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Patient-Reported Outcome Instruments for Surgical and Traumatic Scars: A Systematic Review of their Development, Content, and Psychometric Validation

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Abstract

Background—Patient-reported outcomes (PROs) are of growing importance in research and clinical care and may be used as primary outcomes or as compliments to traditional surgical outcomes. In assessing the impact of surgical and traumatic scars, PROs are often the most meaningful. To assess outcomes from the patient perspective, rigorously developed and validated PRO instruments are essential.

Methods—The authors conducted a systematic literature review to identify PRO instruments developed and/or validated for patients with surgical and/or non-burn traumatic scars. Identified instruments were assessed for content, development process, and validation under recommended guidelines for PRO instrument development.

Results—The systematic review identified 6,534 articles. After review, we identified 4 PRO instruments meeting inclusion criteria: Patient and Observer Scar Assessment Scale (POSAS), Bock Quality of Life Questionnaire for Patients with Keloid and Hypertrophic Scarring (Bock), Patient Scar Assessment Questionnaire (PSAQ), and Patient-Reported Impact of Scars Measure (PRISM). Common concepts measured were symptoms and psychosocial well-being. Only PSAQ had a dedicated appearance domain. Qualitative data were used to inform content for the PSAQ and PRISM, and a modern psychometric approach (Rasch Measurement Theory) was used to develop PRISM and to test POSAS. Overall, PRISM demonstrated the most rigorous design and validation process, however was limited by the lack of a dedicated appearance domain.

Conclusions—PRO instruments to evaluate outcomes in scars exist but vary in terms of concepts measured and psychometric soundness. This review discusses the strengths and weaknesses of existing instruments, highlighting the need for future scar-focused PRO instrument development.

Keywords

scar; cicatrix; quality of life; patient reported outcome; instrument; measure; systematic review

INTRODUCTION

Every year millions of individuals acquire scars following surgical intervention or trauma [1]. These scars vary in both the appearance (size, shape and location on the body) and the potential impact on a patient's physical, social and psychological well-being [2, 3]. An ideal outcome assessment would have the ability to capture this breadth of scar impact on a patient. Traditional outcome assessments of scars, such as the Vancouver Scar Scale [4] and Manchester Scar Scale [5], have focused on the clinician's opinion of the scar's physical properties. These clinician-reported outcome (ClinRO) assessments use clinical judgment and expertise to measure observable signs [6], such as scar color or size and potential physical manifestations of disease. However, such measures do not capture symptoms and unobservable concepts such as pain or quality of life (QOL) impact, which are known only to the patient [6].

Alternatively, patient-reported outcome (PRO) instruments (also known as PRO Measures or PROMs) are questionnaires that measure concepts of interest (COI) relevant to patients, e.g., symptoms or appearance. Since the 1990s, there have been guidelines in place for the development and validation of PRO instruments for use in health outcomes research [7–10]. Instruments that do not undergo a formalized development and validation process are termed *ad hoc*. Such measures lack evidence of reliability and validity and thus should be avoided. Instruments that are rigorously developed and validated, on the other hand, have the potential of measuring important health concepts from the patient perspective in a reproducible manner [11]. Broadly speaking, such instruments may be classified as either generic or disease-specific. Generic instruments cover COI that are relevant to a diverse population of patients, as opposed to the specific concerns of a disease-specific patient group. As such, generic PRO instruments often do not have the sensitivity to measure change within disease-specific COI [12]. In addition, since generic instruments rarely include content to cover appearance-related concerns, disease-specific tools are required for cosmetic, reconstructive and dermatological conditions.

Scars, and their associated symptoms, have the potential to impact multiple health domains, including appearance, as well as psychosocial, physical and even sexual well-being, factors likely well known to the aesthetic surgeon. Given the number of individuals acquiring new scars, as well as the increasing attention to minimally invasive surgery and well hidden surgical scars, it is important to have reliable PRO tools that could be used to evaluate the impact scars have on individuals, separate from the impact of the surgery itself. To this end, we conducted a systematic literature review. Our aim was to identify PRO instruments

designed for and validated in patients with surgical and/or non-burn traumatic scars and critically appraise these instruments based on the recommended steps set by the US Food and Drug Administration for health-related outcome measures development and psychometric validation [7]. Our overall goal was to assist researchers and clinicians in making informed decisions regarding PRO instrument selection.

