



LIMB-Q©

A User's Guide for Researchers and Clinicians

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1. What is the LIMB-Q?

The LIMB-Q is a rigorously developed patient-reported outcome measure (PROM) that can be used internationally to collect and compare evidence-based outcomes data from patients aged 18 years and older after lower extremity trauma. The LIMB-Q is composed of 16 independently functioning scales. The use of a modular approach means that only the subset of scales most relevant to a specific research objective or clinical patient population needs to be administered.

2. How was the LIMB-Q Developed and Validated?

The LIMB-Q represents a new generation of PROMs developed using a modern psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PROM are each designed to measure and score a unidimensional construct. In scale development, data that meet the requirement of the Rasch model provide interval-level measurement. When a scale has high content validity and is targeted to measure a concept as experienced by a sample, accurate tracking of clinical change can be achieved. In addition to their use in research studies, LIMB-Q scales can be used with individual patients to inform clinical care.

We followed internationally recommended guidelines for PROM development to create the LIMB-Q. Figure 1 shows the multiphase mixed-methods approach we use to develop Q-Portfolio instruments [1]. A detailed description of the protocol has been published: <https://www.researchprotocols.org/2019/10/e14397>.

The qualitative phase involved interviews with 33 patients from the United States [2]. The findings from the interviews were used to develop a conceptual framework comprised of the following 10 domains: appearance, environment, finances, physical, process of care, prosthesis, psychological, sexual, social, and treatment. Cognitive interviews with 12 patients from the United States, along with feedback from 43 international lower extremity trauma experts provided input used to refine the scales and to establish their content validity [3].

To facilitate the involvement of non-English speaking countries, the scales were translated and culturally adapted into Dutch, Danish [4], and German (Switzerland) [5] following ISPOR international guidelines. The quantitative phase involved the collection of data from 713 patients following lower extremity trauma in 24 countries [6]. Table 1 shows the sample characteristics. The final conceptual framework and set of scales is shown in Figure 2.

Figure 1: The multiphase mixed methods approach for developing the LIMB-Q (Reprinted from Mundy L, Klassen A, Grier J, Carty M, Pusic A, Hollenbeck S, Gage M. Development of a Patient-Reported Outcome Instrument for Patients with Severe Lower Extremity Trauma (LIMB-Q): Protocol for a Multiphase Mixed Methods Study. JMIR Res Protoc 2019;8(10):e14397)

