilk *et al.* (2018) reported activities orthosis users perceived to be important. Findings of these studies align well with findings of the current study, as walking was an activity ranked as highly important and reported as commonly performed while using an orthosis. Several participants in the current study provided examples of activities, including walking up or down hills, and moving around one's home, that were less affected by use of a mobility aid. They also described movements, including squatting and getting up from the floor to a standing position, that were often restricted by mobility aids. Similarly, participants in the van der Wilk *et al.* (2018) study identified

Table 2.4. Themes and subthemes identified from analysis, and examples of representative quotations

<i>Theme</i>	<i>Subtheme</i>	<i>Exemplary quotation</i>
Personal attributes affect my mobility	My health condition and the way it presents affect my mobility	<i>I was paralyzed January of 2017 and have slowly regained some ability to stand and walk with a walker, and the AFO is a key ingredient to keeping my feet so the toes don't drag, because I don't have any ankle [strength] at all. (Participant 1-6: male, age 67, bilateral AFO user)</i>
		<i>For me, with Charcot-Marie-Tooth disease, I have to lift my knees so my foot clears the floor, because of the drop foot. I also noticed that if I have no support at all, including the AFO, I have to use my arms for balance and put my arms out to my sides. (Participant 2-7: female, age 64, bilateral AFO user)</i>
	Pain and fatigue affect my mobility	<i>Without the brace on, I wouldn't be leaving the house, or wouldn't be working, or wouldn't be even pleasant to be around [due to] the level of pain and fatigue from having to limp around until my ankle collapses. (Participant 1-2: female, age 41, right AFO user)</i>
		<i>I [walk] half a mile with comfort and, longer distances, when needed for a hike or long walk. But it's usually then I'll pay for it in some sort of pressure sore or something. (Participant 4-1: male, age 48, bilateral KAFO user)</i>
Fear and confidence affect my mobility	Fear and confidence affect my mobility	<i>I think for me a lot of it is walking safely and with confidence outside. Around the apartment is one thing because I know where everything is, and walls are close enough that I could lean against them if need be. But outside I need the extra safety margin. I could probably get by without it, but it would be high risk and I really don't want to fall and hit my head. (Participant 4-5: male, age 48, left AFO user)</i>
		<i>To take a hike somewhere, even a short hike on a straight path, that's extremely difficult for me and it's the fear of falling that prevents me from doing that kind of thing. (Participant 2-7: female, age 64, bilateral AFO user)</i>
Self-motivation and emotions affect my mobility	Self-motivation and emotions affect my mobility	<i>When I'm walking without my brace, it's...very tense, and I don't want to talk to other people. I don't want to be around them even. (Participant 1-2: female, age 41, right AFO user)</i>
		<i>When I'm really motivated and I'm doing Pilates, going to physical therapy, and working on my strength and balance, I very much trust my balance a lot more with my AFO. (Participant 3-1: female, age 61, bilateral AFO user)</i>

<i>Theme</i>	<i>Subtheme</i>	<i>Exemplary quotation</i>
Situations affect my mobility	Different types of terrain and obstacles affect my mobility	<i>Anything that isn't a real level, hard-packed surface is difficult. I slow down even for mud puddles and things on the trail. (Participant 4-4: female, age 76, right AFO user)</i>
		<i>The worst surface to walk on or run on would be loose rocks or large rocks. I actually snapped one of my AFOs because my ankle went over the side of a rock and just snapped it. Carpet, grass, things like that, are still difficult to move on. Obviously polished floors and wood floors are the easiest. (Participant 3-6: male, age 45, left AFO user)</i>
		<i>We have quite a few uneven sidewalks, and even with the KAFOs or with bigger AFOs, there are times where I still stumble if there's a pothole.. (Participant 2-6: female, age 38, bilateral KAFO user)</i>
Ambient conditions affect my mobility		<i>If the weather is really cold, so I had like bad speed, bad posture, and stuff like that. Maybe because of the area I'm from, it's quite hot over there, so if the weather is a bit warmer, I feel like more blood circulation in my legs and stuff like that, so I feel like more energy and I feel more control. (Participant 4-3: male, age 29, bilateral AFO user)</i>
		<i>Going into a dark room or coming into a dark house, if it's my home, I have it pretty well memorized, you know, what to anticipate, but going out to a dark parking lot, that can be a challenge. (Participant 2-2: male, age 65, right AFO user)</i>
		<i>Walking around in the dark is very difficult, especially [because] I don't really know where my foot is in relation to where I'm walking. It is just coming along with me. So, if I can't see where I'm going, I tend to kick a lot of things or swing my foot into them. (Participant 3-6: male, age 45, left AFO user)</i>
Attentional demands and multitasking affect my mobility		<i>Even with [AFOs]on, I have to be very aware of where I'm stepping. If I'm going to step on something uneven, I really need to be aware spatially or I will go down really fast really hard. (Participant 2-1: female, age 39, bilateral AFO user)</i>
		<i>Using [my AFO] helps me do multiple things at one time, [like] carrying kids, diaper bags, talking on the phone, cooking dinner while stepping over dogs. (Participant 3-6: male, age 45, left AFO user)</i>
		<i>I have to be pretty focused on just walking without any distractions, so there's nothing else really that I'm doing during that time. There's no phone or anything really that I can be doing while walking. (Participant 3-2: female, age 39, left KAFO user)</i>

<i>Theme</i>	<i>Subtheme</i>	<i>Exemplary quotation</i>
Mobility aids affect my mobility	Mobility aids can enhance my mobility and if I do not use them, I experience consequences	<i>When I don't use AFOs I get tired. [I walk] a mile, mile and a half, and I feel a lot of pain. But with the AFOs, I can go even five miles and I still don't feel tired. And I can do activities like hiking, sailing, and skiing, but to a very limited amount. (Participant 4-3: male, age 29, bilateral AFO user)</i>
		<i>I couldn't really walk at all without my AFO. I can maybe go from the bedroom to the bathroom and I use a walker with the AFO. And without it, my ankle would start hurting. I would have to move very, very slowly and try to pick my foot up each time. (Participant 1-4: female, age 61, left AFO user).</i>
		<i>I used to walk inside the house [without my KAFO], but I can no longer do that. So, first thing in the morning, I just put it on and, if I go to shower, I just take it before I go to shower and put it on after the shower, and it has given me lots of strength, endurance, so I can do whatever I need to do, and it's been wonderful to have that. (Participant 2-8: female, age 60, left KAFO user)</i>
Mobility aids do not always enhance my mobility and can sometimes limit my mobility	Mobility aids do not always enhance my mobility and can sometimes limit my mobility	<i>I can't go to a place where there are just high stools to sit on because you can't bend your knee very far...I'm more limited in where I can sit and where I can go depending on, how that adapts to having this big awkward brace. (Participant 3-7: female, age 65, right AFO and left KAFO user)</i>
		<i>With stiff AFOs, going downhill is trickier because you have to bend in a way so as not to fall [forward] (Participant 4-3: male, age 29, bilateral AFO user)</i>
		<i>Walking is definitely faster with the brace going long distances, but for short distances it can be cumbersome. (Participant 1-1: female, age 40, right KAFO user)</i>
There are trade-offs to using mobility aids, so I make decisions to optimize my mobility	There are trade-offs to using mobility aids, so I make decisions to optimize my mobility	<i>I started leaving a second cane upstairs, because with only one functional hand not on the handrail, carrying anything was really tough, so I just had a cane for downstairs and a cane for upstairs. (Participant 4-5: male, age 48, left AFO user)</i>
		<i>If I have a brace on, I can get away with going up and down holding on to one railing. If I don't have a brace on, I really try to hold on to a railing or handrail on each side. (Participant 1-5: female, age 55, right AFO user)</i>
		<i>Because I need the poles to walk when I'm outside, I can't really talk on the phone or anything else if I'm walking [even with my AFOs]. But the braces do help if I am standing in the kitchen and I walk around the kitchen without the poles and cook dinner and everything else. (Participant 3-4: female, age 34, bilateral AFO user)</i>

activities, such as walking down slopes, squatting, and getting up from the floor, performed while using an AFO as less important. A notable difference between the current and previous studies that involved orthosis users was the inclusion of opinions surrounding mobility aids that participants used in addition to their orthoses (i.e., canes, crutches, walkers). The added insight into how participants use handheld mobility aids may provide a more comprehensive picture of orthosis users' mobility.

### 2.5.1 *Mobility experiences and a decision-making process unique to orthosis users*

People who use lower limb orthoses and have sufficient upper limb strength may have opportunities to modify their mobility through use of orthoses only, use of one or two handheld mobility aids only, or simultaneous use of orthoses and handheld mobility aids. In a similar manner, people who have experienced lower limb loss due to an amputation or congenital limb difference may be able to use prostheses only, handheld mobility aids only, or a both devices simultaneously. Hafner *et al.* (Hafner, Morgan, Abrahamson, & Amtmann, 2016) used focus groups to explore mobility of lower limb prosthesis users and identified themes (i.e., individual characteristics, forms of movement, and environmental situations) that partially align with themes identified in the current study. However, a major difference between these device user populations is the degree of mobility maintained without use of a prosthesis versus an orthosis. Prosthesis users may have some ability to hop on a single leg but are unable to ambulate without use of a prosthesis. Conversely, many orthosis users maintain a degree of mobility without their orthosis and are still able to ambulate. This important distinction adds complexity to orthosis users' decision-making processes. These processes were made apparent when study participants described their daily routines and planning strategies. For example, participants described using no mobility aids in their home, their orthosis in their yard, and simultaneous use of their orthosis

and cane when they were out in the community. Others shared experiences of keeping canes in different rooms of their homes, using different combinations of mobility aids for specific activities, and using mobility aids primarily as a warning to others in crowded places (refer to Table 2.4). These experiences shared by participants indicate that themes identified from the qualitative analysis often overlap, and mobility of orthosis users can be affected differently by combinations of personal attributes, situations, and available mobility aids (see Figure 2.1). Thus, mobility of orthosis users is somewhat unique from other clinical populations due to the complex nature of the decision-making process surrounding use of different assistive technologies.

### 2.5.2 *Implications for clinical care*

Provision of an orthotic intervention is often a coordinated effort between rehabilitation specialists, including orthotists, physical therapists, and physiatrists. Candidates for lower limb orthoses include people with different health conditions and functional deficits, requiring clinicians to tailor treatment plans to each patient. As clinicians focus on the design of an orthosis, they may be less aware of situational factors that influence a patient's mobility, and the potential benefits of using other mobility aids (i.e., cane(s), crutch(es), walker) with or without the orthosis. These situations and decisions about whether to use or not use mobility aids were described by participants across all focus groups in the current study. Participants shared experiences of selecting different mobility aids for a variety of activities and scenarios, suggesting that people who receive lower limb orthoses may benefit multiple types of aids and pre-planned strategies for selecting aids in different situations (see Figure 2.1).

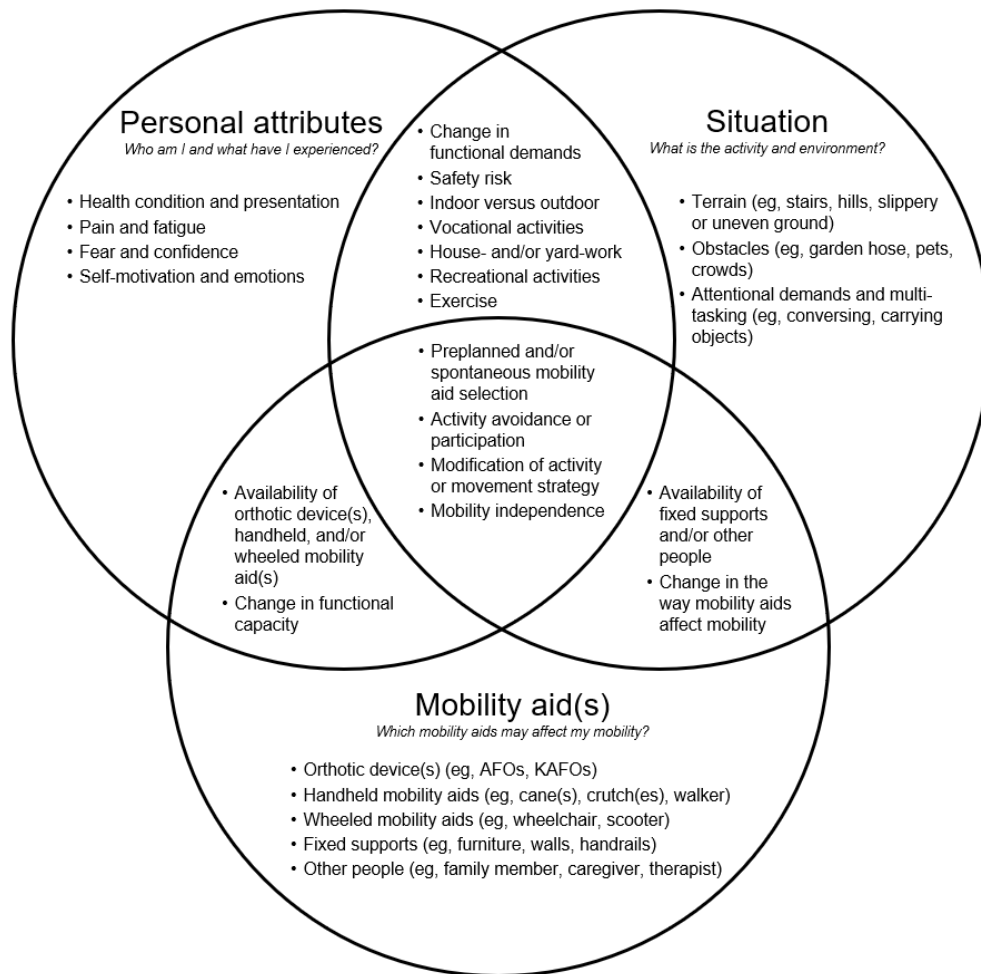


Figure 2.1. Venn diagram visualization of the intersections between personal attributes, mobility, and situations that contribute to mobility of orthosis users. *Note: this figure was not included in the manuscript submitted for publication.*

The intersecting themes of this study align well with an existing conceptual model designed to aid clinicians in selecting assistive device interventions for patients. The Human Activity-Assistive Technology (HAAT) model, was designed to guide evaluation and prescription by assisting clinicians to identify an optimal assistive device for an individual (Cook & Hussey, 2002). The HAAT model includes the following four components: the human, the activity, the assistive technology, and the context. The model describes an “assistive technology

system” in terms of a person using a device to accomplish a specific task in a given environment (Lenker & Paquet, 2003). HAAT developers advise clinicians to consider all four components to identify a suitable device for a patient (Cook & Hussey, 2002). Clinicians can apply the conceptual model by identifying an activity, the context in which it will be performed, and the functional abilities required by the individual to perform the activity. The gap between a person’s functional abilities without a mobility aid and the requirements of the activity can help the clinician identify the appropriate device(s) (Lenker & Paquet, 2003). A distinction between the findings of the current study and the HAAT model is the complexity of the assistive technology component from the perspectives of orthosis users who may opt to use multiple mobility aids simultaneously. When the HAAT model is applied to orthosis users, clinicians who prescribe or fit orthoses could consider all mobility aid types available to the individual, the effect of each mobility aid on the person’s mobility when used alone, and the effect of combinations of two or more mobility aids on their mobility when used simultaneously. While the number of options available to orthosis users may complicate application of a model like HAAT, clinicians may still find value in an organized approach to assisting patients to optimize their mobility (see example in Figure 2.2).