METHODS

Search strategy

An electronic search strategy was created to identify publications describing the development and/or use of a PRO instrument assessing QOL and/or satisfaction in patients with surgical and/or non-burn traumatic scars. The search was carried out in PubMed, Medline, EMBASE, Cochrane, PsychINFO Web of Science, EBSCO, and HaPI from inception to May 2014. Similar search terms were used in each database. The search was limited to English language articles.

Search terms (see Table 1) were developed for three theme areas, including scars, QOL and/or patient satisfaction, and outcome instruments. Search terms were used as text words and then mapped to medical subject headings when appropriate. The search terms within each category were combined with the Boolean operator OR, and categories were combined with the Boolean operator AND.

Selection criteria

Instruments were included if they were published in English and developed or validated to measure QOL and/or patient satisfaction for surgical and/or traumatic scars not secondary to burn. *Ad-hoc*, generic and disease-specific instruments without a primary focus on scars, were excluded from the review. Also excluded were conference abstracts, theses, editorials, review articles, and letters to the editor. A citation review of included articles was performed to identify any PRO instruments that might have been missed by the search. In addition, a targeted search for additional publications for each of the included PRO instruments was performed to identify additional information regarding the instruments' development and validation processes. When necessary, the corresponding author was contacted to clarify ambiguous and/or missing information. Electronic copies of each instrument were obtained, and content for each instrument was summarized and compared.

Data extraction

One author (XXX) reviewed titles and abstracts to screen out non-relevant articles, and two authors (XXX/XXX) worked independently to review the full-text of all remaining articles. Disagreements between authors were resolved by consensus between the two screeners and senior author (XXX).

Validity of HRQOL methodology

PRO instruments meeting inclusion criteria were evaluated based on adherence to instrument development and validation steps published by the US Food and Drug Administration [7]. These steps stress the importance of developing a conceptual framework and content (scales

with items) for a PRO instrument from qualitative patient interviews, expert opinion and literature review, identifying patients' key concerns, field-testing the scales in a large sample of patients, analysis of the field-test data to identify the best set of items to retain in the final measure, and an examination of the instruments psychometric properties, including reliability, validity and responsiveness.

RESULTS

The results of the search are outlined in Figure 1. After removing duplicates, a total of 6,534 articles were identified. The title and abstract screening reduced potential articles to 552 full-text articles, which were all screened in detail. We identified 19 articles utilizing 4 scar-specific PRO instruments meeting inclusion criteria. Secondary searching identified 2 additional articles describing and/or using the 4 scar-specific PRO instruments. The four scar-specific PRO instruments (see Table 2) were the Patient and Observer Scar Assessment Scale (POSAS) [13], Bock Quality of Life Questionnaire for Patients with Keloid and Hypertrophic Scarring (Bock) [14], Patient Scar Assessment Questionnaire (PSAQ) [15], and Patient-Reported Impact of Scars Measure (PRISM) [16]. All were designed and/or validated with the goal of assessing QOL and/or patient satisfaction in patients with surgical and/or non-burn traumatic scars. Table 3 summarizes the content assessed in each instrument, as interpreted by the authors of this review, and Table 4 summarizes the results pertaining the development and validation of each instrument. Where applicable, assessment of the psychometric properties of each instrument reflects the inclusion of the most updated instrument and/or published analysis. The relevant information for each instrument, including item content and adherence to the previously discussed guidelines for instrument development and psychometric testing are described below.

1.0 Patient and Observer Scar Assessment Scale (POSAS)

The POSAS [13] is a 13-item instrument with a 6-question observer- and 7-question patient-reported scale developed initially for burn scars. Despite this, as well as the presence of an observer component, it is widely used, psychometrically evaluated in non-burn scar populations, and has a validated patient-reported component, and thus included in this review [17, 18].

1.1 Instrument development—The authors first formed a conceptual model, and generated items via literature review and expert opinion.

1.2 Instrument content—There are two separate domains, a patient domain and an observer domain. Each domain can be summed to give summary patient and observer scores. Content for the patient-POSAS includes 3 scar appearance questions, 3 physical symptom questions, and 1 summary question, whereas the observer scale assesses appearance and physical characteristics only. All questions are answered on a Likert Scale from 1 to 10. The patient symptom questions, given with the timeframe of the past few weeks, range from “1 = no, as normal skin” to “yes, very different = 10,” patient appearance/characteristics questions, asked at the present, range from “1 = no, not at all” to “yes, very much = 10,” and the observer questions range from “1 = normal skin” to “worst scar imaginable = 10,” with

additional descriptive categories for each question. Lastly, patients are asked of their overall opinion of the scar compared to normal skin with “1 = as normal skin” and “very different = 10.”