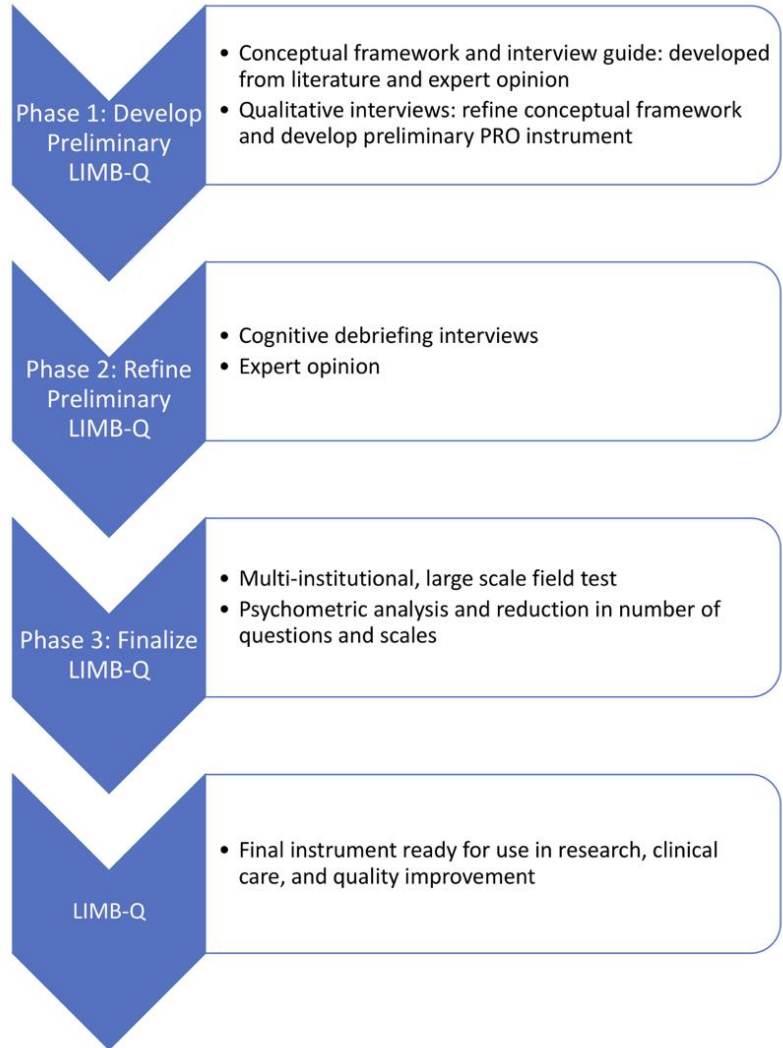


Figure 2: LIMB conceptual framework

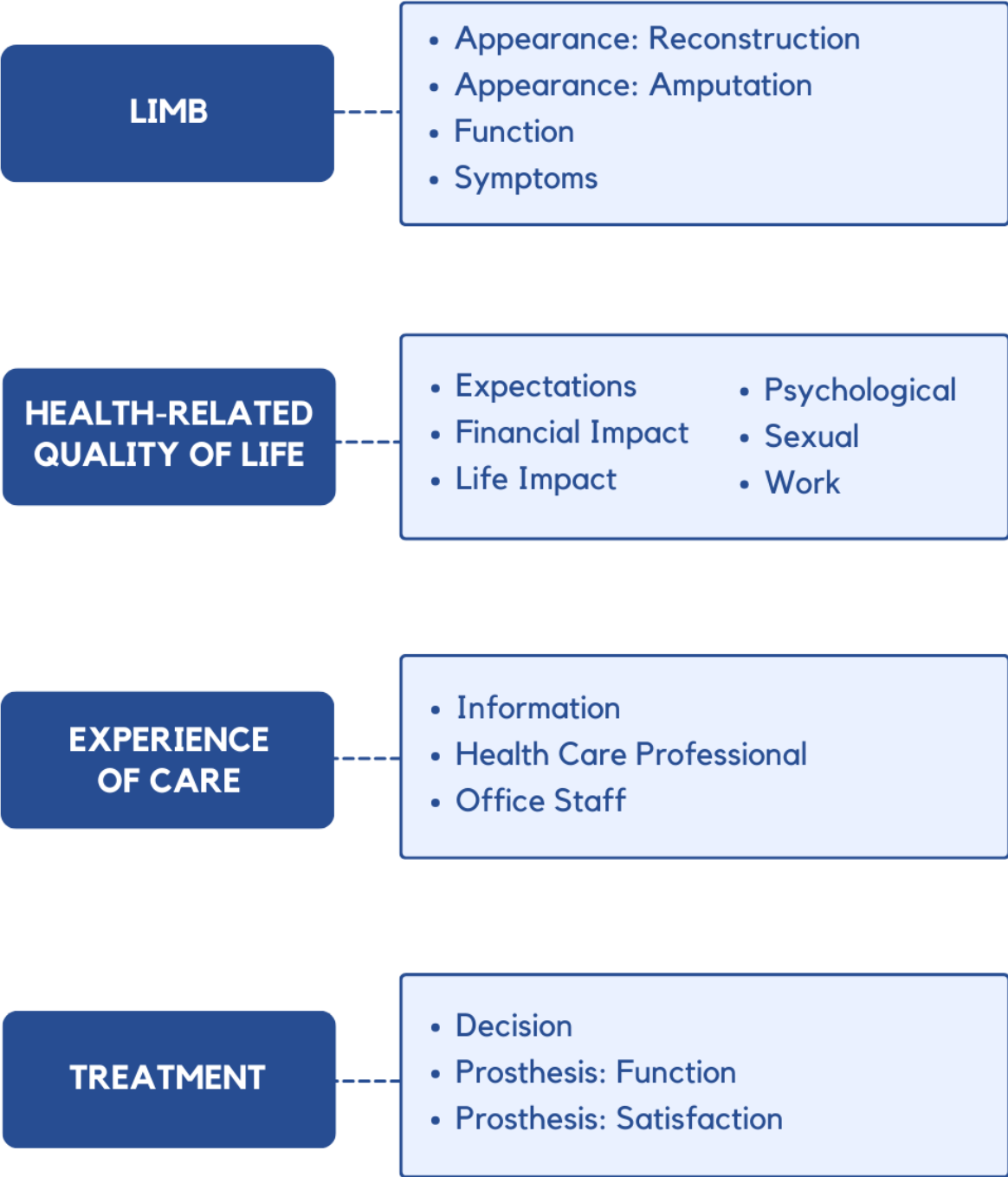


Table 1: Characteristics (Number, %) of field-test participants

		n	%
Gender	Male	413	62
	Female	245	37
	Transgender Man	1	<1%
	Transgender Woman	3	<1%
	Non-binary	5	<1%
Race and Ethnicity	White Non-Hispanic	337	60%
	White Hispanic	42	8%
	Black Non-Hispanic	116	21%
	Black Hispanic	6	1%
	South Asian/East Asian	12	2%
	Asian/Pacific Islander	3	1%
	Native American/Canadian	5	1%
	Mixed	13	2%
	Other/Prefer not to Say	26	4%
Education	Incomplete High School	25	4%
	High School	153	23%
	Trade School	44	7%
	Incomplete College	114	17%
	College/University	222	33%
	Graduate Degree	94	14%
	Prefer not to Say	14	2%
Household Income (USD)	< \$30,000	150	23%
	\$30,000 - \$49,999	125	19%
	\$50,000 - \$69,999	104	16%
	\$70,000 - \$99,999	86	13%
	>\$100,000	90	14%
	Retired	28	4%
	Prefer not to Say	81	12%
Marital Status	Single	317	48%
	Common Law/Married	286	43%
	Widowed	14	2%
	Divorced/Separated	43	6%
	Prefer not to Say	7	1%