Another finding from this study that may apply well to clinical practice was the commonly shared sentiment that orthoses were beneficial to mobility when used outside the home. Indoor environments of clinics may not represent real world situations in which orthosis users would choose to use their orthoses. Thus, a performance-based assessment in a hallway or evaluation room may only provide limited information about the effectiveness of an orthotic intervention. Clinicians may find additional value in using patient-reported survey instruments that include questions about a person’s ability to perform outdoor activities.

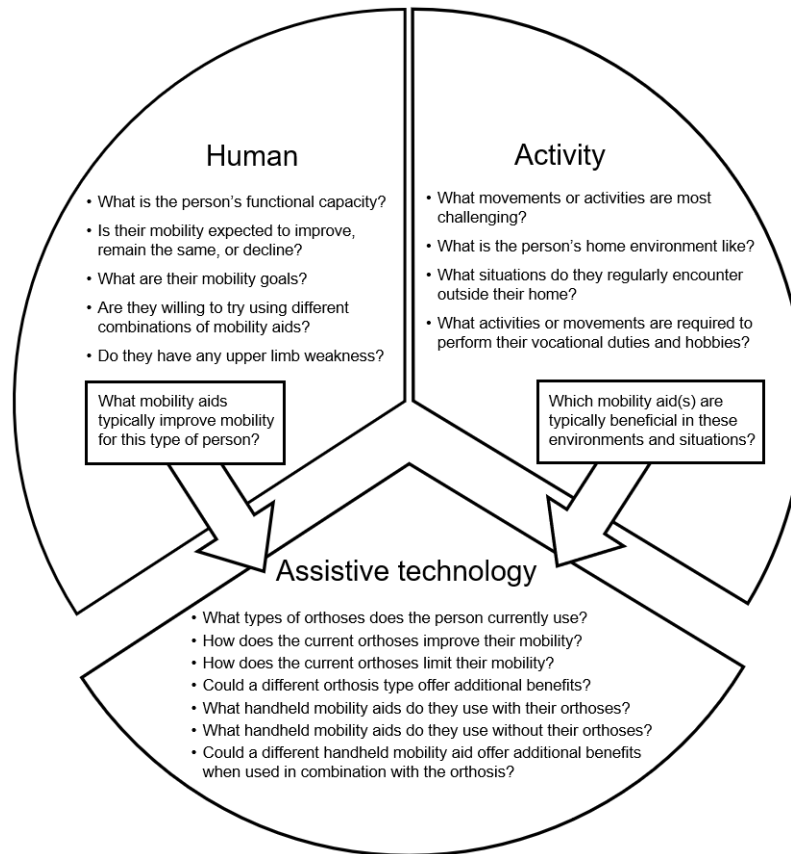


Figure 2.2. Example of the Human Activity-Assistive Technology (HAAT) model applied to selection of mobility aids for orthosis users. *Note: this figure was not included in the manuscript submitted for publication.*

### 2.5.3 Implications for research

Results of this study also provide new insights into testing the effectiveness of orthotic interventions. Experiences described by orthosis users regarding device utility and mobility strategies suggest that indicators of effectiveness in research studies may need to be tailored to the unique experiences of people who use orthoses. For example, several participants in the current study described the most meaningful benefits of orthosis use as improved confidence and increased safety. Studies that focus entirely on performance-based outcomes (e.g., walking

ability) may not capture these important benefits of an orthotic intervention. Additionally, several study participants with severe mobility impairments relied heavily on an orthosis for standing and walking short distances, though they only use the device for short periods each day. For these individuals, daily wear time would not be an ideal indicator of effectiveness. Further, participants in the current study generally agreed on a variety of activities for which orthoses enhance mobility, including stepping over obstacles, walking on grass, and navigating uneven terrain. Greater improvements in mobility may be observed when evaluating performance of an orthosis during these types of activities. Participants in this study, as well as those in other qualitative studies (van der Wilk et al., 2018; Yang et al., 2018), reported the greatest functional benefits during walking. However, other studies showed mixed evidence of orthosis use affecting gait speed (Beckerman et al., 1996; Leung & Moseley, 2003). Thus, while ambulatory outcomes are likely key indicators of effectiveness, gait speed may not be the most appropriate parameter to assess.

Insights into mobility experiences and situations in which orthoses are most useful, as observed in the current study, may also guide development of new outcome measures. Focus groups are often recommended as an initial step for developing patient-reported outcome measures (Dewalt et al. 2007; PROMIS, 2013). Experiences described by participants may be used to identify aspects of mobility important to orthosis users and therefore meaningful to rehabilitation progress. Life situations and daily activities at home and in the community described by participants in the current study may inform development of patient-reported outcome measures that include items most relevant to orthosis users.

#### 2.5.4 *Limitations*

One limitation of the current study may be limited representation of people from different regions of North America where extreme weather conditions may be experienced more frequently. While 21 of the 29 study participants lived in the Western U.S., this group included several people in Colorado and Utah where colder temperatures are common. Only three participants lived in the Southern U.S. where humidity levels and temperatures are higher. However, all four U.S. Census Regions (i.e., West, Midwest, South, and Northeast) were represented by at least one participant across all focus groups. Another limitation of this study was a relative lack of racial and ethnic diversity among participants. Consequently, some experiences, opinions, or perspectives may not have been included in our focus group discussions. Because some health conditions targeted in the study, including stroke (Trimble & Morgenstern, 2008), disproportionately affect people of color, future work should focus on soliciting information from such individuals to see whether they have experiences distinct from people included in this study. Additionally, the current study also did not include people who use HKAFOs. As technologies that extend to the hip, such as exoskeletons (Heinemann et al., 2018), emerge as viable orthotic interventions, it may become important to consider opinions of mobility held by people who use these types of devices.

## 2.6 CONCLUSION

This study broadly explored mobility as experienced by people who use lower limb orthoses. Focus group discussions and subsequent analysis identified aspects of mobility and mobility aid use that are unique to this clinical population. Notably, orthosis users make decisions about which forms of assistance (i.e., mobility aids) to use based on their personal attributes, prior experiences, and planned activities. These insights may inform clinical care by

reminding clinicians to consider an orthosis user's available mobility aids when working to optimize a patient's mobility in different scenarios. The complexities of decision-making expressed by participants suggest a need for future research to investigate the relationships between personal attributes and situations that are most affected by use of a lower limb orthosis and/or other mobility aids. Future investigation into orthosis user mobility may lead to improvements in orthotic prescription and outcomes measurement, thus increasing physical activity of orthosis users and reducing the prevalence of mobility-related disability in this at-risk clinical population.

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# Chapter 3. INITIAL DEVELOPMENT OF AN ITEM BANK TO MEASURE MOBILITY OF LOWER LIMB ORTHOSIS USERS

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## 3.1 ABSTRACT

**Purpose:** Patient-reported mobility may be an important indicator of the effectiveness of orthotic interventions. The aim of this research was to develop candidate items for a new survey instrument to measure mobility of lower limb orthosis users.

**Methods:** Mobility-related survey items were identified from existing instruments through a database search. Focus groups were conducted with orthosis users to confirm key definitions, evaluate the suitability of a conceptual measurement model, and identify new items. Candidate items were selected with advisory panel input. Cognitive interviews were conducted to assess the clarity and comprehension of each item.

**Results:** Lower limb orthosis users participated in focus groups ( $n = 29$ ) and cognitive interviews ( $n = 30$ ). A total of 1,326 items were identified and grouped using an existing conceptual model of mobility developed for lower limb prosthesis users. The item pool was condensed to 118 items by an interdisciplinary advisory panel. Based on feedback from target respondents, 9 items were revised to improve the clarity, and 18 items were removed with evident concerns. The resulting candidate item bank included 100 mobility items.

**Conclusions:** Candidate items for a new survey instrument were generated through a multi-step development process. Next steps include administration of the candidate items to a large sample

of lower limb orthosis users, calibration of the item bank, and psychometric testing of the resulting short forms and computerized adaptive test.

### 3.2 INTRODUCTION

Lower limb orthoses, including ankle-foot orthoses (AFO), knee-ankle-foot orthoses (KAFO), and hip-knee-ankle-foot orthoses (HKAFO) are used by people with a variety of chronic health conditions to preserve or improve mobility and independence (Fisk et al., 2016). Rehabilitation clinicians select from a variety of materials, designs, fabrication techniques, and technologies to tailor orthotic interventions to the needs of each patient (Murphy et al., 2020). The effectiveness of a lower limb orthosis is commonly assessed by measuring changes in a user's mobility (Robinson & Fatone, 2013). Patient-reported outcome (PRO) measures, or survey instruments, are particularly useful for evaluating aspects of mobility that may be challenging to observe in a clinical setting (Coster et al. 2006). These instruments can provide clinicians with insights into a patient's ability to perform a variety of activities across a range of situations and/or environmental conditions. Despite their utility, PRO instruments designed to measure mobility are rarely used in research studies that evaluate orthotic interventions (Figueiredo et al., 2019; Mcdaid et al., 2017; Ramstrand & Stevens, 2021; Tyson & Kent, 2013). An explanation for this paucity may be the recognized need for brief assessment tools that are tailored to lower limb orthosis users and can measure the effects of orthoses (Ewers & Stevens, 2010). A psychometrically robust PRO instrument that can efficiently measure aspects of mobility most relevant to orthosis users may address this need.

Attributes of a PRO instrument, including its population focus and theoretical underpinnings, can affect its relevance to a measurement objective, psychometric performance, and efficiency. An instrument can be generic (i.e., intended to measure across a range of clinical

conditions and interventions) or condition-specific (i.e., intended to assess a particular clinical population). Generic instruments can be used to compare outcomes across groups of people with different health conditions, as long as the outcome is conceptualized similarly by the individuals in each group. (Cella et al., 2015). Conversely, condition-specific instruments are designed for a people whose experiences and perspectives related to an outcome of interest differ from those in other populations. When an outcome, like mobility, involves experiences that are distinct to a clinical population, a generic instrument may be less applicable. Condition-specific instruments often include items (i.e., survey questions) that are more relevant to people with the same diagnosis or receiving a common intervention (Cella et al., 2015). People who use lower limb orthoses, for example, may value aspects of mobility (e.g., those that are affected by orthotic interventions) that people who do not use orthoses might consider less important to their overall functioning.

The theoretical underpinnings of a PRO instrument, determined by the development process, also contribute to its performance and efficiency. Classical Test Theory (CTT) methods, which are commonly used in instrument development efforts, produce static survey instruments. Alternatively, Item Response Theory (IRT) methods can be used to produce dynamic instruments, referred to as item banks. While many widely-used PRO instruments, such as the Medical Outcomes Study Short Form 36 (Ware & Sherbourne, 1992), are CTT-based static instruments, contemporary item banks have several advantages. Item banks can be briefly administered using different formats (Fries et al., 2014) and have been shown to have greater sensitivity to change (Jabrayilov et al., 2016). Therefore, a PRO instrument that is both condition-specific and IRT-based would be ideally suited for measuring mobility of lower limb orthosis users.

An example of a condition-specific item bank is the Prosthetic Limb Users Survey of Mobility (PLUS-M™), designed to assess mobility of people with lower limb loss who use prosthetic devices (Hafner, Morgan, Abrahamson et al., 2016). PLUS-M can be administered as a short form or as a computerized adaptive test (CAT) and has been found to be a valid and reliable instrument for measuring mobility of prosthesis users (Amtmann et al., 2018; Hafner et al., 2017; Hafner, Morgan, Askew et al., 2016). Development of PLUS-M was informed by stakeholder involvement, including feedback from prosthesis users who described the complex nature of mobility when using a lower limb prosthesis (Hafner, Morgan, Abrahamson, et al., 2016). While prosthesis users rely on the use of a prosthesis for ambulation, orthosis users can often ambulate without an orthosis. Mobility of orthosis users is also complex, as orthosis user may choose to use or not use an orthosis for different purposes. While a condition-specific item bank similar to PLUS-M does not exist for orthosis users, several existing PRO instruments are relevant to orthotic care due to their device-user focus or their history of administration among orthosis users.

One such instrument is the Orthotic and Prosthetic User's Survey - Lower Extremity Functional Status (OPUS-LEFS), a fixed-length subscale of a PRO instrument designed to measure orthotic and prosthetic clinical outcomes (Heinemann et al., 2003). The OPUS-LEFS was initially tested with a sample of adult and pediatric orthosis and prosthesis users and found to have desirable measurement properties (Heinemann et al., 2003). Subsequent testing of OPUS-LEFS, however, has primarily involved only prosthesis users (Jarl et al., 2015; Resnik & Borgia, 2011). A second PRO instrument applicable to orthosis users is the Lower Extremity Functional Scale (LEFS), a fixed-length survey developed to measure clinical populations associated with musculoskeletal dysfunction (Binkley et al., 1999). Although the LEFS has not

been psychometrically evaluated among orthosis users, it has been shown to have excellent measurement properties when tested with clinical populations that are commonly associated with lower limb orthosis use, including people with orthopedic disorders (Mehta et al., 2016) and those affected by stroke (Verheijde et al., 2013). The LEFS has also been used to measure mobility of military personnel receiving AFO interventions (Ikeda et al., 2019). Despite their apparent relevance, the LEFS and OPUS-LEFS were designed for clinical populations broader than only lower limb orthosis users, and their application to measuring meaningful changes due to an orthotic intervention may be limited. Additionally, their CTT underpinnings and fixed-length format may limit their efficiency when compared to item banks.

Finally, a third instrument relevant to orthosis users is the Patient-Reported Outcome Measure Information System - Physical Function (PROMIS-PF), a contemporary item bank with a generic population focus (Rose et al., 2008). PROMIS-PF has been psychometrically evaluated with several clinical populations related to lower limb orthosis use, including people with lower extremity health conditions (Hoch et al., 2019), spine disorders (Hung et al., 2014), ischemic stroke (Katzan et al., 2017), and multiple sclerosis (Senders et al., 2014). Weber *et al.*, (2018) tested PROMIS-PF in a sample of 98 lower limb orthosis users and reported evidence of known groups construct validity. While this finding is encouraging for applications of PROMIS-PF in orthotic patient care, differences in how the construct of mobility is experienced by orthosis users and other individuals may affect individual responses, and ultimately, the score produced by the instrument. In summary, LEFS, OPUS-LEFS, and PROMIS-PF are applicable to orthotic patient care, but their clinical use may be limited by their population focus and/or theoretical design. A new condition-specific item bank could overcome these limitations and be an effective tool for both clinicians and researchers interested in measuring orthotic mobility outcomes.