1.3 Psychometric properties—The POSAS was the first PRO scar instrument published and has undergone subsequent Rasch analyses published in 2012 and 2014 [19, 20]. In patients with surgical scars, the instrument demonstrated good internal consistency (Cronbach’s $\alpha = 0.86$ (observer), 0.90 (patient)) and reliability for the observer scale (using three observers), total overall score ($r = 0.96$, $p < 0.001$), and separate items ($r = 0.86$, $p < 0.001$) [17].

1.4 Instrument strengths and limitations—This instrument demonstrates good overall psychometric properties, and was the first PRO instrument for scars. Limitations include a lack of qualitative patient data in development of the content, and limited scope in constructs measured such as no dedicated appearance domain. Additionally, there is no published data describing the responsiveness of the measure [21, 22].

2.0 Bock Quality of Life questionnaire for patients with keloid and hypertrophic scarring (Bock)

The Bock questionnaire [14] is a 15-item instrument developed for adult and pediatric dermatology patients with hypertrophic and keloid scars.

2.1 Instrument development—A conceptual model was developed and item content was generated via expert opinion and literature review, with questions specifically derived from two previously published dermatologic questionnaires [23, 24].

2.2 Instrument content—Questions were divided into two domains, physical symptoms ($n=5$) and psychosocial well-being ($n=10$). Answer choices are on a Likert Scale with the following choices: -5 (totally inaccurate), -3 (inaccurate), -1 (somewhat inaccurate), 1 (fairly accurate), 3 (accurate), 5 (completely accurate). A timeframe for symptom evaluation is not given.

2.3 Psychometric properties—The Bock questionnaire is psychometrically sound with evidence showing acceptability, internal consistency (Cronbach’s $\alpha = 0.88$ (psychological), 0.78 (physical)), reliability ($r = 0.96$ (psychological), 0.94 (physical)) and validity.

2.4 Instrument strengths and limitations—This instrument demonstrates good overall psychometric properties. Limitations are similar to POSAS in that the developers did not include patient input in development of the content, it has limited content scope, and it has not yet demonstrated responsiveness to clinical change.

3.0 Patient Scar Assessment Questionnaire (PSAQ)

The PSAQ [15] is a 39-item multi-scale questionnaire developed for patients with linear surgical scars to evaluate the patient perception of scarring.

3.1 Instrument development—A conceptual model was formulated and questionnaire items were generated via literature review, expert opinion and qualitative patient interview data. Interviewed patients had surgical scars from a variety of etiologies, including healthy volunteers receiving 1 cm full-thickness incisions for an anti-scarring trial as well as patients undergoing nevi excision, varicose vein excision, cardiothoracic surgery, or scar revision.

3.2 Instrument content—This questionnaire measures 5 domains as follows: appearance (n=10), symptoms (n=7), consciousness (n=7), satisfaction with appearance (n=9), and satisfaction with symptoms (n=6). Timeframes for answering are not provided and answer choices are variable by question.

3.3 Psychometric properties—The PSAQ underwent a thorough psychometric evaluation, demonstrating internal consistency with Cronbach's $\alpha > 0.70$ for all domains. Reproducibility was demonstrated with the following Intraclass Correlation Coefficients (ICC) for each domain in each patient subgroup: appearance (0.60 to 0.83; only <0.70 for scar revision patients), consciousness (0.74 to 0.87), satisfaction with appearance (0.37 to 0.83; scar revision and healthy volunteers <0.70), and satisfaction with symptoms (0.48 to 0.79; scar revision and nevi groups <0.70). There was no psychometric evaluation of the symptoms domain as the scar symptoms in the studied population were, per author report, "largely irrelevant."

3.4 Instrument strengths and limitations—This instrument utilized qualitative interview data, with overall good psychometric properties. Similar to the above instruments, the PSAQ has not yet demonstrated responsiveness across all domains. However, the appearance domain was found to capture improvements in patient opinions of scar appearance in the nevi excision group from 3 to 6 months, and again from 6 to 12 months. These decreases in appearance scores correlate with the time course of scar healing and fade. Lastly, further assessment of the test-retest reliability was not identified in the literature.

4.0 Patient-Reported Impact of Scars Measure (PRISM)

The PRISM [16] is a 37-item instrument that measures QOL and physical symptoms in patients with various types of scars.

4.1 Instrument development—A conceptual model was developed and questionnaire items were generated via qualitative patient interviews, expert opinion and literature review. Qualitative data was generated from interviews of patients who were seeking scar revision in a plastic surgery office.