Country	Australia	2	<1%
	Canada	8	1%
	Chile	4	<1%
	Czech Republic	3	<1%
	Denmark	1	<1%

		n	%
Country cont.	Finland	3	<1%
	France	3	<1%
	Germany	3	<1%
	Greece	6	<1%
	Hungary	4	<1%
	Ireland	1	<1%
	Italy	5	<1%
	Mexico	12	2%
	Netherlands	111	16%
	Norway	1	<1%
	Poland	33	5%
	Portugal	13	2%
	Slovenia	1	<1%
	South Africa	77	11%
	Spain	3	<1%
	Sweden	2	<1%
	Switzerland	1	<1%
	United Kingdom	66	9%
	United States	342	48%
Injury Etiology	Fall	199	32%
	Gunshot Wound	12	2%
	Explosive Device	4	1%
	Crush Injury	45	7%
	Car Accident	217	35%
	Other	142	23%
Injury Characteristics	Unilateral	480	91%
	Bilateral	50	9%
	Polytrauma	181	34%
	Military Injury	6	1%
Treatment Outcome	Reconstruction	219	38%
	Amputation	77	13%
	Amputation and Reconstruction	59	10%
	Fracture Surgery Only	221	39%

Note: Table 1 is adapted from Mundy LR, Klassen A, Pusic AL, DeJong T, Hollenbeck ST, Gage MJ. The LIMB-Q: Reliability and Validity of a Novel Patient-Reported Outcome Measure for Lower Extremity Trauma Patients. *Plast Reconstr Surg.* 2024 Jan 15.

