



Beyond the physician's perspective: A review of patient-reported outcomes in dermatologic surgery and cosmetic dermatology^{☆,☆☆}

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ABSTRACT

Patient-reported outcome measures (PROMs) are utilized in health care to quantify the patient's perspective of a health condition or treatment on outcomes, such as health-related quality of life (HRQoL) and patient satisfaction. In dermatology, this is particularly relevant because the patient's perspective is critical in evaluating the outcome of cosmetic procedures as well as skin cancer treatment. We review seven validated PROMs that have been reported in the dermatologic surgery and cosmetic dermatology literature. For patients undergoing cosmetic procedures, the use of PROMs provides additional valuable outcome data beyond physician assessment. For patients with skin cancer, women experience a unique and often greater impact on HRQoL during treatment, which has been captured through PROMs. The recent development of multi-module instruments, such as the FACE-Q and FACE-Q Skin Cancer, have facilitated comprehensive assessments of treatment that impact multiple domains of HRQoL. The use of PROMs allows for dermatologists to reliably capture important disease- and treatment-related concerns, thus improving the patient experience.

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Introduction

In 2017, 17.5 million cosmetic procedures were performed in the United States. Of these, minimally invasive procedures such as botulinum toxin injections and soft tissue fillers account for the majority and continue to rise in popularity ([American Society of Plastic Surgeons, 2017](#)). Furthermore, female patients account for 92% of all minimally invasive cosmetic procedures performed, for a total of >12 million procedures per year ([American Society of Plastic Surgeons, 2016](#)). Several factors influence this increasing trend, including the growing presence of social media and the acceptability of cosmetic procedures on these platforms as well as today's selfie culture that promotes heightened awareness of one's facial appearance ([American Academy of Facial Plastic and Reconstructive Surgery, 2014](#); [Menzel et al., 2011](#)).

The number of younger women who undergo cosmetic procedures is also increasing. One study found a high prevalence of dissatisfaction in women age <30 years with the appearance of their skin, which was attributed to bags and darkness under the eyes, fine wrinkles, freckles, and patchy hyperpigmentation ([Gupta and Gupta, 2001](#)). Aging skin also has psychosocial consequences for older women, including social anxiety, isolation, and even workplace discrimination ([Gupta and Gilchrest, 2005](#)). These findings are all extremely relevant for dermatologists, who perform approximately a third of the cosmetic procedures in the United States and thus play a significant role in this increasing demand ([Ahn et al., 2013](#)).

In addition to providing a wide range of cosmetic procedures, dermatologists diagnose and treat skin cancers. More than 3 million nonmelanoma skin cancers (NMSCs) are diagnosed each year in the United States, for which dermatologists perform the majority of excisions ([Chen et al., 2016](#); [Jemal et al., 2011](#); [Rogers et al., 2015](#)). Treatment success is often defined by outcomes such as low complication and recurrence rates, but other factors such as the functional and esthetic outcome of surgery are important considerations as well.

A study of patients who underwent facial surgery for skin cancer found that the esthetic outcome after surgery had important implications to the patients' psychological and social well-being ([Lee et al.,](#)

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2016). Scarring after surgery may also lead to anxiety about appearance and a decreased quality of life (Sobanko et al., 2015). In addition, patients' perception of their scars after skin cancer surgery significantly influences their overall satisfaction with the medical care (Dixon et al., 2007). Patients' assessment of esthetic outcomes can also greatly differ from the physician's perspective. One study found that with regard to scarring, discordance existed in patient-physician communication with regard to expectations after surgery (Young and Hutchison, 2009).

For both cosmetic procedures and the treatment of skin cancer, capturing the patient's perspective is increasingly recognized as essential to providing patient-centered care. Patient-reported outcome measures (PROMs) are questionnaires in which responses are collected directly from the patient. PROMs can quantify various outcome variables such as health-related quality of life (HRQoL) and psychosocial burden. The development of a PROM involves building a conceptual framework through a literature search, qualitative patient interviews, and expert opinion. Validation of the questionnaire includes assessment of three important characteristics: reliability (i.e., ability to produce consistent and reproducible scores), validity (i.e., ability to measure what is intended to be measured), and responsiveness (i.e., sensitivity in detecting a difference; Deshpande et al., 2011). These characteristics are integral in extrapolating results and using them in clinical decision-making. The purpose of this article is to review relevant existing PROMs and their use in dermatologic surgery and cosmetic dermatology, with a focus on pertinent findings in women.