4.2 Instrument content—Questions are separated into 2 domains, psychosocial well-being (n=24) and symptoms (n=13). Answer choices were "true" or "not true," and the timeframe for symptom reporting was one week.

4.3 Psychometric properties—The PRISM underwent a rigorous psychometric analysis, including a Rasch analysis, demonstrating two unidimensional scales with good internal consistency (Cronbach's $\alpha = 0.85$ (symptom), 0.93 (QOL)), and test-retest

reliability (ICC = 0.83 (symptoms), 0.89 (QOL)). A floor effect of the symptoms scale was noted, with 26.7% reporting the minimal symptoms score.

4.4 Instrument strengths and limitations—This instrument utilized qualitative interview data, with overall good psychometric properties. Similar to the PSAQ, the floor effect of the symptoms scale limits the acceptability of this portion of the instrument. An additional limitation of the PRISM is the lack of an appearance domain.

DISCUSSION

This systematic literature review aimed to identify and evaluate PRO instruments developed specifically for patients with surgical and/or non-burn traumatic scars. Four PRO instruments met inclusion criteria and were analyzed based on development, content, and psychometric properties.

Content was variable between instruments, with psychosocial well-being and physical symptoms the most frequently evaluated. However, a key consideration in the evaluation of surgical scars, both in clinical care and research, especially in the setting of aesthetic surgery, is an assessment of scar appearance and/or satisfaction with scar appearance. Appearance is a key COI for a scar PRO instrument; it is thus a significant limitation that only one PRO instrument, PSAQ, has a scale dedicated to appearance. The PSAQ appearance domain contains 10 questions that evaluate various components of scar appearance, such as size, color, shine and overall appearance. Additionally, PSAQ has a domain evaluating satisfaction with appearance, with 10 questions evaluating satisfaction with various appearance characteristics. The PSAQ appearance domains demonstrated good internal consistency, however both had variable test-retest reliability. Of the remaining three instruments, one (POSAS) includes only three items that ask about the shape, color and surface, within a larger scale that includes items about symptoms and overall satisfaction. Given its lack of conceptual clarity, this scale has limited utility in research or clinical care for the evaluation of appearance, symptoms, or overall satisfaction. Additionally, neither PRISM nor Bock evaluates appearance.

In addition to appearance, a comprehensive scar evaluation tool should have the capabilities to assess symptoms. In order to facilitate this, the test population must have a diversity in symptoms to allow the symptom domain within the instrument to be psychometrically evaluated. This was not accomplished in full for either the PSAQ or PRISM, and is a limitation of these instruments.

In the creation of a PRO instrument, qualitative patient research is crucial for developing a conceptual framework and generating question content to ensure the instrument is capable of capturing the multidimensionality in the ways scars impact patients. The importance of using qualitative patient data is supported by the FDA in their guidance document for the industry [7]. Without a clear conceptualization of the items appropriate for inclusion in each scale, the content and domains within each instrument will vary according to the specific expert opinion framing each instrument's development. We found this to be the case in our review, as there was a lack of consensus on concepts important to scar patients that should

be included in a PRO instrument. In the four scales reviewed here, only two instruments utilized qualitative patient interviews in the development process, i.e., PSAQ and PRISM. Importantly, only one (PRISM) used qualitative patient interview data to create instrument content to help ensure that the language of the instrument would resonate with patients as they read and complete the questions.

In addition to comprehensive content and rigorous development methods, an ideal PRO instrument should demonstrate excellent psychometric properties. As a component, the ability to assess responsiveness is one of the hallmark reasons to use a specific PRO instrument. This allows the researcher or clinician to evaluate clinical change following intervention and/or the passage of time in relation to scars. Responsiveness may not be an important property of an instrument that is used for cross-sectional purposes; however, it is important for longitudinal studies that attempt to demonstrate change over time. In a similar note, interpretability, which qualifies the degree of clinical meaning captured within the instrument's results, also has high utility for clinical research. Within the instruments evaluated, only the appearance domain of PSAQ in the nevi excision cohort was shown to demonstrate responsiveness to clinical change.

CONCLUSION

With millions of patients acquiring scars from surgical and traumatic events each year, it is important to have a reliable, sensitive and specific PRO instrument developed with rigorous methodology to assess QOL and satisfaction in the surgical and traumatic scar patient population. Furthermore, the development of new surgical techniques, a focus on scar-minimizing aesthetic surgery, and various scar treatment options necessitates a PRO instrument that can provide high quality evidence for use in clinical trials in the assessment of these innovative techniques, with both responsiveness and interpretability. Of the four instruments reviewed, PRISM and PSAQ were most rigorously designed with a foundation in qualitative patient data, with the PRISM most closely meeting criteria. However, all instruments evaluated demonstrated limitations. Primary limitations of the PSAQ and PRISM specifically, included the lack of an appearance domain for the PRISM, and a lack of symptom evaluation and responsiveness for both the PSAQ and PRISM.

