

Challenges of Large-scale Patient-reported Outcome Measures Collection in a Multidisciplinary Limb Salvage Center

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Completion of patient-reported outcome measures (PROMs) is a labor-intensive but crucial cornerstone in advancing patient-centered care. PROMs attempt to quantify subjective information regarding patient function and quality of life, which allows clinicians to assess the patient's perspective on their health and guide surgical decision-making.^{1,2} However, PROM reporting is infrequent and inconsistent in chronic lower extremity (LE) wound patients.³ Implementation in clinical practice is challenging due to the lack of standardized methods for collection and reporting, as well as the complex and time-consuming nature of data analysis in this highly comorbid population.³ We report challenges experienced during implementation of PROM collection in our high-volume, multidisciplinary tertiary limb salvage center.

During this pilot study, 500 sets of PROMs were administered to 420 patients over 2 months with a completion rate of 90% or greater for each PROM. Many aspects of PROM collection posed unique challenges in the chronic LE wound patients. Patients completed surveys through iPads, which proved difficult because this tended to be an older population (mean age 63.2±16.4 years) largely unfamiliar with the technology. Patients surveyed had a median Charlson Comorbidity Index of 4 (IQR: 3–6); due to patients' highly comorbid nature, several barriers prevented independent completion of PROMs (eg, blindness, dementia), requiring research assistants to help complete the surveys. Additionally, many PROM questions were phrased either too ambiguously (eg, patients with multiple wounds not knowing whether to report general pain vs. pain at specific location) or were irrelevant to certain patients (eg, wheelchair users answering questions about walking upstairs), resulting in inconsistent responses.

Surgical categorization of this patient population also proved arduous. Many patients' complex surgical histories [eg, patient with a transmetatarsal amputation on the left

limb and below-knee amputation on the right limb] made organizing each patient into their respective LE wound cohort difficult (Fig. 1). This was exacerbated by the need to create inclusion and exclusion criteria for each LE wound category, such as categorizing partial resections of phalanges and metatarsals as transmetatarsal amputation versus ray amputations.

Additional challenges were faced regarding the clinical applicability of PROMs utilized. While PROM scores could be used to compare the patient's score to the general populous or between LE wound groups, clinical extrapolations, such as determining what a PROM score of one SD below the mean suggested about patient functionality, were challenging. Future research correlating functionality and PROM scores is imperative in understanding the impact of our care in this population and providing standard measures of functionality that can be used to influence treatment options, such as insurance coverage for higher quality prosthetics to improve patient ambulation. Table 1 highlights recommendations to address these challenges.

As the first study highlighting the challenges of obtaining PROMs in a limb salvage center, we acknowledge that while survey implementation in this setting is difficult, it is still feasible. The need for a standardized collection and analysis system that overcomes these challenges, as well as PROMs specifically designed to study this complex population, is imperative for enhancing our assessment and care for these patients.

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Sample patient: 47-year-old male with surgical history of BKA and ray amputation on the left limb, and ray amputation, and TMA on the right limb. The patient's surveys were categorized within the BKA group