Therefore, the purpose of this research was to develop a new item bank to assess mobility of lower limb orthosis users.

### 3.3 METHODS

The methods used in this study to develop candidate items for a new PRO instrument were modeled after guidelines proposed by the Patient Reported Outcome Measure Information System (PROMIS) initiative (DeWalt et al., 2007; PROMIS, 2013). Items for the new instrument were generated through identification of activities included in existing instruments, feedback obtained from focus groups, and input from stakeholders. Candidate items were classified, selected, and revised through advisory panel input, and then evaluated through cognitive interviews to assess their quality (DeWalt et al., 2007). All procedures involving human subjects (i.e., focus groups and cognitive interviews) were approved by the University of Washington Human Subjects Division.

#### 3.3.1 *Participants*

Lower limb orthosis users were recruited to participate in two qualitative studies through flyers displayed in clinics, and information posted online through a prosthetics and orthotics list-serv, and a social media platform (Facebook, Menlo Park, CA). A telephone screening process was used to determine eligibility. To participate in either study, individuals were required to: (1) be at least 18 years of age, (2) be able to read, write, and understand English (3) use an AFO, KAFO, or HK AFO for one or both legs most days of the week, (4) have at least six months of experience using an orthosis, and (5) allow discussions or interviews to be audio-recorded. Individuals were excluded from the study if they had a lower limb amputation, to avoid inclusion of people whose mobility may be affected differently by simultaneous use of orthotic and

prosthetic devices.

Purposive sampling methods were employed to include orthosis users with various perspectives and experiences. The focus group aimed to include at least two participants with the following characteristics across the sample: (1) 65 years of age or older; (2) high school or lower education level, or an affirmative response to a screening question indicating a possible cognitive impairment, defined as “having trouble remembering, learning new things, concentrating, or making decisions that affect one’s everyday life;” (3) current use of an assistive device (e.g., cane, crutch, walker); (4) current use of a KAFO; and diagnosis of (5) stroke, (6) spinal cord injury, (7) cerebral palsy, (8) multiple sclerosis, or (9) lower limb injury. For the cognitive interview study, the target characteristics above, as well as an additional characteristic, (10) self-reported ability to run, were represented by at least five participants, to ensure all candidate items were reviewed by a participant with each target characteristic.

### 3.3.2 *Measures*

Participants were asked to complete an online survey that included questions about their general health, lower limb impairment(s), orthosis use, assistive device use, and demographics. The Lower Extremity Functional Scale (LEFS) was included in the survey to gauge each participant’s level of mobility. LEFS includes 20-items, each having a maximum (high physical function) score of 4, summed as a total score out of 80 (Binkley et al., 1999). The Numeric Pain Rating Scale (NPRS) was included to provide context to a person’s reported impairment and mobility information (Jensen & Karoly, 2011). The NPRS asked the respondent to rate their average pain level over the previous seven days, on a scale from 0 to 10, where 0 indicates “no pain” and 10 indicates “worst pain imaginable.”

### 3.3.3 Conceptual model

The PLUS-M conceptual measurement model, a framework for characterizing mobility of people who use lower limb prostheses (Hafner, Morgan, Abrahamson, et al., 2016), was assessed for applicability to lower limb orthosis users. The model conceptualized mobility as movement (i.e., postural transitions or locomotion) performed within a given context, termed “situational modifier.” The initial PLUS-M measurement model included the following situational modifiers: time, distance, external loads, obstacles, terrain, ambient conditions, and attentional demands. PLUS-M developers have since expanded the model to include “strategy” as an additional situational modifier (see Figure 3.1) (Morgan et al., 2020). This model was selected as a starting point for characterizing mobility in the current study, as it can be generally applied to lower limb mobility and the included forms of movement and situational modifiers were not dependent upon use of a prosthesis.

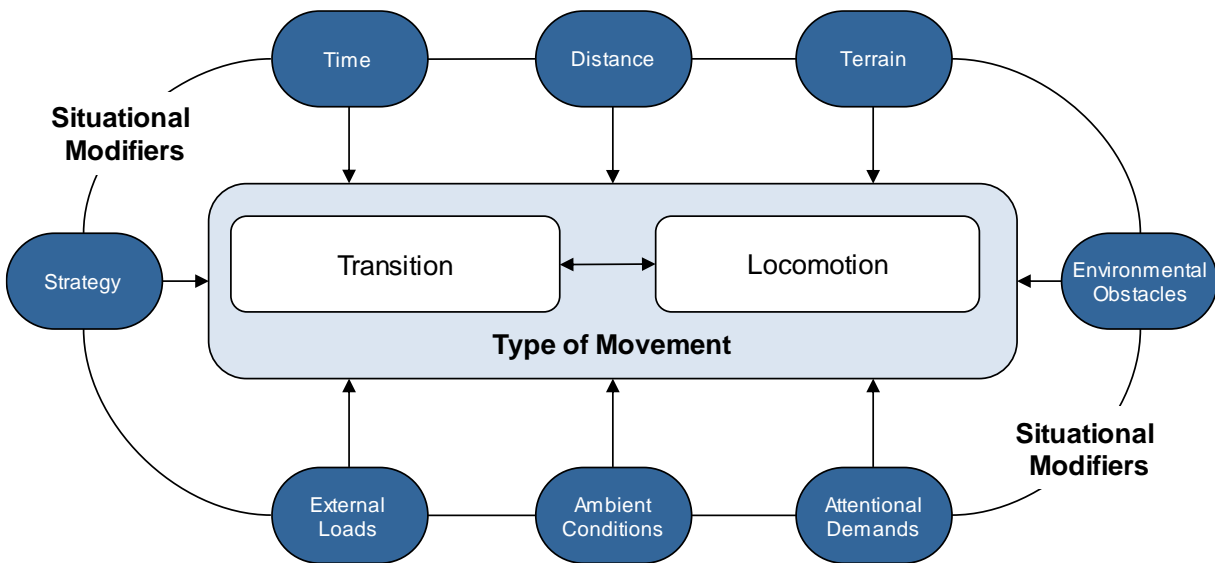


Figure 3.1. An updated version of the PLUS-M conceptual measurement model

### 3.3.4 *Procedures*

#### *Advisory panel*

An interdisciplinary advisory panel was assembled to provide input throughout the instrument development process. Advisory panel members included nine professionals in the orthotics field with experience working in patient care (n=7), academic (n=1), and manufacturing (n=1) settings. The clinicians included those with experience working for a national orthotic provider (n=2), private practice (n=1), military (n=2) and non-military hospitals (n=1), and a physical therapy clinic (n=1). Advisory panel meetings were held virtually to reach a consensus on important decisions related to survey instructions, response options, and item content (i.e., activities and movements applicable to lower limb orthosis users). Advisory panel members also assisted with generation and selection of candidate items.

#### *Identification of extant items*

A search of existing survey items was performed to identify those currently used in clinical practice and to identify gaps that new items may address. Rather than search for all PRO instruments in the literature that may apply to orthosis users, investigators searched for recent review articles to identify those instruments that are relevant to people with health conditions commonly associated with orthotic interventions. A search strategy was developed to identify reviews of PRO instruments in the PubMed database that were available in English and published between 2013 and 2018 (see Table 3.1). Search terms included applicable health conditions (e.g., stroke, multiple sclerosis, cerebral palsy, spinal cord injury, orthopedic injury) and those related to mobility (e.g., physical function, ambulation, independence, balance). Publication dates were constrained to the most recent five years to identify instruments that are

widely used in current clinical practice and research. Articles were then reviewed to identify PRO instruments that measured lower limb mobility or related constructs. Selected PRO instruments were retrieved to identify the items included in each instrument. Items were also sourced from additional instruments known to the investigators as being potentially applicable to lower limb orthosis users. All identified items were entered into an item library. Item information recorded in the library included the instrument of origin, context or instructions, stem (i.e., mobility related situation or activity), and response options (DeWalt et al., 2007). Next, two research staff members independently screened items and indicated whether each should be retained or removed from the library. Items were removed if they described (1) an action that did not require mobility of the lower limbs, (2) allowed for assistance from another person, (3) a generic movement without context, or (4) a static posture. Decisions to retain or remove items were compared and discrepancies were reconciled.

Table 3.1. Search algorithm used to identify PRO review articles

<i>Field</i>	<i>Terms</i>
1 Title	survey* OR questionnaire* OR "item bank*" OR "outcome measure*" OR "patient-report*" OR "self-report"
2 Publication Type	review OR "meta-analysis"
3 Title/Abstract*	stroke OR "cerebral vascular accident" OR CVA OR "post-stroke"
4 Date - Publication	"2013/12/31" : "2018/12/31"
5	1 AND 2 AND 3 AND 4
6	Restrict to English language

\* *The population-specific terms searched in line 3 were replaced with terms related to each clinical population of interest.*

### *Focus groups*

Focus groups were held with lower limb orthosis users to (1) explore the construct of mobility with an orthosis, (2) confirm terminology definitions, (3) assess the suitability of the PLUS-M conceptual model, and (4) identify activities and situations to include as candidate items. The first objective, to investigate how orthosis users conceptualize mobility, has been described in detail elsewhere (refer to Chapter 2). Focus groups were held virtually (Zoom Video Communications, San Jose, CA) and facilitated by a trained investigator with five years of clinical experience in orthotics. A definition for “mobility” was confirmed by soliciting feedback from focus group participants. The discussion facilitator used guiding questions to ask participants about their mobility in a range of scenarios and environments to determine the suitability of the situational modifiers described in the PLUS-M conceptual measurement model. (Hafner, Morgan, Abrahamson, et al., 2016). Each discussion was audio-recorded and transcribed. An investigator and research staff member, both trained as clinical orthotists, used Dedoose qualitative software (SocioCultural Research Consultants, LLC, Los Angeles, CA) to independently assign codes to quotations in the transcripts. Codes were used to identify topics discussed by participants and situational modifiers that corresponded to the PLUS-M conceptual measurement model. Assigned codes were compared and discrepancies were reconciled. Investigators reviewed portions of the transcripts that applied to the conceptual model to determine its applicability to lower limb orthosis users. New candidate items were generated based on activities and situations identified during the coding process and added to the item library.

### *Item classification and selection*

Study investigators worked closely with advisory panel members, including professionals with backgrounds in clinical care, academia, manufacturing, and research, to standardize, group, and narrow the pool of candidate items. Candidate items were formatted to begin with the same verbiage so that investigators and panel members could more easily compare items with similar content. Items that included multiple activities or movements were flagged as “multi-barreled” and often separated as individual items (DeWalt et al., 2007). An investigator with a clinical background, and a research staff member experienced in PRO instrument development research, independently classified items into bins that corresponded to the situational modifiers defined in the conceptual measurement model, and then reconciled differences with input from a third investigator as needed. To narrow down the number of items in the initial item pool, a process referred to as binning and winnowing was performed (DeWalt et al., 2007). First, investigators, a research staff member, and an advisory panel member reviewed items within each bin. Items in the bin were grouped by the type of activity or situation described. Items that were redundant or determined as not applicable to the target population were removed. Next, members of the research team and advisory panel independently selected items within each bin that were deemed to be most and least suitable to measuring mobility of orthosis users. Those items that were selected as most suitable by at least two panel members were included in the final candidate item pool and prepared for testing through cognitive interviews.

### *Cognitive interviews*

Semi-structured cognitive interviews were conducted by phone with individuals who use lower limb orthoses to assess the clarity, comprehension, and quality of each candidate item

(Willis et al., 2005). An interview guide was prepared with specific questions to probe participants' overall impressions and interpretations of the instructions, items, and response options. During each interview, participants were asked to respond to a maximum of 25 candidate pool items, without guidance from the interviewer. This number of items was determined to be appropriate for reviewing during a single interview without excessive burden to participants and resembled the length of a typical survey that a patient might complete in a clinical setting. The interviewer then used verbal probing to solicit information about the movements, activities, and environments a participant visualized while responding to each item. Participants were also invited to share feedback related to their understanding of the instructions, response options, and overall format of the instrument. Each candidate item was initially reviewed by at least five participants, following the model described by DeWalt *et al.* (2007). Investigators used audio recordings and field notes to review feedback from participants and determine whether items should be retained, modified, or removed (Morgan et al., 2014). Items that required significant revisions were retested in subsequent rounds of cognitive interviews with at least three more participants. After all candidate items were removed or retained, investigators provided advisory panel members with the list of candidate items and solicited feedback as to whether any member had objections, prior to finalizing the candidate item bank.

### 3.4 RESULTS

#### *Item identification*

The PubMed database search yielded 23 review articles, from which 77 mobility-related PRO instruments were identified. An additional 4 instruments known to investigators were also included for review. 1,180 extant items were identified from PRO instruments and screened for

eligibility. 366 items that did not meet screening criteria were removed and 360 items were created after separating multi-barreled items. 1,174 items were retained in the candidate item pool prior to adding items identified from focus groups (see Figure 3.2).