3. LIMB-Q Scales

Table 2 shows the LIMB-Q scales including number of items, the population included in the Rasch Measurement Theory analysis, response options, recall period, and scoring. Of note,

the patients in the field test included patients with a history of a lower extremity traumatic injury below the mid-femur. Patients either underwent surgery for management of the fracture only (“fracture”) or required soft tissue reconstruction with a flap (“reconstruction”) and/or an amputation (“amputation”) in addition to fracture management. Below the table is a brief description of the content of each scale.

Table 2: Description of LIMB-Q scales

Scale	Items	Population	Response options	Recall	Scoring
Limb					
Appearance: Reconstruction	8	Any	Very Bothered → Not at All Bothered	Now	0-100
Appearance: Amputation	10	Any	Very Bothered → Not at All Bothered	Now	0-100
Function	15	Any*	Extremely Difficult → Not at All Difficult	Past Week	0-100
Symptoms	10	Any	Severe → None	Past Week	0-100
Health-Related Quality of Life					
Expectations	11	Any	Unlikely → Very Likely	Fully Recovered	0-100
Financial Impact	8	Age <50 years	Very Much → Not at All	Now	0-100
Life Impact	10	Any	Very Much → Not at All	Now	0-100
Psychological	10	Any	Always → Never	Past Week	0-100
Sexual	8	Any	Definitely Disagree → Definitely Agree	Now	0-100
Work	8	Any	Definitely Agree → Definitely Disagree	Now	0-100
Experience of Care					
Information	12	Any	Very Dissatisfied → Very Satisfied	Now	0-100
Health Care Professional	12	Any	Definitely Disagree → Definitely Agree	Recent Appointment	0-100
Office Staff	12	Any	Disagree → Definitely Agree	Recent Appointment	0-100
Treatment					
Decision	6	Flap or Amputation	Definitely Disagree → Definitely Agree	Now	0-100
Prosthesis: Function	12	Amputation**	Very Dissatisfied → Very Satisfied	Past Week	0-100
Prosthesis: Satisfaction	12	Amputation**	Very Dissatisfied → Very Satisfied	Past Week	0-100

*Applicable to ambulatory patients (with or without assistive device)

**Applicable to patients who use a prosthesis

LIMB

Appearance: Reconstruction: This 8-item scale measures how (very, quite, a little, not at all) bothered someone is about how the reconstructed part of their limb looks. Items ask about the appearance of the reconstructed part of the lower limb in terms of size, shape, contour, surface, and scars, as well as how it looks unclothed and in comparison to the uninjured limb.

Appearance: Amputation: This 10-item scale measures how (very, somewhat, not at all) bothered someone is about how their amputated lower limb looks. Items ask about the appearance of the residual lower limb in terms of color, contour, length, shape, and scars, as well as how it looks unclothed and the impact on clothes.

Function: This 15-item scale measures how (extremely, moderately, a little, not at all) difficult it is to perform physical tasks. Items ask about walking in different directions, on different surfaces, on different inclines, as well as more various levels of physical exercise.

Symptoms: This 10-item scale measures the severity (severe, moderate, mild, none) of physical symptoms. Items ask about pain, cramps, swelling, tingling, numbness, stiffness, as well as the impact of symptoms on sleep.

HEALTH-RELATED QUALITY OF LIFE

Expectations: This 11-item scale measures how (unlikely, somewhat likely, very likely) patients expect themselves to feel when they are fully recovered from their injury. Items ask about physical activity, symptoms, and appearance.

Financial Impact: This 8-item scale measures how much (very much, quite a bit, a little bit, not at all) a financial burden or stress the injury has been for patients. Items ask about the cost of activities, medical devices, medications and supplies, transportation, financial debt, and housing and living expenses.