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Figure 1.
Flow diagram for systematic review methodology using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines

Table 1

Search Terms

Category	Terms
Scars	Scar, keloid, hypertrophic scar, cicatrix
Quality of Life and/or Patient Satisfaction	Quality of life, health related quality of life, quality adjusted life years, functional status, well-being, health status, health status disparity, quality-adjusted life years, patient satisfaction
Outcome measure	Patient reported outcome, questionnaire, survey, instrument, measure, scale, assessment, treatment outcome, consumer satisfaction, psychometrics, data collection

Table 2

PRO measures meeting inclusion criteria

PRO Instrument	POSAS	Bock QoL	PSAQ	PRISM
Lead author	Draaijers	Bock	Durani	Brown
Publication year	2004	2006	2009	2010
Country of origin	Netherlands	Sweden	United Kingdom	United Kingdom
Specialty population scale developed within	Burn	Dermatology	Post-surgical	Seeking plastic surgery scar revision
Domains (# of items)	Patient (7), Observer (6)	Physical (5), psychological (10)	Appearance (10), symptoms (7), consciousness (7), satisfaction with appearance (9), satisfaction with symptoms (6)	Quality of life (24), symptoms (13)

Table 3**Patient-Reported Scar Outcome Instruments: Content Analysis**

Themes and Subthemes	POSAS	Bock	PSAQ	PRISM	Descriptors
Appearance					
Size			2		Length, width, total size
Shape	1				Overall shape, straight line
Color	1		3		Color, shade, match to skin
Surface	1		2		Raised, surface quality
Visibility/Location			1		Noticeable, prominence
Tissue quality			2		Hard on palpation, texture
Change over time					Fade
Physical Symptoms					
Pain	1	1	2 ^b	8	Pain, tenderness, sore
Paresthesias			2 ^b	3	Pins and needles, burns, stings
Pruritus	1	3	1 ^b	2	Itch
Contractures	1 ^a	1	1 ^b		Pulling, stiffness
Psychosocial Well-Being					
Self-worth (+/-)		2	1	3	Attractiveness, self-confidence
Acceptance (+/-)		1		2	Comfort, scar is part of me
Emotions (+/-)		2		2	Happiness, proud, embarrassed
Importance (+/-)		1	2	2	Not important, big deal to me
Other people (+/-)		1	2	8	Talking about, looking at scars
Camouflaging activities		1	1		Hiding, covering scars
Impact on social/sex life		2		7	Change in activities or sex life
Satisfaction with Outcome					
Overall satisfaction	1				Fantastic, pleased with result
Compared to expectations					Result is as expected
Appearance			10		Satisfaction with appearance
Symptoms			7		Satisfaction with symptoms

Numbers represent the number of questions per subtheme within each instrument, as determined by the reviewers. Several questions addressed multiple concepts, however each question was assigned to only one subtheme above. For POSAS, only the patient instrument is listed in this table.

Positive and negative factors

Not psychometrically evaluated due to limited physical symptoms of the test population

This question was in regards to skin stiffness

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Table 4**Patient-Reported Scar Outcome Instruments: Development and Validation Criteria**

	POSAS	Bock	PSAQ	PRISM
Item generation				
Patient interviews			•	•
Literature	•	•	•	•
Expert opinion	•	•	•	•
Develop conceptual model	•	•	•	•
Item reduction				
Expert opinion		•		•
Item redundancy				•
Endorsement frequencies				•
Missing data				
Factor analysis	•	•		•
Tests of scaling assumptions				•
Psychometric analyses				
Acceptability	•	•		⁺
Internal consistency reliability	•	•	•	•
Item total correlations	•	•	•	•
Interrater reliability	•	n/a	n/a	n/a
Test-retest reliability	•	•	•	•
Validity within scale		•	•	•
Validity comparison with other measures	•		•	•
Validity hypothesis testing	•	•	•	•
Responsiveness			++	

n/a: not applicable, only POSAS has a portion that is not completed by the patient

⁺ Acceptability was demonstrated in the quality of life domain, the symptoms domain demonstrated a floor effect of 26.7% (<10% is acceptable) reporting the lowest symptoms scale

⁺⁺ The appearance domain was the only portion of the instrument that demonstrated responsiveness