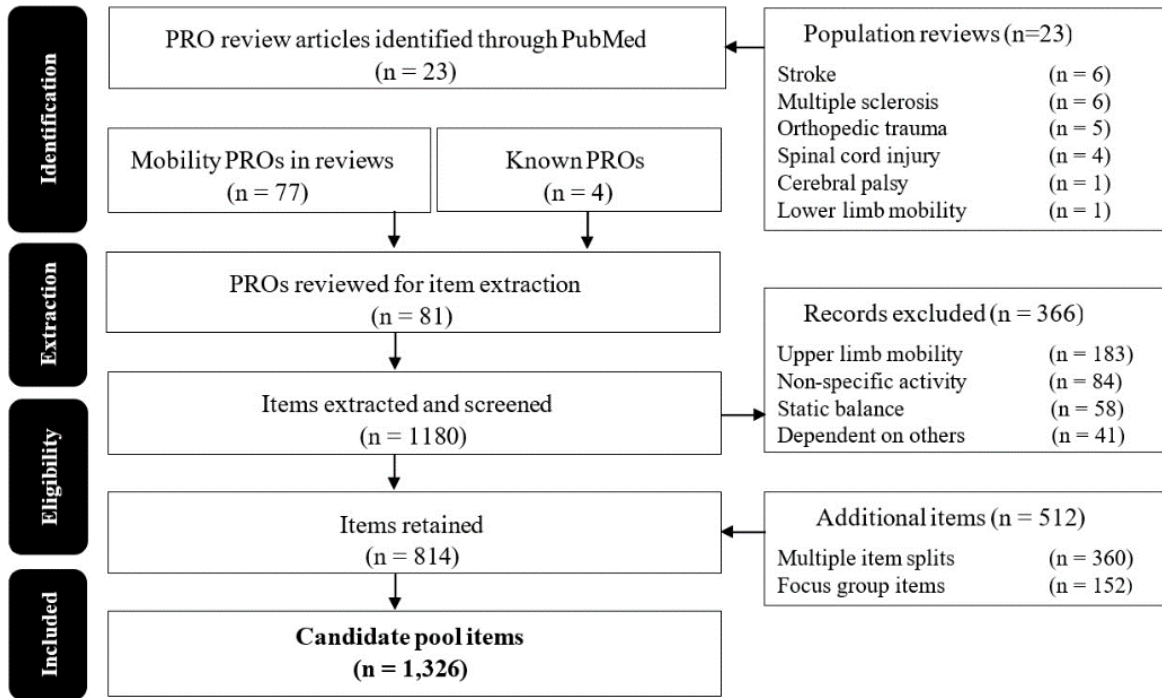


Figure 3.2. Flow chart describing item identification process

### *Focus groups*

Lower limb orthosis users (n=29) with a variety of health conditions participated in four focus group discussions (see Table 3.2 for participant characteristics). Participants provided feedback on the following proposed definition of mobility: "to move intentionally, without the help of another person." Alternative definitions were also probed, that replaced "without the help of another person" with the words "independently" and "without assistance." Participants preferred the first definition that specified "another person." As an example of the feedback received from participants, one participant advised:

*You should include "without the assistance of another person" in the definition and say that specifically. I use a lot of other assistive equipment and it is really not a barrier to being independent. It's a barrier when I have to schedule time with somebody to do something or ask them and it would be on them to say, 'yes' or 'no'.*

All situational modifiers in the measurement model were coded during analysis of focus group transcripts. The most frequently coded modifier was terrain (n=239), and the least was external loads (n=52). The PLUS-M conceptual measurement model was determined to be appropriate for characterizing mobility of orthosis users. All items could be classified by the model, and no additional modifications were needed.

New candidate items (n=152) were inspired by activities and movements that arose from focus group discussions and added to the item library (see Figure 3.2). Examples of novel items generated from focus group discussions included "step over a garden hose," "walk without looking down at the ground," and "walk indoors without touching walls." Results of the focus groups also influenced decisions to remove and select candidate items. For example, when evaluating items, investigators considered those items that focus group participants agreed upon as being important (e.g., walking moderate distances, stepping over obstacles) and less important (e.g., squatting, getting up from the floor) to everyday mobility. Focus groups also informed decisions related to the instructions, such as the inclusion of commonly used terms (e.g., brace, rather than orthosis).

### *Item selection*

Candidate items (n=1326) were organized into eight categories, corresponding to situational modifiers of the conceptual measurement model. Initial winnowing resulted in

Table 3.2. Target characteristics of focus group and cognitive interview participants

	Focus groups n=29	Cognitive interviews n=30	Overall n=59
<b>Sex</b>			
Female, <i>n</i> (%)	18 (62.2)	17 (56.7)	35 (59.3)
Male, <i>n</i> (%)	11 (37.9)	13 (43.3)	24 (40.7)
<b>Age</b>			
18 to 29, <i>n</i> (%)	4 (13)	1 (3.3)	5 (8.5)
30 to 44, <i>n</i> (%)	8 (27)	8 (26.7)	16 (27.1)
45 to 64, <i>n</i> (%)	12 (40)	15 (50.0)	27 (45.8)
65 or older, <i>n</i> (%)	5 (17.2)	6 (20.0)	11 (18.6)
<b>Ethnicity and race</b>			
Non-Hispanic White <i>n</i> (%)	24 (82.8)	24 (80.0)	48 (81.4)
Non-Hispanic Black or African American	1 (3.4)	3 (10.3)	4 (6.8)
Non-Hispanic Asian	3 (10.3)	2 (6.9)	5 (6.8)
Hispanic or Latino	1 (3.4)	1 (3.4)	9 (15.3)
<b>Education</b>			
High school diploma or equivalent	2 (6.9)	2 (6.7)	10 (16.9)
Some college or technical degree	7 (24.1)	9 (30.0)	16 (27.1)
Bachelor's degree	10 (34.5)	11 (36.7)	21 (35.6)
Master's or doctoral degree	10 (34.5)	8 (26.7)	18 (30.5)
<b>Health diagnosis</b>			
Spinal cord injury <i>n</i> (%)	6 (20.7)	7 (23.3)	13 (22.0)
Stroke <i>n</i> (%)	3 (10.3)	5 (16.7)	8 (13.6)
Charcot-Marie-Tooth disease <i>n</i> (%)	3 (10.3)	2 (6.7)	3 (5.1)
Post-polio syndrome <i>n</i> (%)	2 (6.9)	3 (10.0)	2 (3.4)
Cerebral palsy <i>n</i> (%)	1 (3.4)	5 (16.7)	6 (10.2)
Multiple sclerosis <i>n</i> (%)	1 (3.4)	5 (16.7)	6 (10.2)
Lower limb injury <i>n</i> (%)	5 (17.2)	1 (3.3)	6 (10.2)
Other <i>n</i> (%)	8 (27.6)	2 (6.7)	5 (16.9)
<b>Orthosis type</b>			
Unilateral ankle-foot orthosis <i>n</i> (%)	15 (51.7)	15 (50.0)	14 (23.7)
Bilateral ankle-foot orthosis <i>n</i> (%)	8 (27.6)	7 (23.3)	15 (25.4)
Unilateral knee-ankle-foot orthosis <i>n</i> (%)	3 (10.3)	3 (10.0)	6 (10.2)
Bilateral knee-ankle-foot orthosis <i>n</i> (%)	2 (6.9)	3 (10.0)	5 (8.4)
Ankle-foot-, & knee-ankle-foot orthoses <i>n</i> (%)	1 (3.4)	0	1 (1.7)
Unilateral hip-knee-ankle orthosis <i>n</i> (%)	0	2 (6.7)	2 (3.4)

removal of 483 items. Remaining items were binned into 35 sub-categories and presented to advisory panel members for review. Item selections submitted by nine advisory panel members narrowed the final pool to 118 candidate items (see Table 3.3). Consensus was reached among advisory panel members regarding instructions and response options for the instrument. Respondents were instructed to think about using the assistive device they would normally use when responding to each item. Initially, candidate items began with the context, “Are you able to...” to imply an immediate recall timeframe. Response options included “without any difficulty,” “with a little difficulty,” “with some difficulty,” “with much difficulty,” and “unable to do.”

#### *Cognitive interviews*

Thirty lower limb orthosis users participated in cognitive interviews. Four of these individuals previously participated in the focus group study (see Table 3.3). Following the first round of interviews, nine items were revised to improve the clarity and comprehension. Ten “high-level mobility” (i.e., items that included activities like running, jumping, etc.) items were identified as requiring additional testing, as they were less applicable to participants with whom they were initially tested. Several participants who experienced daily changes in their symptoms were unsure as to whether the phrase, “Are you able to...” referred to their mobility at the current moment or their highest capacity for mobility when they are less limited by symptoms. To clarify the context for those with varying symptoms, the phrase was changed “Are you currently able to...” A second round of interviews was performed to retest revised items, high-mobility items, and the revised context. Problems were identified in three of the nine revised items and the others were well-understood. All high-mobility items were determined to be

Table 3.3. Sub-categories of the PLUS-M conceptual measurement model situational modifiers

<i>Situational modifier</i>	<i>Sub-category bin</i>	<i>Item example Are you currently able to...</i>
Time	Fast-paced walk	...keep up with others when walking?
	Endurance walk	...walk for 10 minutes without a break?
	Run or jog	...run for 5 minutes on level ground?
	Exercise or work	...aerobic exercise for 5 minutes without stopping?
Distance	Distance walk	...to walk a short distance in your home?
	Distance run or jog	...run one mile?
	Backwards/side step	...take 2 steps backwards?
	Reach/Bend	...bend down and pick up clothing from the floor?
Terrain	Outdoor Uneven Surfaces	...hike about 2 miles on uneven surfaces, including hills?
	Up Stairs/Steps	...climb up 2-3 steps without a handrail?
	Down Stairs/Steps	...walk down a flight of stairs with a handrail?
	Ramps/Hills	...walk down a steep gravel driveway?
	Slippery Surfaces	...walk across a slippery floor?
External Loads	Carry	...walk while carrying a shopping basket in one hand
	Bumped	...keep walking when people bump into you?
	Outdoor Chores	...heavy outdoor work like digging or spreading soil?
	Push/Pull/Move	...move a chair from one room to another?
	Indoor Chores	...vacuum a large, carpeted room?
	Pick up/Lift	...lift a bag of groceries from the floor?
Ambient Conditions	Lighting	... walk from one room to another in the dark?
	Weather	...walk outside in a strong wind?
Attentional Demands	Focus	...walk without having to concentrate on each step?
	Visual	...walk outside without looking at your feet?
Environmental Obstacles	Step On/Off	...step off of an escalator?
	Get Into/Out of Car	...get in and out of the back seat of a 4-door car?
	Avoid Static Obstacles	...walk between rows of occupied seats like those in a theater or Church?
	Avoid Moving Obstacles	...stop quickly to avoid bumping into the person in front of you?
	Step Over	...step over a hose on the ground?
	Hop/Jump	...jump over a large puddle?
	Crowds	...move through a large crowd of people?
Strategy	Without support	...stand up from a chair without using arm rests?
	Specified technique	...regain your balance after a trip or slip?
	Without deviation	...walk at a normal pace without tripping?

applicable to orthosis users who were able to run. All revised items were found to be understood as intended by those who had misinterpreted the meaning previously. A third round of interviews was required for the three items that underwent multiple revisions. In total, 19 items were removed through the cognitive interviewing process. For example, one item that asked about doing “yard work that requires getting down on the ground” was inconsistently described by participants as involving various postures, movements, and use of assistive devices. Some participants imagined strenuous tasks that involved lifting heavy objects, while others thought about performing light garden maintenance from a seated position, and one other person described getting in and out of a wheelchair to pull weeds, without using an orthosis. Redundant items that described similar situations were reviewed and one was identified for removal, based on interview responses. Other reasons for removing items included misalignment of the intended meaning and inclusion of phrases that were not well-understood. The final candidate item bank included 100 items (see Figure 3). Advisory panel members did not have any objections to the instructions, items, and response options included in the candidate item bank.

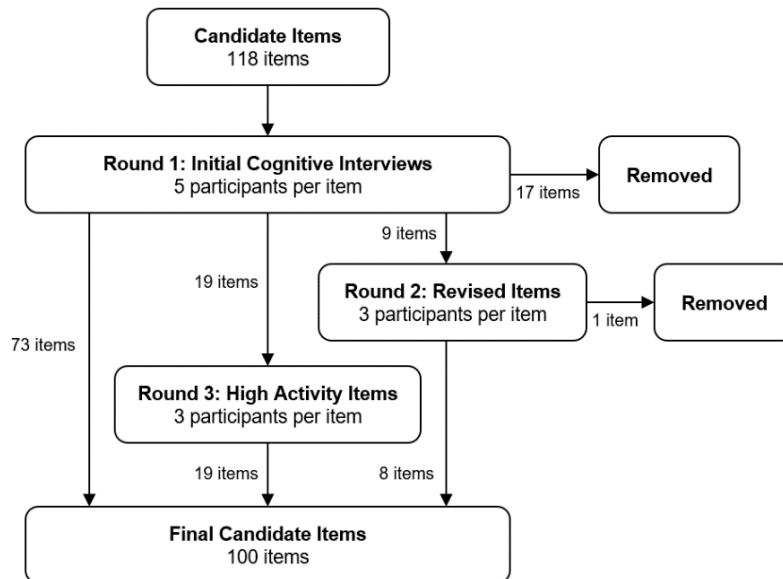


Figure 3.3. Cognitive interview flow diagram

### 3.5 DISCUSSION

The purpose of this study was to identify candidate items for a new survey instrument to measure mobility of lower limb orthosis users. The procedures used to identify, classify, select, and evaluate items were all critical to the development of the resulting candidate item bank. The item identification process was important to understanding the breadth of available instruments. Several of the PRO instruments identified in the database search were specifically designed for patients diagnosed with stroke (Duncan et al., 1999; Williams et al., 1999) or multiple sclerosis (Cella et al., 1996; Hobart et al., 2001). Instruments designed for patients with stroke frequently included questions related to walking without stumbling and climbing stairs, while instruments designed for patients with multiple sclerosis included items related to walking long distances or sustaining activities for a period of time. As lower limb orthosis users include people with a variety of conditions, it was important to become familiar with available diagnosis-specific instruments and include items in the candidate item bank that might assess different types of mobility challenges known to affect people with these conditions.

Focus groups provided insight into language commonly used by orthosis users when referring to orthoses and other assistive devices. For example, participants most frequently referred to an orthosis as a “leg brace” and less frequently as an “AFO.” Also, several participants referred to their assistive device as a walking stick and did not consider the term “cane” reflective of that device. The new items identified from focus groups revealed possible gaps in existing instruments that may not have been identified otherwise. For example, participants described meaningful aspects of mobility, such as walking without catching one’s toes and stepping over different types of obstacles, that are not included in available instruments. Further, participants identified several activities described in available outcome measures as

being less relevant to orthotic mobility. Examples include activities described in the LEFS, such as rolling over in bed, sitting for an extended period, and squatting; as well as those described in OPUS-LEFS, such as bathing, getting up from the floor, and donning an orthosis. The item selection process, informed by stakeholder input, provided opportunities to include orthosis users and field experts in the development of the instrument. The U.S. Food and Drug Administration views stakeholder involvement in the item generation process as a necessary step that provides evidence of content validity (U.S. Department of Health and Human Services, 2006).

Cognitive interviews provided opportunities to identify words and phrases that may be misinterpreted in a PRO instrument. This insight informed modifications to the instructions and context of the instrument, that may have been overlooked otherwise. Results of the cognitive interview study suggest that terms related to falls (e.g., catch toes, trip, slip, stumble) may be viewed as different events. Further, several participants of the focus group and cognitive interview studies described their symptoms as being variable, and some described day-to-day fluctuations that affected their mobility. These perspectives should be considered when designing future research studies.

#### *Future research efforts*

The candidate items can now be administered to a large sample of orthosis users. Responses collected from a large-scale study will be used to calibrate the items to an item response theory model. Subsequent steps include development of short forms and CAT, as well as psychometric testing (see Figure 3.4). The long-term goal of this research is to produce a valid and reliable assessment tool that can be used by clinicians to document progress, communicate with patients and interdisciplinary team members, justify clinical decisions, and measure effectiveness of orthotic interventions.