Life Impact: This 10-item scale measures how much (very much, quite a bit, a little bit, not at all) the injury has had a negative impact on the patient's life. Items ask about social relationships and activities, sexual relationships, independence, emotional well-being, and participating in life.

Psychological: This 10-item scale measures how much the injury (always, often, sometimes, never) affects how patients feel. Items are negatively worded asking about frequency of symptoms of depression, anxiety, and frustration.

Sexual: This 8-item scale measures how much patients disagree or agree (definitely disagree, somewhat disagree, somewhat agree, definitely agree) that the injury has impacted their sexual life. Items ask about sexual intercourse in regard to enjoyment, confidence, comfort, satisfaction, lower limb symptoms, and physical ability.

Work: This 8-item scale measures how much patients agree or disagree (definitely agree, somewhat agree, somewhat disagree, definitely disagree) that the injury impacts their ability to work. Items ask about changing jobs, changing how their job is performed, relying on others, and the quality of their work.

EXPERIENCE OF CARE

Information: This 12-item scale measures how dissatisfied or satisfied (very dissatisfied, somewhat dissatisfied, somewhat satisfied, very satisfied) patients are about the information they received. Items ask about information received in regard to steps of treatment as well as post-operative and recovery expectations.

Health Care Professional: This 12-item scale measures if (definitely disagree, somewhat disagree, somewhat agree, definitely agree) patients were satisfied with the care they received from their health care team following the injury. Items ask about professionalism, knowledge, bedside manner, shared decision making, and the quality of care provided.

Office Staff: This 12-item scale measures if (disagree, somewhat agree, definitely agree) patients were satisfied with the care they received from the office staff following the injury. Items ask about professionalism, respectfulness, knowledge, and the quality of care provided.

TREATMENT

Decision: This 6-item scale measures how (definitely disagree, somewhat disagree, somewhat agree, definitely agree) patients felt about the decision making in their care. Items ask about decisions that were made, regret about treatment choices, and how the outcome compared to expectations.

Prosthesis: Function: This 12-item scale measures how dissatisfied or satisfied (very dissatisfied, somewhat dissatisfied, somewhat satisfied, very satisfied) patients are with the function of their lower limb prosthesis. Items ask about use of the prosthesis to perform different physical activities, on different surfaces, and ambulation in different settings.

Prosthesis: Satisfaction: This 12-item scale measures how dissatisfied or satisfied (very dissatisfied, somewhat dissatisfied, somewhat satisfied, very satisfied) patients are with the appearance, comfort, and fit of their lower limb prosthesis. Items ask about appearance, comfort, and fit.

4. Administration of the LIMB-Q

The LIMB-Q is designed to be completed by patients on their own (self-report). Each scale is independently functioning, which means that only scales relevant to the clinical situation or research question need to be completed. Patients can thus be asked to complete a subset of scales relevant to their situation. Brief instructions and the timeframe for reporting are provided at the start of each scale. The LIMB-Q was field-tested using online data collection, i.e., Research Electronic Data Capture System (REDCap) as well as paper-and-pencil. You may use the paper and pencil format or create an online version for ease of administration in non-profit academic research (e.g., REDCap) and in clinical care (e.g., hospital EMR such as Epic). If you plan to have an ePRO company capture and manage LIMB-Q data collection, the ePRO company may need a license. If you have had or plan to have an ePRO company convert LIMB-Q scales into an electronic format, e-conversion review and certification is required. Please email gportfolioteam@gmail.com for more information.

5. Scoring the LIMB-Q

There is no overall or total LIMB-Q score. Instead, the LIMB-Q is composed of independently functioning scales (see Table 2).