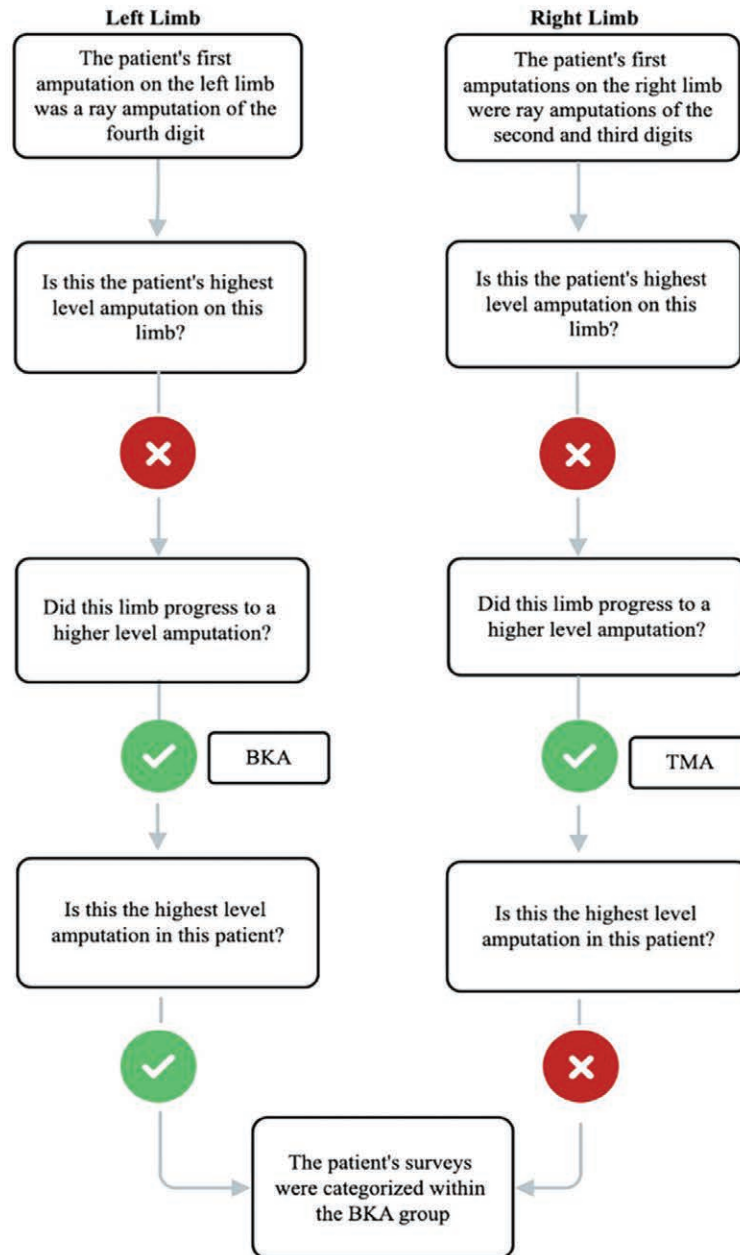


Fig. 1. Example of the process used to categorize a surveyed patient for further subanalysis of PROM scores by operative procedure. BKA, below-knee amputation; TMA, transmetatarsal amputation.

Table 1. Proposed Solutions to Address Challenges Associated with PROM Collection in a Highly Comorbid, Chronic Lower Extremity Wound Population

	Challenge	Proposed Solution	Example
PROM collection	Older patients were unfamiliar with iPad technology used for digital survey collection	Hire designated research assistants in the clinic to assist with survey completion on the iPads Have paper copies of the surveys available for patients who do not know how to use the iPads	Research assistant guides the older patient as they answer survey questions on the iPad or offers the older patient a paper copy of the survey questions
	Highly comorbid patients could not complete the surveys independently	Hire designated research assistants in the clinic to assist with survey completion	Research assistant reads survey questions aloud to the patient who is visually impaired
PROM content	Ambiguously phrased questions used in the surveys led to inconsistent responses	Creation of PROMs that are specifically designed to study this highly comorbid lower extremity wound population	For a question used in the PROMIS Pain Intensity survey (“In the past 7 days, how intense was your pain at its worst?”), a patient with multiple wounds did not know which pain to report. This problem can be addressed by changing the question to specify the location of pain to report (“In the past 7 days, how intense was the pain associated with your most recent surgery at its worst?”)
	Included survey questions inapplicable to certain patients led to inconsistent responses	Creation of PROMs that are specifically designed to study this highly comorbid lower extremity wound population	For a question used in the Neuro-QOL Lower Extremity Function (Mobility) survey (“How much difficulty do you currently have walking around one floor of your home?”), a patient who uses a wheelchair may have no trouble moving around their home but would have to answer “Can’t do” because they cannot walk. This problem can be addressed by modifying the survey questions to include use of assistive devices (“How much difficulty do you currently have using your assistive device to move around one floor of your home?”)
PROM analysis	Highly comorbid patients were difficult to categorize into respective wound cohorts for analysis due to their complex surgical histories	Creation of clear inclusion/exclusion criteria for each lower extremity wound category Creation of a standardized stepwise process to categorize patient based on the level of their procedure (Fig. 1)	When designing the study, the researchers specify that the “partial foot amputation” cohort should include ray, transmetatarsal, mid-foot, and Syme amputations, but should exclude toe amputations When categorizing a patient with multiple wounds (left below-knee amputation and right toe amputation), the researchers decide to assign the patient based on the highest level amputation (“below knee amputation” cohort)
	Inability to make clinical extrapolations about patient status from the PROMs used in this study	Future research focused on identifying correlations between patient functionality/QOL and PROM scores in order to create clear guidelines for clinical interpretations of PROM scores	A patient with a PROMIS Pain Intensity score that is X standard deviations higher than the mean is a better candidate for amputation versus limb salvage

Neuro-QOL, Neurology Quality of Life; PROMIS, Patient-Reported Outcomes Measurement Information System; QOL, quality of life.