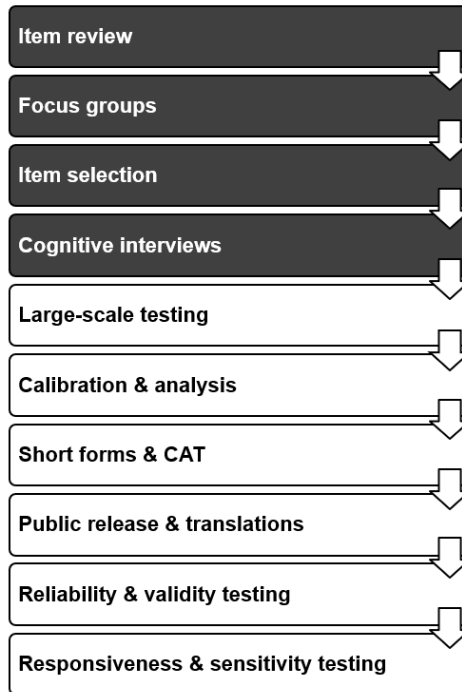


Figure 3.4. Previous and future research efforts for continued development and testing

### *Limitations*

This study had several limitations. The review article search was limited to the previous five years and may have excluded older instruments with additional items that may be applicable to orthosis users. Investigators determined that identifying items in instruments currently used in clinical practice and research was more important than including a larger number of instruments, some of which may be obsolete. Another limitation is the lack of representation across focus groups and cognitive interviews of all health conditions for which people are prescribed lower limb orthoses. Due to the nature of orthoses addressing functional limitations that apply to many health conditions, inclusion of all relevant diagnoses was not feasible for this qualitative research effort. To address this issue, efforts were made to broadly include people with both orthopedic and neurological impairments who use different types of orthoses. Demographic characteristics

such as racial and ethnic backgrounds other than non-Hispanic white were not well-represented by participants of focus groups and cognitive interviews. Greater demographic diversity across participants may have provided important insights that were not captured in the current study.

### 3.6 CONCLUSION

The key deliverable of this study was a candidate item bank ready for large-scale testing and calibration. The final candidate bank includes 100 items that include mobility-related activities and situations that were found to be meaningful to lower limb orthosis users. Future efforts to calibrate the item bank and evaluate its psychometric properties are expected to result in a valid and reliable PRO instrument that can be quickly administered to measure aspects of mobility most relevant to patients receiving orthotic interventions.

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# Chapter 4. JAPANESE TRANSLATION AND LINGUISTIC VALIDATION OF THE PROSTHETIC LIMB USERS SURVEY OF MOBILITY (PLUS-M)

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## 4.1 ABSTRACT

*Background:* Survey instruments can be used to improve clinical care for lower limb prosthesis users on a global scale by pooling comparable health outcomes data from multiple countries. The language translation process is critical to the quality and comparability of a translated survey instrument.

*Objectives:* The goals of this research were to translate the Prosthetic Limb Users Survey of Mobility (PLUS-M) item bank from English to Japanese using established guidelines, and linguistically validate the translated instrument with Japanese prosthesis users by assessing its clarity, comprehension, and cultural applicability.

*Study Design:* Self-report instrument translation and qualitative interviews

*Methods:* The translation process included two forward translations, reconciliation, backwards translation, and review by clinical experts in Japan. Adult lower-limb prosthesis users participated in a linguistic validation study by responding to translated survey items and providing feedback through cognitive interviews.

*Results:* Following expert reviews, translated items were classified as grammatically and contextually unchanged (n=21), minor revision (n=19), major revision (n=3), or removed (n=1). Cognitive interviews with 10 participants resulted in additional revisions and retesting of items until all translated items were determined to be clear, well understood, and culturally applicable.

*Conclusions:* Use of a multi-step translation and linguistic validation processes resulted in a linguistically comparable Japanese translation of the PLUS-M item bank. Translated short forms have been made publicly available for use in clinical practice and research. Availability of these instruments will also facilitate opportunities for international comparison of prosthetic mobility data.

## 4.2 INTRODUCTION

Health conditions related to lower limb amputation, including diabetes and peripheral arterial disease, are becoming increasingly prevalent throughout the world (Ogurtsova et al., 2017; Song et al., 2019). Pooling and comparison of multinational health outcomes data may provide insights into prevalence of health conditions, burden of disease, and effectiveness of rehabilitation interventions. However, a lack of standardized reporting methods between countries currently limits comparison of key health indicators (Harding et al. 2019). In the *2011 World Report on Disabilities*, The World Health Organization provided recommendations for improving availability and quality of data to improve the lives of people with disability (World Health Organization [WHO], 2011). Their recommendations included cross-cultural testing of standardized instruments for collecting health outcomes data, in an effort to obtain datasets that are comparable at both the national and international levels. The report indicated that self-report survey instruments, in particular, are cost-effective tools for collecting data on important aspects of disability, such as physical functioning, use of services, and quality of life (WHO, 2011).

Since this call to action, collaborative research groups have accepted the challenge to develop and test contemporary survey instruments. For example, the Patient-Reported Outcomes Measurement Information System (PROMIS) initiative has resulted in instruments that measure health outcomes applicable to a range of chronic health conditions (Cella et al., 2007). PROMIS instruments were constructed using Item Response Theory (IRT), a measurement framework used to assess the performance of individual items (i.e., questions) (Nguyen et al., 2014). IRT methods facilitate the calibration of an item bank that can be administered as a computerized adaptive test or as fixed-length short forms (Alonso et al., 2013). These brief administration formats allow instruments derived from item banks to be flexible and efficient, without significantly affecting measurement precision (Cella et al., 2010). PROMIS investigators advocated instruments be translated into other languages for international use, with a goal of “improving patient-centered research, clinical trials, reporting, population monitoring, and healthcare worldwide” (Alonso et al., 2013 pp. 3). The investigators also proposed language translation standards, based on established methods, to ensure that equivalent meaning was maintained between translations and the source instruments (PROMIS, 2013). Subsequently, PROMIS item banks have been translated into more than 50 languages and are used to compare health outcomes across the world (Devine et al., 2018; Fischer et al., 2017; PROMIS, 2020; Vilagut et al., 2019).

PROMIS item banks were initially developed for use across a wide range of people, including healthy individuals and those with a variety of clinical conditions (Cella et al., 2010). However, a construct of interest may not be conceptualized in the same manner by all groups of people. For these individuals, a widely applicable survey instrument may not be ideal, and development of a new instrument may be warranted. An example of an instrument developed for

a specific population is the Prosthetic Limb Users Survey of Mobility (PLUS-M), an IRT-based item bank designed to measure mobility of people with limb loss who use a prosthesis (Hafner et al., 2016; Morgan et al., 2014). The PLUS-M's development was modeled after methods used to develop PROMIS instruments, and item content was largely informed by feedback from prosthesis users (Hafner, Morgan, Abrahamson, et al., 2016; Morgan et al., 2014). Testing of PLUS-M alongside other instruments produced evidence of excellent convergent construct validity (Hafner et al., 2017) and high reliability (Hafner, Morgan, Askew et al., 2016). Like PROMIS instruments, PLUS-M can be briefly administered as a computerized adaptive test or short form, and has been translated into more than 15 languages to-date (Amtmann et al., 2018; PLUS-M, 2013a). In the same manner that PROMIS instruments can be used to compare outcomes between countries, continued translation and cross-cultural adaptation of PLUS-M will facilitate comparison of prosthetic mobility outcomes internationally.

Item banks, like PLUS-M, are well suited to language translation because instruments (e.g., short forms) can be created from any combination of items. Therefore, if an item in the bank does not apply well to a target language or culture, it can be removed from the bank and other items that measure at a similar level of the trait could be used as alternatives without a significant loss of precision in the resulting score. In contrast, conventionally developed survey instruments often require that all items be translated and used to produce a sum or average score that can be directly compared to the original (i.e., source) instrument. This advantage of item bank instruments becomes important when translating between languages with major differences. English and Japanese, for example, differ in their respective characters, syntax, and cultural norms.

Japanese characters include both phonographic symbols that are mapped to syllables, referred to as *Kana*, and logographic characters that can each have multiple pronunciations, referred to as *Kanji* (Koyama et al., 2008). In Japanese education, children are introduced to all 92 Kana characters and 80 Kanji characters during first grade. Kanji characters, adopted from the Chinese language, are more complex and numerous than Kana. Although proficiency in over 3,000 Kanji is required for reading a newspaper, a sixth-grade reading level is associated with mastery of around 1,000 (Kess & Miyamoto, 1999). Japanese syntax also differs from English, in that subjects and objects in a sentence can be rearranged, and a single phrase can be created using only Kanji, only Kana, or a combination of both (Sasanuma, 1975). Additionally, Japanese adults are expected to use increasingly polite social phrases as they grow older, and their use of vocabulary and grammar changes at different stages of life (Kawasaki, 2017). Due to these language differences, the versatility of an item bank may be particularly beneficial when translating from English to Japanese.

Translation of PLUS-M to Japanese may be timely, as recent rapid growth of the aging population in Japan (Muramatsu & Akiyama, 2011) has led to increased prevalence of diabetes (Goto et al., 2016) and critical limb ischemia (Japanese Society for Vascular Surgery, 2016), both of which are precursors to lower limb amputation (Boyko et al., 2017). Japan has the largest proportion of older adults in the world, and is projected to maintain that position through 2050 (He et al., 2016). In preparation for the projected growth of the Japanese older adult population, health experts in Japan have advocated for health promotion and disability prevention (Muramatsu & Akiyama, 2011). Lower limb amputation may occur more frequently as a result of the changing age distribution, and measuring key health indicators (e.g., mobility) will likely become increasingly important.

Currently, few survey instruments that apply well to prosthesis users are available in the Japanese language (Sakai, 2019), and only the translation of the Prosthesis Evaluation Questionnaire (PEQ), a conventional (i.e., not IRT-based) survey, includes mobility-related items (Legro et al., 1998; Tobimatsu et al., 2004). A Japanese translation of PLUS-M would provide clinicians and researchers in Japan with an additional tool for efficient collection of mobility data. Moreover, optional removal of culturally inappropriate items and use of a rigorous translation process may result in a Japanese translation that closely mirrors the source instrument and can later be used to confidently compare international mobility outcomes. Therefore, the goals of this study were to translate PLUS-M from English to Japanese and assess the linguistic validity of the translated instrument.

## 4.3 METHODS

### 4.3.1 *Survey*

The Prosthetic Limb Users Survey of Mobility (PLUS-M™) Version 1.2 item bank includes 44 items that ask respondents about their perceived ability to perform various activities, ranging from household ambulation to outdoor recreation (PLUS-M, 2013b). Prosthesis user respondents are instructed to answer each item as if they are wearing the prosthesis they use most often and choose one of five response options to indicate whether they are able to do the activity, and the degree of difficulty with which they could do it. Respondents are also instructed to think about using the assistive device (i.e., cane, crutch, or walker) they would normally use when performing the activity described by the item, if applicable. However, “unable to do” should be selected if they would need to use a wheelchair or receive help from another person to perform the activity, or if they deem the activity to be unsafe. PLUS-M T-scores have a mean of 50 that references the mean score of a development sample of 1091 adults in North America with

transtibial and transfemoral amputations (Amtmann et al., 2015). A higher PLUS-M T-scores signifies greater mobility (PLUS-M, 2013b). PLUS-M can be administered as a 12-item or 7-item short form, or as a computerized adaptive test that can produce an accurate score in as few as four items (Amtmann et al., 2018).

#### 4.3.2 *Translation procedures*

Translation procedures were modeled after guidelines established by the Functional Assessment of Chronic Illness Therapy (FACIT) group and updated by PROMIS instrument developers (Eremenco et al., 2005; PROMIS, 2013). The process included forward translations, reconciliation of forward translations, backwards translation, and clinical expert review, with multiple points throughout the process for review and revision. (see Figure 1). Two bilingual investigators, GB (prosthetist, first language: English, second language: Japanese), and SS (physical therapist, first language: Japanese second language: English) independently translated all PLUS-M Version 1.2 items, response options, and instructions from English to Japanese. A translation guide, provided by the PLUS-M developer, was referenced by the translators to better understand the developers' intent with each of the PLUS-M items. After completing the independent translations, the translators met with the PLUS-M principal developer, BH, to review and reconcile the forward translations. Investigators discussed the discrepancies between translations and determined the most suitable translation for each word, phrase, sentence, or paragraph. A published guideline was used to code reconciliation decisions (i.e., the extent to which either forward translation was included in each reconciled translation) and justification for each decision (Koller et al., 2012). Forward translations, reconciled translations, and decision codes were entered into a documentation record.

Backwards translation (or “back-translation”) refers to the process of translating an instrument that was already translated to a different language back to the source instrument language. Backwards translation can aid in the translation process by highlighting conceptual errors in the reconciled translation (Beaton et al., 2000; Eremenco et al., 2005). A third translator, DA (graduate student, first language: Japanese, second language: English) with minimal familiarity with the source survey instrument performed the backwards translation by translating the Japanese items, response options, and instructions to English. The English backwards translation was then reviewed by the principal developer and forward translators. Backwards translated items that diverged from the meaning of the source instrument items were revised in Japanese, retranslated to English by the back translator, and reviewed again. This process was repeated until the backwards translation was approved by the principal developer.

Bilingual experts in the field of prosthetics, with backgrounds in prosthetic patient care, research, and education, were identified in Japan through professional contacts to review the translation process. The expert reviewers examined the translation and documentation record, approved or refuted decisions made by investigators, and offered alternative recommendations. Investigators studied the feedback from reviewers with the principal developer, revised translations to incorporate their suggestions, and prepared the Japanese translation of PLUS-M for cognitive interviews with target respondents.

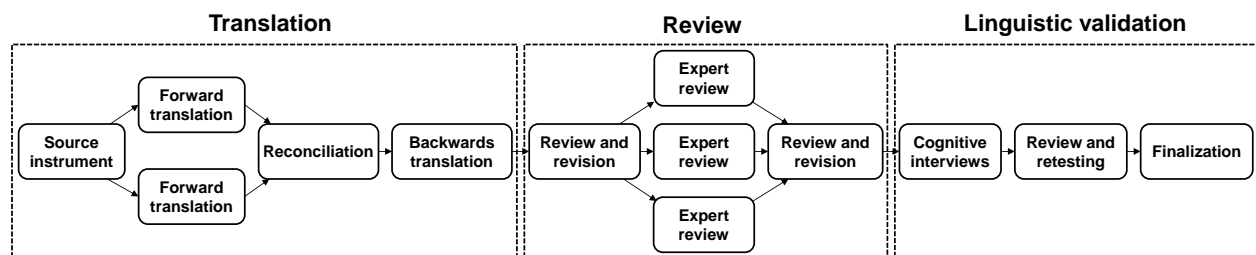


Figure 4.1. Procedures used to translate the Prosthetic Limb Users Survey of Mobility (PLUS-M)

### 4.3.3 *Participants*

Lower limb prosthesis users residing in Japan were recruited for the linguistic validation study. Participants were required to meet the following criteria: 1) 18 years of age or older; 2) agree to have the interview recorded; 3) able to read, write, and understand Japanese; 4) amputation in one leg between the ankle and hip; 5) and have at least three months of experience using a prosthesis. Participants were excluded if they had an upper limb amputation or history of a medical condition (e.g., stroke, spinal cord injury), other than lower limb amputation, that affected their balance or ability to walk.