To score a scale, the raw scores for the set of items in a scale are added together to produce a total raw score. The choice of how to handle missing data, such as whether or not to impute the mean when there is missing data, is ultimately up to the end user of LIMB-Q. Our suggestion follows the most popular method for scoring when there is missing data, which is to impute a missing value by the mean response to completed items if more than 50% of items are answered. This method is recommended in the scoring manuals of numerous widely used PROMs, such as the SF-36 generic questionnaire used extensively in research for decades [7-8]. As such, LIMB-Q scores can be computed if missing data is less than 50% of the scale's items. In this approach, the within person mean for the completed items can be imputed for the missing items prior to computing a total raw score. For example, if there is a 10-item scale and someone has not responded to all the items, but has responded to ≥ 5 items, all other items for that person can be imputed with a within-person mean (rounded to the nearest integer), and a summed score can be calculated. Alternatively, for a 10-item scale, if someone has responded to ≤ 4 items, the summed score for this person cannot be computed and is classified as missing data.

Once a total raw score for the scale is computed, the Conversion Table can be used to convert the raw score into a score that ranges from 0 (worst) to 100 (best). The conversion, which linearizes the scores, is based on the findings from the Rasch analysis. Higher scores for LIMB-Q scales reflect a better outcome. The Conversion Tables for

changing raw scores into 0 to 100 scores are available after a licensing agreement is signed.

6. Conditions of Use

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- You will not modify, adapt, or create another derivative work from the LIMB-Q
- You will not sell, sublicense, rent, loan, or transfer the LIMB-Q to anyone
- You will not reproduce any LIMB-Q scales in publications or other materials
- You will not translate the LIMB-Q without permission from our team

For questions regarding study design and optimal use of LIMB-Q scales, please contact either:

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7. Frequently Asked Questions

Do I have to use all of the LIMB-Q scales?

Each scale functions independently; therefore, patients can be asked to complete one or all of the LIMB-Q scales. It is not necessary for a patient to complete all of the scales as there is no overall or total LIMB-Q score. A researcher or clinician may therefore select a subset of scales depending on the particular purpose of the study or use.

Can I delete or add or change any items or response options of the LIMB-Q?

You cannot delete or add or change the wording of any items or response options of the LIMB-Q. Any modification to the content of the LIMB-Q is prohibited under copyright laws. Also, making any changes to LIMB-Q scales would invalidate their psychometric properties.

Can I reproduce LIMB-Q scales in a publication or other public document (e.g., PhD thesis)?

According to the licensing agreement, you cannot reproduce the content of LIMB-Q scales verbatim in a publication. However, it is possible to show shortened versions of items. The short forms of items that can be used in a publication are shown in Table 3 below.

Can I translate LIMB-Q scales into a new language?

Yes, with permission, you can translate the LIMB-Q into different languages. Before starting a translation, check our translations list on www.qportfolio.org to see if there is a translation in the language you need. If there is not a translation in the language you need, you will need to obtain permission from our team, sign a translation licensing agreement, and receive information on the methods you need to follow. Email us at qportfolioteam@gmail.com for more information. Please note that the developers of the LIMB-Q own the copyright of all translations of the LIMB-Q.

Are there specific time points when patients complete the scales?

A researcher or clinician can decide the time points they would like to administer the scales.

Does it cost money to use the LIMB-Q?

Use of LIMB-Q scales is free for non-profit users. For-profit users should contact McMaster University for information about fees (milo@mcmaster.ca).

8. Acknowledgements

Development of the LIMB-Q has involved more than 700 patients with a history of lower extremity traumatic injuries, along with the collaboration of numerous health care professionals and researchers around the world. We are truly grateful for their dedication and help with our research. The LIMB-Q study has been generously funded by the following grants:

Phase I: Qualitative

Hollenbeck ST, Mundy LR. Development of a PRO Instrument for Use in Severe Lower Extremity Trauma. Duke Surgical Center for Outcomes Research and Duke Musculoskeletal Program. Duke University. 2017 – 2018.

Phase II: Cognitive Debriefing Interviews

Mundy LR, Gage MJ. Development of a Patient-Reported Outcome Instrument for Severe Lower Extremity Trauma: Cognitive Debriefing Interviews. Foundation of Orthopaedic Trauma. 2018 – 2020.

Table 3: Shortened items for LIMB-Q scales to use in a publication

APPEARANCE - RECONSTRUCTION	EXPECTATIONS	SEXUAL
Size	Stairs	Enjoy
Shape	Moderate activity	Confident
Contour	No medication	Attractive
Surface	Stand	At ease
Unclothed	Right size	Satisfied
Scars	Usual activities	Without limb interfering
Different	Walk	Move around
Noticeable	Pain free	Physically easy
APPEARANCE – AMPUTATION	Vigorous activity	WORK
Color	Any physical activity	Rely on people
Contour	As well as before injury	Change what you do
Scars	FINANCIAL IMPACT	Quality down
Length	Leisure	Trouble performing
Shape	Accessible	Accommodations
Dress to hide	Medical devices	Breaks
Clothes fit	Medications and supplies	Physically hard
Restrictions wear	Transportation	Reduce amount
Unclothed	Debt	INFORMATION
How much	Housing	Who would be involved
FUNCTION	Living	Use during recovery
Step to side	LIFE IMPACT	How surgery done
Change directions	Fit in	Weight on limb
Step down	Relationships	How many surgeries
Carry	Take care of yourself	Complications
Backwards	Sexual life	Time to heal
Sudden movement	Independence	Walk first time
Moderate exercise	Emotional well-being	Pain during recovery
Downhill	Contribute	Look
Quickly	Participate fully	Long-term symptoms
Up stairs	Activities	Other patients
Uneven	Physically active	HEALTH CARE PROFESSIONAL
Down stairs	PSYCHOLOGICAL	Respect
Slippery surface	Hopeless	Professional
Jump	Sorry	Knew
Intense exercise	Angry	Easy to talk to
SYMPTOMS	Depressed	Experience
At rest	Overwhelmed	Answered questions
Touched	Anxious	Attentive
Cramps	Fed up	High level care
Disturbing sleep	Worried	Listened
Swelling	Irritated	Involved you
Shooting sensation	Frustrated	Enough time
Tingling		Available
Numb		
Pain putting weight		
Stiff		

OFFICE STAFF	PROSTHESIS: FUNCTION	PROSTHESIS: SATISFACTION
Respect	Flat surface	Easy take off
Comfortable	Balance	Looks
Privacy	Energy to walk	Quickly put on
Professional	Stand long period	Fits
Friendly	Up stairs	Weighs
Thorough	Backwards	Comfortable
Knowledgeable	Down stairs	Hours in a day
Attentive	Uneven surface	Enjoy life
Caring	Walk far	Physical changes
Welcomed	Sudden movements	Skin impact
Answered questions	Physically active	Forget
Available	Slippery surface	Part of your body
DECISION		
Happy with decisions		
How decisions made		
No regrets		
Treatment again		
Tell others		
Met expectations		

9. Publications Related to LIMB-Q Development and Validation

1. Mundy LR, Klassen A, Grier J, Carty MJ, Pusic AL, Hollenbeck ST, Gage MJ. Development of a Patient-Reported Outcome Instrument for Patients With Severe Lower Extremity Trauma (LIMB-Q): Protocol for a Multiphase Mixed Methods Study. *JMIR Res Protoc*. 2019 Oct 17;8(10):e14397. doi: 10.2196/14397. PMID: 31625944; PMCID: PMC6913330.
2. Mundy LR, Klassen A, Grier AJ, Gibbons C, Lane W, Carty MJ, Pusic AL, Hollenbeck ST, Gage MJ. Identifying Factors Most Important to Lower Extremity Trauma Patients: Key Concepts from the Development of a Patient-Reported Outcome Instrument for Lower Extremity Trauma, The LIMB-Q. *Plast Reconstr Surg*. 2020 May;145(5):1292-1301. doi: 10.1097/PRS.0000000000006760. PMID: 32332555.
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