Participants were recruited through flyers posted in Sawamura Prosthetic and Orthotic Services in Kobe, Japan. A minimum of five participants were needed to review each translated PLUS-M item (PROMIS, 2013; Willis, 2005). Purposive sampling was used to identify people with specific personal characteristics to ensure that each survey item was reviewed by at least one participant with the following attributes: 1) female, 2) 65 years of age or older, 3) 12<sup>th</sup> grade or lower education level, 4) transfemoral amputation level, 5) dysvascular amputation etiology, 6) low mobility level (i.e., household or limited community ambulator), and 7) high mobility level (i.e., active adult or athlete).

### 4.3.4 *Linguistic validation study procedures*

Linguistic validation refers to the process of assessing conceptual equivalence between language translations, and consists of testing translated survey items with target respondents by conducting cognitive interviews to determine whether components of a survey instrument are equivalent (Eremenco et al., 2005). Prior to testing, PLUS-M items were divided into two subsets in an effort to reduce survey length, minimize respondent burden, and improve recall (Willis,

2005). Items were ordered by their difficulty parameter ( $b_i$ ), and alternatively placed in each subset to ensure that participants reviewed items that spanned a broad range of mobility.

Interview guides were created for the two item subsets, to remind interviewers of important discussion points or concerns related to instructions, items, and response options. These points often addressed terms, situations, and/or Japanese characters that were challenging to translate, controversial among expert reviewers, or flagged for potential problems with cultural applicability.

The linguistic validation study protocol was reviewed and determined to qualify for exempt status by University of Washington Human Subjects Division. Interviews were conducted entirely in Japanese using web video conferencing software (Zoom Video Communications, Inc., San Jose, California, United States). Participants joined interviews from a prosthetics clinic in Kobe, Japan, where one investigator, KF, was located. The two interviewers, GB and SS, were located in Seattle, Washington, United States. At the beginning of each interview, the onsite investigators provided the participant with a study information statement and one of two PLUS-M item sets. Interviewers reviewed study information with participants and confirmed their willingness to participate. Participants were then asked a series of questions about their amputation, prosthesis use, and personal characteristics. Next, participants were asked to respond to PLUS-M survey items. Upon completion, participants were asked to immediately recall their thoughts and impressions while responding to the survey. Interviewers used scripted and unscripted questions to probe the linguistic clarity, comprehensibility, and cultural applicability of survey items, and logged field notes to document participants' interpretations of the context and meaning of each item (Eremenco et al., 2005; Willis, 2005). Interviews were audio-recorded and lasted about 60 minutes. Following each interview,

investigators compared and reconciled field notes, and determined whether each item possibly required revisions. The principal PLUS-M developer then reviewed interview responses and field notes for flagged items and determined whether revisions were required. Interviewers revised problematic items (i.e., those items that were unclear or misunderstood) and retested them in subsequent rounds of cognitive interviews. The process was repeated until items were approved by the principal developer. Item revisions, interviewer field notes, and developer comments were added to the documentation record. After all items were linguistically validated, the Japanese translation of PLUS-M was finalized, and short forms were formatted in the Japanese language.

#### 4.3.5 *Analysis plan*

Reconciliation decisions and justifications were coded using the approach described by Koller *et al.* (2012). For example, if a reconciled translation was mostly derived from Translator A but underwent a minor modification, the number “3” would be documented. Next, a subcode was applied to identify the reason for the reconciliation decision. In the previous example, if translators based their decision on the conceptual similarity between the selected translation and the source instrument, then a justification code (.1) would be added, and the final reconciliation code would be “3.1.” Codes were tabulated to quantify frequency of selections. Item and response option modifications were tabulated following the reconciliation, backwards translation, and expert review stages. After revising items during the finalization stage, each item was classified by the degree to which it varied from a “literal” translation of the English PLUS-M item. Translated items that generally aligned with the source PLUS-M items were classified as “unchanged.” Those that underwent grammatical changes to improve clarity and comprehension were classified as “minor revisions.” Translations that were subjected to modification of scenarios and/or objects described in PLUS-M items to improve cross-cultural applicability were

classified as “major revisions.” These classifications were tabulated for comparison. A literacy review was performed using Obi3 (Nagoya Obi Project, Nagoya University, Nagoya, Japan), a Japanese readability predictor developed by Sato *et al.* (2008). PROMIS guidelines recommend that items should be at or lower than a sixth grade reading level (PROMIS, 2013), and PLUS-M was designed to be understood by individuals at an eighth grade reading level (Morgan et al., 2014). The translated PLUS-M items were assessed as to whether they achieved these reading level standards.

## 4.4 RESULTS

### 4.4.1 *Reconciliation of forward translations*

Reconciliation of forward translations required the use of 7 of 9 decision codes, and 13 of 15 decision justifications described by Koller *et al.* (2012; see Table 4.1). Reconciled translations of items and response option sets included verbatim forward translations from one investigator (n = 19), translations from either investigator with minor modifications (n = 6), combinations of verbatim components of both translations (n = 13), combinations of both translations with modifications (n = 4), and a completely new translation (n = 1). Additionally, one item that described shag (i.e., high-pile) carpet was removed during reconciliation, as translators were unable to identify a comparable indoor surface common in Japan.

Over half of the reconciliation decisions were attributed to comprehensibility of a translation or conceptual alignment with the source instrument. For example, one forward translation of an item, “Are you able to carry a laundry basket up a flight of stairs?” used a Japanese verb “運び登る” (carry up) and the other translation used “もって...あがる” (hold and go up). The latter translation sounded more natural and reduced the reading level, while maintaining the

Table 4.1. Reconciliation decision criteria for items translated in the current study, denoted according to recommendations by Koller *et al.* (2012)

<i>Decision type</i>	<i>Decision option</i>	<i>Number of items coded (n)</i>
Single translation verbatim	Forward translation A as it is	0
	Forward translation B as it is	19
Single translation modified	A with minor modifications	2
	B with minor modifications	4
Merged translations verbatim	Merge as is and adapted A to B	9
	Merge as is and adapt B to A	4
Merged translations modified	Merge, modify, and adapt A to B	4
	Merge, modify, and adapt B to A	0
New or removed	Prepare a new translation C	1
	Remove	1
<i>Decision criteria type</i>	<i>Decision criteria</i>	
Source and comprehensibility	Best reflects the conceptual meaning of the source text	5
	Best reflects the stress (i.e., main point) of the source text	3
	Is understandable for a lay person without medical knowledge	3
	Is understandable to a population of varied education levels	9
	Is as close as possible to the source text	0
	Reads more naturally in the target language	9
Cultural	Is culturally appropriate in the scope of sensitive topics	0
	Is culturally appropriate in the scope of cultural differences	3
Grammatical	The syntax is correct	2
	The verbal forms and tenses are correct	3
	Gender and number are adapted and correct	2
	Other elements (e.g., articles and prepositions) are correct	2
Terminology	Includes all the keywords	2
	Is semantically precise	4
	Vocabulary/terminology is consistent throughout translation	2

intended meaning. Another 20% of reconciliation decisions were based on grammatical differences between translations, and included discrepancies in sentence structure, verbal forms, numeric adaptations, and preposition differences.

As an example, one forward translation of the English item that states, “Are you able to move heavy furniture with the help of another person?” used the nonspecific phrase “他の人の助け”

(the help of another person or other people), while the other translation used a numeric counting unit “もうひとりの人の助け” (the help of one more person) that provided more clarity. About 14% of justification criteria related to terminology, including presence of key words, semantic precision, and consistency of vocabulary throughout the translation. In one example, forward translators differed in word selection for the PLUS-M item “Are you able to walk across a 4-lane road at a crosswalk before the light changes?” One translation clearly described a crosswalk at an intersection but used the term “道” (road) that describes a general road or path and may refer to either two or four lanes moving in each direction. The second translation specified a 4-lane street with two lanes moving in each direction but did not include the term “横断歩道” (crosswalk). The translations were combined to include the preferred term for “4-lane road” as well as “crosswalk.” Finally, 9% of reconciliation decisions were attributed to cultural differences. Examples include “a curb of a sidewalk” that was translated to “道路と歩道の段差” (the step between the street and sidewalk), and distance term, “a block” that was initially translated as “サッカー場の長さぐらい” (about the length of a soccer field) and “学校の運動場トラック一周と同じ距離” (the same distance as the length of a school running track), then changed to “信号から次の信号まで” (from one traffic light to the next traffic light).

#### 4.4.2 *Post-backwards translation revisions*

Subsequent translation steps also informed item revisions. Three items were revised following the backwards translation. For example, the PLUS-M item, “Are you able to walk down a flight of stairs with a handrail?” was back-translated as “Can you descend stairs using one handrail?” To specify “a flight,” the Japanese phrase “1 階分の階段” (stairs that extend one floor or story) was added to clarify the length of the of stairway. The back-translation process

also informed revision of the five response options. The reconciled translation of the response option, “with a little difficulty” was back-translated as “mostly not difficult,” and the response option, “with some difficulty” was returned to English as, “a little difficult.” These results allowed investigators to identify differences in the degree of difficulty implied by each response option. Specifically, two response options were interpreted as describing a similar level of difficulty. After revising the two options and retesting, the second round of backwards translations resulted in two distinct levels of difficulty, “A little difficult” and “difficult” that matched the English phrases, “with a little difficulty” and “with some difficulty.”

#### 4.4.3 *Post-expert review revisions*

All four expert reviewers independently advised to retain 15 of the item translations without any changes. All reviewers also recommended revising 3 of the items. For the remaining 25 items, recommendations to revise or retain were mixed across reviewers. After reviewing recommendations, investigators opted to revise eight items. These revisions addressed issues with characters and grammar. Expert reviewers provided helpful guidance regarding when best to use Kana and Kanji, to balance readability and politeness. As an example, reviewers advised that the word “ライン” (line, using Katakana) be replaced in the item, “Are you able to walk placing one foot in front of the other as if walking on a line?” Reviewers proposed three alternatives, including “一本のライン” (one line), “直線” (straight line), and “線” (line, using Kanji). The latter was selected, as the generic nature of the word aligned well with the similarly non-descriptive English word, “line,” in the English PLUS-M item.

After revisions were made based on suggestions received from expert reviewers, each translation was classified by the extent to which the Japanese translation varied from the source instrument (see Table 4.2). Investigators classified 21 of the 44 items as “unchanged,” meaning

that the Japanese and English items maintained similar grammar and content. For example, the PLUS-M item, “Are you able to push a shopping cart?” was directly translated, as the Japanese phrase, “あなたはショッピングカートを押すことができますか?” uses the same terminology, and using a shopping cart at a grocery store is scenario familiar to most people residing in Japan. Another 19 items were classified as “minor revision,” meaning that changes were made to grammar or terminology for clarity and/or comprehension. As an example, the PLUS-M item, “Are you able to keep walking when people bump into you?” could not be directly translated, as a direct translation implied a person was purposefully attacking the respondent. The item was revised to include the word “不意に” (suddenly), and the Japanese translation reads, “あなたはだれかに不意にぶつかられたとき、歩き続けることができますか?” (Are you able to keep walking when someone suddenly bumps into you?). Finally, three items were classified as “major revision,” meaning that changes were made to the context or activity described by an item to improve cultural applicability. For example, a PLUS-M item includes “church” as an example of a place where one might walk

Table 4.2. Examples of translation classifications used to summarize the extent to which the Japanese translation of PLUS-M required revisions

PLUS-M item	Japanese translation	Differences	Classification
Are you able to walk while carrying a shopping basket in one hand?	あなたは買い物かごを片手に持ったまま歩くことができますか? Are you able to walk while holding a shopping basket in one hand?	Similar verb “holding” used in translation	Unchanged
Are you able to step up and down curbs?	あなたは道路と歩道の段差を上がり下りできますか? Are you able to go up and down a step between the road and the sidewalk?	Descriptive terms and grammar used in translation	Minor revision
Are you able to walk a block on flat ground?	あなたは信号から次の信号まで歩くことができますか? Are you able to walk from one traffic light to the next traffic light?	Alternative scenario used in translation to estimate distance	Major revision

between rows of occupied seats. Places of worship in Japan rarely include pews or rows of seats and most people have not attended a church that resembles the scenario intended by this item. The Japanese translation replaced “church” with “劇場” (performing arts theater), and expert reviewers unanimously agreed that the change was culturally appropriate and reflected the mobility situation described in the original PLUS-M item.

#### 4.4.4 Linguistic validation

A total of 10 participants were interviewed for the linguistic validation study between February and April 2020 (see Table 4.3). The cognitive interviewing process revealed equivalence issues that were not identified in previous steps of the translation. One issue was an unfamiliarity with a situation described in an item. For example, when responding to the question, “あなたは信号から次の信号まで歩くことができますか？” (Are you able to walk from one traffic

Table 4.3. Cognitive interview participant characteristics

Identifier	Age (years)	Sex	Education	Lower limb amputation level	Amputation etiology	History of prosthesis use (years)	Avg. daily prosthesis use (hours)	Prosthetist-reported mobility level	“Do you ever use an assistive device?”
1-1	39	Male	Vocational college	Transtibial	Congenital	38	15	High	No
1-2	75	Male	High school	Transfemoral	Cancer	52	12	Mid	No
1-3	50	Female	University	Transtibial	Dysvascular	18	11	Low	Yes
1-4	33	Male	Vocational college	Transfemoral	Trauma	5	12	High	No
1-5	27	Female	Vocational college	Transtibial	Congenital	26	14	High	No
2-1	53	Male	Vocational college	Transfemoral	Cancer	37	16	Mid	No
2-2	25	Male	High school	Transtibial	Trauma	4	12	High	No
2-3	29	Female	University	Hip disarticulation	Congenital	29	14	Mid	No
2-4	79	Male	High school	Transfemoral	Dysvascular	52	12	Low	Yes
2-5	75	Female	High school	Transtibial	Congenital	68	15	Mid	No

light to the next traffic light?), two participants imagined crossing a pedestrian crosswalk of a 4-lane road, rather than walking a moderate distance from one traffic light to the next traffic light. Four other participants were unsure how to respond because the distance was not clear. After investigators explained the intended meaning of the item, several participants recommended stating a specific distance range for clarity. The question was rephrased to “あなたは街中で 50 - 100 メートルを歩くことができますか?” (Are you able to walk 50-100 meters on a city street?) (see Table 4.4). Minor grammatical issues were also identified as factors affecting equivalence between the Japanese and English instruments. For example, when testing the PLUS-M item, “Are you able to move a chair from one room to another,” three participants imagined moving a chair by pushing or pulling it across the floor. The intention of the source language item was to ask a respondent about lifting and carrying a chair a short distance. The verb “動かす” (move) was replaced with a similar word, “移動させる” (move) that was suggested previously by an expert reviewer. The item was retested with three other participants who described the intended actions of picking up and moving chairs.

One item required a revision due to cultural differences between the U.S. and Japan. The PLUS-M item, “Are you able to walk across a parking lot?” was designed to present a scenario where a person would be required to walk a moderate distance outside on asphalt that may be uneven (e.g., grocery store parking lot). However, several cognitive interview participants indicated that they considered a typical parking lot to be a relatively short distance (i.e., a row of 3 or 4 parking spaces). To address this issue, the word “広い” (wide) was added before “駐車所” (parking lot). The revised item was retested, and all three participants thought about walking a larger distance (i.e., a department store parking lot) that was more consistent with the intent of the PLUS-M item. Cognitive interviews were also useful for identifying characters that elevated


Table 4.4. Example of translation documentation record for one PLUS-M item

PLUS-M item (English)	Are you able to walk a block on flat ground?
Forward translation A (Japanese)	サッカー場の長さぐらいに平らな地面を歩く？ Are you able to walk on flat ground, about the length of a soccer field?
Forward translation B (Japanese)	あなたは学校の運動場トラック一周と同じ距離を歩くことができますか？ Are you able to walk about the same distance as one loop around a school running track?
Reconciled translation	あなたは信号から次の信号まで歩くことができますか？
Decision option	9: Create an entirely new translation
Decision criteria	2.2: The word "block" does not translate well to Japanese, and examples in A and B did not include the nuances of the English term. We decided that "from one traffic signal to the next traffic signal" was the best replacement.
Back translation (English)	Can you walk from one stop light to the next stop light?
Back-translator comments	Does the distance between one stoplight to the next stoplight vary depending on the city and block?
Developer comments	Developer decided it was ok for the exact distance to vary (it does in English too); reconciled translation deemed acceptable
Revision	None required
Developer comments	Reconciled translation deemed acceptable
Final translation	あなたは信号から次の信号まで歩くことができますか？
Reviewer 1 revision	あなたは歩道を 50~100m 程度歩くことができますか？
Reviewer 2 revision	None
Reviewer 3 revision	あなたは交差点から次の交差点まで歩くことができますか？
Revision	None required
Developer comments	The current translation may describe "a block" more effectively than specifying a distance or "next intersection"
Classification	Major revision
Post-review translation	あなたは信号から次の信号まで歩くことができますか？
Cognitive interviews: Round 1 summary	6 of 8 participants imagined crossing a crosswalk and walking across several lanes of traffic. Two others somewhat understood the idea of walking a longer distance to another traffic light, but they were unable to clearly visualize the situation. The most common suggestion was to specify a distance. We think it would be best to revise the translation to: "Walk 50-100 meters on city streets." We will retest the revised item.
Cognitive interviews: Round 2 summary	3 of 3 participants imagined a walking between 50 and 100 meters on a city sidewalk or street. The situations they described sounded similar to the meaning and nuances of the term "block"
Final translation	あなたは街中で 50 - 100 メートルを歩くことができますか？

the reading level of the translated instrument. As an example, an expert reviewer recommended using Kanji characters, “砂利” to describe “gravel” in the PLUS-M item “あなたは砂利道を歩くことがで



formatted as short forms. The Japanese translation of the PLUS-M 7-item and 12-item short forms were published online and made freely available (PLUS-M, 2018b) (see Figure 4.3).



Name: \_\_\_\_\_ Date: \_\_\_\_\_

**Instructions:** Please respond to all questions as if you were wearing the prosthetic leg(s) you use most days. If you would normally use a cane, crutch, or walker to perform the task, please answer the questions as if you were using that device.


Please choose "unable to do" if you:

- Would need help from another person to complete the task,
- Would need a wheelchair or scooter to complete the task, or
- Feel the task may be unsafe for you

Please mark one box per row.

Question	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
1. Are you able to walk a short distance in your home?	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
2. Are you able to step up and down curbs?	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
3. Are you able to walk while carrying a shopping basket in one hand?	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
4. Are you able to keep walking when people bump into you?	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
5. Are you able to keep up with others when walking?	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
6. Are you able to walk down a steep gravel driveway?	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
7. Are you able to hike about 2 miles on uneven surfaces, including hills?	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)

www.plus-m.org PLUS-M™ 7-item Short Form (v1.2)  
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名前: \_\_\_\_\_ 日付: \_\_\_\_\_

**説明:** すべての質問には、あなたが常用している義足の使用を前提にお答えください。あなたが特定の課題を行うときに、日頃から杖、松葉杖、または歩行器を使っている場合、それらの器具を使っている前提で質問に答えてください。

もしあなたが下記のいずれかが当てはまる場合は、選択肢のうち「できない」を選んでください：  
「他人の助けが必要である」  
「車椅子又は電動カートを用いる必要がある」  
「安全でないと感じる」

各質問ごとに、一つのボックスをチェックしてください。

質問	全く 難しい ない	やや 難しい	難しい	とても 難しい	全く できない
1. あなたは自宅の中で短い距離を歩くことができますか？	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
2. あなたは道路と歩道の段差を上がり下りできますか？	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
3. あなたは買い物かごを片手に持ったまま歩くことができますか？	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
4. あなたはだれかに不意にぶつかられたとき、歩き続けることができますか？	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
5. あなたは歩いているときに他の歩行者についていくことができますか？	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
6. あなたはジャリりの急な下り坂を歩いておろしていくことができますか？	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)
7. あなたは約3キロのデコボコな山道を歩くことができますか？	<input type="checkbox"/> (5)	<input type="checkbox"/> (4)	<input type="checkbox"/> (3)	<input type="checkbox"/> (2)	<input type="checkbox"/> (1)

www.plus-m.org PLUS-M™ 7 項目簡易評価表 (v1.2)  
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Figure 4.3. English PLUS-M V1.2 7-item short form (left) and Japanese translation (right)

## 4.5 DISCUSSION

This study aimed to create a high-quality Japanese translation of the PLUS-M item bank and linguistically validate the translated instructions, items, and response options. Multi-step translation processes, like the methods employed in the current study, have been shown to improve the overall quality of survey instrument translations (Acquadro et al., 2008). A high-quality translation is more likely to approach equivalence with the source language instrument and produce comparable scores. Evidence for achieving equivalence is obtained gradually, and different types of equivalence can be assessed at specific phases of translation and testing

(Herdman et al., 1998). Results of the current study provide initial evidence of semantic equivalence, defined as "the transfer of meaning across languages...achieving a similar effect on respondents in different language" (Herdman et al., 1998). In the current study, the meaning of each item was investigated through cognitive interviews and issues with language clarity and cultural applicability were addressed through revisions. Future studies may address other types of equivalence, including item equivalence, that refers to measurement properties of translated items; operational equivalence, that refers to usability of the same modes of administration (e.g., short forms) in both languages; and measurement equivalence, that refers to both language instruments achieving acceptable evidence of psychometric properties (e.g., reliability, validity, responsiveness).

Each step of the translation process used in the current study yielded valuable information. Translated items were modified at each review step of the process, including reconciliation of forward translations, review of backwards translation, review of expert feedback, and following cognitive interviews. These modifications improved readability, cultural applicability, and conceptual equivalence of the translation. Exclusion of one or more of the translation steps from the current study may have resulted in fewer modifications and limited translation precision. Established guidelines for translating survey instruments lack consensus regarding translation processes (Epstein et al., 2015). Several guidelines recommended using all steps included in this study (Beaton et al., 2000; Eremenco et al., 2005), while others advise fewer steps. For example, Mathias *et al.* (1994) suggested an abbreviated translation process that includes only a single forward translation, eliminating the need for reconciliation prior to backwards translation. Swaine-Verdier *et al.* (2004) advised against the backwards translation step, to reduce the potential for introducing information that may mislead the developer by

shifting the focus to literal, rather than conceptual, equivalence. Instead, the authors recommended an increased number of forward translations for comparison (Swaine-Verdier, 2004). In the current study, multiple forward translations, reconciliation, and backwards translation steps provided opportunities for investigators to identify issues and fine tune the translations. Other translation guidelines include all of the steps used in the current study, apart from clinical expert reviews. For example, the European Organisation for Research and Treatment of Cancer Quality of Life Group recommendations do not include expert review (Kuliš et al., 2017). Similarly, American Association of Orthopedic Surgeons translation guidelines advise that the review be performed by an expert committee, consisting of the forward and backwards translators and/or non-specified field experts (Beaton et al., 2000). Another guideline for survey translation in healthcare research leaves out the expert review step completely (Sousa & Rojjanasrirat, 2011). These differences between translation guidelines may explain the variety of survey translation methods reported in the literature.

The translation of the PEQ from English to Japanese is an example of a study that used a different approach to translate and assess linguistic comparability. Tobimatsu *et al.* (2004) used a traditional forward-backwards approach (Brislin, 1970) to translate the ten PEQ scales from English to Japanese, then administered the items to a sample of 154 prosthesis users and quantitatively compared properties of the translated and source instruments. The authors reported that two of the ten scales, Appearance and Social Burden, were found to have poor internal consistency (Cronbach's  $\alpha = 0.54$  for both scales). Interestingly, the translated Transfers scale was found to have high internal consistency ( $\alpha = 0.91$ ), whereas the same scale in the source instrument was found to have poor internal consistency ( $\alpha = 0.47$ ) (Legro et al., 1998; Tobimatsu

et al., 2004). These differences may suggest that further testing may be warranted to assess the linguistic equivalence between the English and Japanese translations of the PEQ.

Other research efforts to translate PRO instruments from English to Japanese have similarly excluded the expert review and cognitive interview steps. For example, Fukuhara *et al.* (1998) translated the Short Form 36 (SF-36) health survey (Ware & Sherbourne, 1992) from English to Japanese using forward and backwards translation techniques, and compared floor and ceiling effects by testing the translated survey with a sample of healthy Japanese adults. The authors identified a ceiling effect and similar scores across all physical functioning items that were intended to vary in level of difficulty. Focus groups were later held to investigate whether the items were misunderstood (Fukuhara et al., 1998). Another study that used a repeated forward-backwards translation method did not report issues with comparability. Hamamoto *et al.* (2015), translated the Knee Society Scoring System (KSSS) using a process that included three blind forward translations, reconciliation, and dual back translations, repeated until the back translation was deemed suitable. The authors conducted a repeated measures study with 55 adults and found that the translated KSSS had adequate internal consistency across subscales, good test-retest reliability, and no evidence of floor or ceiling effects (Hamamoto et al., 2015). These examples from the literature suggest that when translating PRO instruments from English to Japanese, a simple forward-backwards process may not be adequate, and the addition of qualitative methods or repeated processes should be considered.

The translation effort described in the current study involved two distinct languages and cultures. Cheung & Thumboo (2006) described several potential issues related to translating English PRO instruments into Asian languages, including Japanese. The authors noted the difficulty in overcoming cultural differences when translating surveys and compared the benefits

of adapting rigorously developed English language instruments to developing entirely new instruments specific to Asian countries. The authors advised that researchers adapt existing, psychometrically robust instruments to Asian languages, unless presented with differences in culturally specific constructs (Cheung & Thumboo, 2006). Constructs related to social interactions, emotions, and communication have been identified as being influenced by language and culture (Matsumoto et al., 2005). Lower limb mobility, however, is likely to be less affected by language and culture, as ambulation and basic changes in posture (e.g., standing up from a seated position) are universally experienced. In the current study, cognitive interviews confirmed that mobility did not differ significantly due to culture. Cheung & Thumboo (2006) also advised that translation efforts should include back-translation and linguistic validation interviews to assess the understanding of native language speakers. Use of both backwards translation and linguistic validation steps in the current study contributed to the resolution of cultural differences (e.g., removal of an item that describes “deep-pile or shag carpet”) allowing for a successful translation.

Translations of survey instruments can be used to pool and compare prosthetic mobility data. As more translations of PLUS-M are performed, additional opportunities will emerge for comparing effectiveness of interventions and improving patient care on a global scale. For example, new language translations may help a country better understand the status of prosthetic mobility within or across regions. Further, mobility outcomes can be used to determine the effectiveness of interventions used in a geographical region. This data may inform the prosthetic needs of a community and help policy makers allocate resources. A reliable survey instrument translated into many languages can also be used to ask important scientific questions. For example, international multi-centered research studies may investigate outcomes associated with

prosthetic mobility in different regions of the world. Use of PRO data obtained from comparable translated instruments, has been recommended as a cost-effective solution for increasing sample sizes for these types of studies (Wild et al., 2009). Other research efforts may focus on the societal or financial advantages of prosthetic limb use. Finally, prosthetic mobility outcomes can be compared between countries to learn which practices are most effective and identify areas for improvement.

#### 4.5.1 *Limitations*

This study had limitations. Eremenco *et al.* (2005), recommended that both forward translators speak the target language as their first language. Forward translators in the current study included one investigator whose native language was Japanese, and another whose native language was English. As a result, nearly half of forward translations selected during reconciliation were those put forth by the native Japanese investigator. Remaining selections were combinations of forward translations from both investigators (refer to Table 1). The disproportionate selections suggest that forward translations produced by the native English-speaking investigator may have contributed less to the translation. However, expert reviews likely resolved the issue, as four additional bilingual translators who speak Japanese as their first language suggested alternative translations and provided new insights. This experience demonstrates the importance of the expert review stage of a translation effort. Also, an advantage of including one native speaker of each language was the opportunity to share insights into the nuances of both English and Japanese during reconciliation and subsequent revision stages.

All linguistic validation study participants were recruited from a single prosthetics clinic in one area of Japan. Regional dialects vary in different parts of Japan, and a survey item that was understood well by a participant of the current study, may be less clear to a resident of

another part of Japan. To address this limitation, investigators and expert reviewers avoided using region-specific terminology and strived for a balance between generic (i.e., polite) and understandable language. Findings of the literacy review and feedback from participants with a high school level-education suggest that the translated instrument will be well understood by most adults who speak Japanese.

#### 4.5.2 Conclusion

Measurement of health outcomes will become increasingly important as prevalence of health conditions associated with lower limb amputation increases in Japan and other parts of the world. Survey instruments, like PLUS-M, with strong evidence of reliability and validity can improve patient care when used to facilitate communication, monitor mobility status, and evaluate interventions. The current study demonstrated the value of a rigorous multi-step translation process for navigating cultural differences and confirming clarity and comprehension of a translated instrument. As PLUS-M and other survey instruments are increasingly adapted to new languages, the international field of prosthetics will have new opportunities for research collaborations.

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## Chapter 5. CONCLUSION

### 5.1 SUMMARY OF STUDIES

As a body of work, the research presented in this dissertation used qualitative procedures to perform initial steps to develop a patient-reported outcomes (PRO) instrument and a model for future language translations. The included studies aimed to gain an understanding of an important health-related construct, generate and select candidate items for a new item bank, and establish a model for translating an item bank to other languages. Findings of this research included new insights into mobility of orthosis users gained through a focus group study, completion of initial steps to develop a condition-specific item bank, and identification of a language translation model. Together, these findings establish a foundation for future research efforts, which include administering candidate items to a national sample of lower limb orthosis users, calibrating the item bank, psychometrically testing the resulting instruments, and translating these instruments to other languages to facilitate measurement of mobility outcomes worldwide.

In Chapter 2, a focus group study was conducted to learn how lower limb orthosis users conceptualize mobility. Qualitative analysis methods were used to identify themes that reflected the shared experiences and opinions of the participants. Personal factors, situations, and assistance were identified as cross-cutting themes that influenced orthosis users' mobility. Participants described a process for modifying their mobility capabilities through the use (or non-use) of different types of mobility aids. Findings of this study suggest that orthosis users encounter distinct challenges and decisions related to their mobility, and a new instrument designed specifically for measuring these experiences may be warranted.

In Chapter 3, a qualitative item review process was used to develop a candidate item bank (DeWalt et al., 2007). This process incorporated findings from the focus group study described in Chapter 2, namely, verification of definitions, evaluation of an existing conceptual model, and identification of content for new items. This effort also included a review of existing PRO items applicable to lower limb orthosis users, an item selection process, and cognitive interviews to assess the quality of candidate items. The activities and movements depicted in candidate items were informed by content of existing PRO items and input from orthosis users and expert stakeholders in the field of orthotics. The study resulted in a set of candidate items that were determined to be clear and understandable. However, several steps of the instrument development process remain to be completed, including administration of candidate items to a large sample of orthosis users, calibration of the items to a statistical model, creation of short forms and a computerized adaptive test, and psychometric testing to establish evidence of reliability, validity, sensitivity, and responsiveness.

In Chapter 4, a model for language translation was applied to a PRO instrument translation effort. A study was conducted to translate an existing item bank, the Prosthetic Limb Users Survey of Mobility (PLUS-M), into the Japanese language and evaluate the linguistic validity of the translation through cognitive interviews. Established translation methods and techniques, including two forward translations, reconciliation, backwards translation, and expert reviews were used to translate the instrument, under the direction of instrument's principal developer. Investigators were able to translate all but one PLUS-M item. The Japanese translation was further evaluated through a linguistic validation study with prosthesis users in Japan and was determined to be clearly understood and culturally applicable. In addition to producing a new language translation of PLUS-M, this study assessed the suitability of a

standardized approach to translating a condition-specific item bank. The translation process combined an established translation methodology (Eremenco et al., 2005) with a reconciliation and documentation technique (Koller et al., 2012) that was found to be comprehensive and effective. Robust language translations of a PRO instrument may allow for increased inclusivity when comparing outcomes within a country, and lead to new opportunities to combine or compare outcomes internationally.

## 5.2 COALESCENCE OF STUDIES

A common element between dissertation chapters was the application of qualitative research methods. Chapters 2 and 3 utilized results from the same focus group study. However, the objectives and analysis processes of each chapter differed. The purpose of the focus groups in Chapter 2 was to broadly explore how participants conceptualized mobility and determine whether mobility-related themes could be identified across individuals and groups. Investigators read and re-read transcripts, coded data, organized codes, and identified themes through consensus meetings. In contrast, the purpose of the focus groups in Chapter 3 were to establish a definition for “mobility” informed by participant feedback, evaluate the suitability of an existing measurement model to characterize mobility, and identify activities and situations discussed by participants to include as candidate PRO items.

When compared to Chapter 2, analysis methods for Chapter 3 were less exploratory in nature. Investigators reviewed transcripts and coded and classified excerpts relevant to the mobility definition, measurement framework, and participants’ experiences that could be used to generate new items. The focus group objectives and analysis procedures described in each chapter contributed unique and important insights. For example, the thematic analysis in Chapter 2 uncovered a variety of situations commonly experienced by participants in which an orthosis

enhanced or limited their mobility; whereas the coding and classification of terms in Chapter 3 allowed investigators to identify terminology frequently used by participants (e.g., “leg brace” rather than “orthosis”). Together, findings from both chapters improved investigators’ understanding of how orthosis users conceptualize and talk about mobility with an orthosis.

Chapters 3 and 4 differed in terms of study design and objectives, however, both chapters included cognitive interviews to assess the clarity and comprehension of PRO items. A difference between the cognitive interview studies was the evaluation of cultural applicability described in Chapter 4. In a language translation study, cultural applicability is a critical component of adapting the concepts of a source language to a target language (Eremenco et al., 2005). While the purposes for the cognitive interviews in each study varied, the type of interviews (i.e., semi-structured) and goals (i.e., to assess clarity, comprehension, and applicability of items across a diverse group of individuals) were similar. Further, the analysis procedure used in both studies consisted of parallel steps, including field note review, revisions, and retesting of items. These similarities suggest that the translation and linguistic validation processes used in this study may be efficient for future applications (i.e., translation of mobility items for orthosis users), as investigators are familiar with cognitive interviewing techniques and procedures.

Chapters 2, 3, and 4 represent different stages of development and translation of a PRO instrument. As stated above, additional efforts are needed to complete development of the new item bank to measure mobility of lower limb orthosis users. The research described in this dissertation consisted primarily of qualitative methods. The next steps to advance development of the instrument include mostly quantitative methods and require large sample sizes and resources.

### 5.3 OVERALL LIMITATIONS

A potential limitation of this research was the use of a measurement model that was previously developed for characterizing mobility of lower limb prosthesis users (Hafner et al., 2016). It is possible that other insights may have been identified had investigators developed an entirely new conceptual model for measuring mobility of orthosis users. However, investigators of the research presented in Chapter 3 opted to use the PLUS-M model as starting point, hypothesizing that the model could be generally applied to lower limb mobility, as the included forms of movement and situational contexts were not dependent upon use of prosthesis. Each of the situational contexts included in the PLUS-M model were identified as being applicable to orthosis users, after reviewing coded transcripts and classifying candidate items.

The research described in Chapter 3 resulted in a candidate item bank, however, application of the instrument will be limited until the next phases of development are completed. Although the PRO development procedures used in the study were modeled after those used to develop psychometrically-robust and well-accepted instruments, such as PROMIS item banks (Reeve et al., 2007), the performance of the new item bank relative to existing instruments is not yet known.

### 5.4 FUTURE DIRECTIONS

The next steps in the item bank development process include administration of the candidate items to a large sample of orthosis users, calibration of the items to an item response theory (IRT) model, and creation of multiple administration formats (e.g., paper short forms, electronic short forms, and computerized adaptive test). Subsequent testing of the calibrated item bank will aim to establish evidence of psychometric properties, including validity, reliability,

sensitivity, and responsiveness. In Chapter 3, other PRO instruments, including LEFS, OPUS-LEFS, and PROMIS-PF, were identified as being applicable to orthosis users due to their history of use in or focus on clinical populations that use orthoses. However, few studies have evaluated their measurement properties when applied to lower limb orthosis users (Jarl et al., 2015; Weber et al., 2018). To address this gap in knowledge, we will co-administer these three PRO instruments alongside the new item bank to compare their measurement properties and facilitate their use in clinical practice and research. Future research efforts will involve three major phases, including a large-scale administration and calibration, reliability and validity testing, and sensitivity and responsiveness testing.

#### 5.4.1 *Large-scale administration and calibration*

A cross-sectional observational study will be conducted to collect a sufficient number of responses needed to calibrate the new item bank and establish normative reference data. A national sample of lower limb orthosis users ( $n = 1000$ ) will be recruited for the study. Eligibility criteria will resemble the participation requirements of prior focus group and cognitive interview studies outlined in Chapters 2 and 3. Eligible participants will be asked to complete a survey that includes candidate items for the new instrument, existing PRO items applicable to orthosis users (i.e., LEFS, OPUS-LEFS, and PROMIS-PF), additional PROMIS items that measure a variety of health-related constructs, and other questions that address an individual's health condition, orthosis use, and demographic characteristics.

Analysis methods will follow the PROMIS Psychometric Evaluation and Calibration Plan (Reeve et al., 2007). Survey responses will be used to evaluate the measurement characteristics of candidate items and calibrate the item bank. Investigators will fit the data to an item response theory (IRT) statistical model and assess whether the items satisfy required assumptions for

calibration, including unidimensionality, local independence, monotonicity, and invariance (Nguyen et al., 2014; Reeve et al., 2007). Unidimensionality assumes that all items only measure the construct of mobility and will be assessed by (1) performing a confirmatory factor analysis and examining a scree plot that indicates the number of factors measured and by (2) using tests of model fit to identify misfitting items. Local independence assumes that all items are statistically independent of responses to all other items and will be assessed by (1) examining discrimination slope angles of each item to identify those with excessive covariance and by (2) using a residual correlation matrix to identify significantly correlated items. Monotonicity assumes that the probability of endorsing an item will continuously increase as an orthosis user's mobility level increases and will be assessed by plotting item characteristic curves to examine S-curve shapes. Invariance assumes that item characteristics (i.e., parameters) will be constant across different groups of orthosis users with the same level of mobility and will be assessed by performing a differential item functioning analysis to determine whether items function with bias due to age, gender, or health condition. Problematic items will be removed and the remaining items that meet all IRT assumptions will be calibrated using a graded response IRT model, recommended for items with ordered polytomous response categories (Samejima, 1997). Calibration of the items will produce estimates of item parameters, including difficulty (i.e., location along the mobility continuum where the item functions best) and discrimination (i.e., ability to differentiate orthosis users with different levels of mobility) needed to administer and score the instrument (Nguyen et al., 2014; Reeve et al., 2007). Survey responses and participant characteristics will be used to establish normative reference scores for the new instrument, LEFS, OPUS-LEFS, and PROMIS-PF. Additionally, initial known-groups validity of the new

item bank will be evaluated by comparing responses of participants with specific attributes (e.g., age group, sex, orthosis type).

#### 5.4.2 *Short forms, CAT, and language translation*

Investigators will create targeted short forms and a computerized adaptive test (CAT) and make them freely available through a public website. Short forms can be targeted to different levels of mobility (i.e., low, mid, high) or general to include items across the difficulty spectrum. Short forms may also be created through stakeholder input to include items within the bank that are most relevant to sub-populations of orthosis users (e.g., those diagnosed with stroke or multiple sclerosis). A users guide will be created to provide look-up tables to convert raw scores to T-score estimates. Reference scores, based on the normative data from the large-scale study, will be available to guide interpretation. The item bank will be translated into other languages using the model presented in Chapter 3 of the dissertation. Translation efforts will be overseen by instrument developers to ensure each step is carried out appropriately and the process is well-documented.

#### 5.4.3 *Reliability and validity testing*

In the subsequent phase, a repeated-measures validation study will be conducted with lower limb orthosis users ( $n = 100$ ) to assess and compare the content validity, construct validity, and test-retest reliability of the new item bank relative to existing mobility-related PRO instruments and performance-based tests. Data will be collected by trained clinicians at select patient care facilities. The new item bank, LEFS, OPUS-LEFS, and PROMIS-PF will be concurrently administered with the Timed Up and Go (Podsiadlo & Richardson, 1991), Two-Minute Walk Test (Butland et al., 1982), and 10 Meter Walk Test (Wade et al., 1987).

Convergent construct validity will be assessed by calculating correlation coefficients, using scores from PRO instruments and performance tests, and comparing them to established thresholds (Dancey & Reidy, 2007). Content validity will be assessed by examining PRO instrument scores and quantifying the percentage of individuals that score at the upper and lower ends of each instruments' scoring range. Test-retest reliability will be assessed by calculating intraclass correlation coefficients (ICC), using scores from repeated administration of PRO instruments, and comparing them to recommended thresholds (Reeve et al., 2013). Additionally, measurement error and minimal detectable change (MDC) statistics will be computed to enhance clinical interpretation. Results of this study will provide a psychometric assessment of the reliability and validity of a new item bank relative to three existing PRO instruments.

#### 5.4.4 *Sensitivity and responsiveness testing*

A longitudinal cohort study will be conducted to evaluate each PRO instrument's ability to measure changes in mobility due to orthotic intervention and establish thresholds for clinically meaningful change. The study will take place in patient care settings over a six-month period with 245 patients receiving orthotic treatment. The instrument derived from the candidate item bank, LEFS, OPUS-LEFS, PROMIS-PF, and a self-rating scale of change in mobility, will be administered before, and multiple times after provision of an orthosis to assess the sensitivity and responsiveness of scores produced by PRO instruments. Sensitivity will be evaluated by comparing scores at baseline and six months later, using statistical tests to identify significant differences in scores. Results will be compared between groups of patients who received different types of interventions (i.e., new, replacement, or upgraded orthotic devices). Additionally, relative sensitivity to change will be assessed for each PRO instrument by computing effect sizes and standardized response means for each cohort (Husted et al., 2000).

Responsiveness will be assessed by comparing correlations between PRO instrument scores and self-rated change in mobility. Next, patients who experienced a meaningful change, and those who did not will be evaluated separately using a receiver operating characteristic (ROC) curve analysis. The area under the curve will be calculated for each group to determine whether each of the PRO instruments are able to correctly classify individuals as those who experienced a meaningful change in mobility. The ROC analysis will also be used to establish the minimum clinically important difference (MCID) by identifying the score for each PRO instrument that best distinguishes patients who experienced a meaningful change in mobility. Results of this study will provide estimates of sensitivity and responsiveness and further inform their application of these PRO instruments to research and clinical purposes.

## 5.5 CONCLUDING STATEMENT

The goals of the research described in this dissertation were to explore how mobility is conceptualized by orthosis users, perform the qualitative steps required to develop a contemporary condition-specific item bank, and identify a model for translating an item bank to other languages. Future efforts aim to calibrate the item bank, evaluate its psychometric properties, and make the instrument available in multiple formats and languages.

Accomplishment of these objectives will result in a new assessment tool to aid the efforts of rehabilitation professionals worldwide to evaluate orthotic interventions, document mobility scores, monitor changes over time, justify selection of orthotic interventions, communicate with interdisciplinary team members, and encourage patients.

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## VITA

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