Methods

We conducted a comprehensive literature search using PubMed with the search terms "patient reported outcome" and "dermatologic surgery" or "cosmetic dermatology". Original research studies, review articles, and case series were included. Single-case reports, articles not written in English, nonhuman studies, studies of children or adolescents, studies of nondermatologic procedures, and studies without patient-reported outcomes were excluded. A total of 460 articles were identified, and the titles and abstracts were screened, which yielded 104 full-text articles for review. References were also reviewed for additional relevant articles. Seven PROMs that were the most pertinent in the cosmetic and dermatologic surgery literature and with an emphasis on issues pertaining to women were chosen by the authors for review in the current article.

Results and discussion

Cosmetic procedures

Patient-reported outcomes play a particularly important role in cosmetic dermatology, largely due to the fact that many of these procedures are elective. Therefore, patient satisfaction is critical in determining a successful outcome. Few PROMs have been validated and studied in patients undergoing cosmetic procedures. One systematic review found only nine PROMs that were developed and/or validated to assess patient satisfaction and quality of life (QoL) after facial cosmetic surgery and nonsurgical facial rejuvenation. However, the majority of these instruments underwent limited and variable development and validation (Kosowski et al., 2009). Furthermore, beyond satisfaction with appearance, few PROMs also assess important QoL determinants, such as psychosocial impact (Imadojemu et al., 2013). In the following section, patient-reported outcomes for facial rejuvenation procedures, such as botulinum toxin injections, soft tissue fillers, and laser therapy, are discussed. The results of our search are summarized in Table 1.

Facial line satisfaction questionnaire

The facial line satisfaction questionnaire (FLSQ) was developed and validated to assess patient satisfaction with esthetic treatments to correct facial lines. Seven relevant areas of treatment outcome were identified: Overall satisfaction, treatment effectiveness, discomfort or side effects, convenience of treatment, ease of treatment, flexibility, and time to onset (Carruthers and Carruthers, 2007).

The questionnaire was pilot tested in 152 patients (mostly women) undergoing botulinum toxin A treatment, and most patients were either satisfied or very satisfied with their treatment (Cox et al., 2003). In a randomized, double-blind study, 125 subjects with moderate-to-severe glabellar lines and crow's feet lines were randomized to either onabotulinumtoxin A injections or placebo. Patient satisfaction per the FLSQ was significantly greater during the 60 days after treatment with onabotulinumtoxin A compared with placebo (81.7% vs. 0%; $p < .001$; Rivers et al., 2015).

Facial lines outcomes questionnaire

The facial lines outcomes (FLO) questionnaire was developed as a PROM to assess the impact of upper facial lines and psychological impact of crow's feet lines (Fagien et al., 2007). The questionnaire was tested for content validity after 66 qualitative patient interviews (Yaworsky et al., 2014). In this questionnaire, patients rate the degree to which their upper facial lines bother them, detract from their facial appearance, make them look older, or make them look tired, stressed, or angry when that is not how they feel (Carruthers and Carruthers, 2007).

An 11-item version of the FLO questionnaire (FLO-11) exists, as well as a 7-item version (FLO-7), which retains the original version's psychometric properties (Fagien et al., 2007). The FLO-7 was used in a double-blind study for patients with moderate-to-severe glabellar lines. Seventy female patients were randomly assigned to either 20U of botulinum toxin or placebo. At week 4 after treatment, there was a significant difference in mean FLO score in patients who received botulinum toxin compared with placebo.

In a prospective, randomized, double-blind study, the FLO-11 was used to assess botulinum toxin in 60 female patients with upper facial lines (Carruthers and Carruthers, 2009). The scores on the FLO-11 significantly improved by week 2 for patients receiving 32U, 64U, and 96U of botulinum toxin (all groups), and remained significantly improved through week 16, except for the 32U group. The FLO-11 was also used in an open-label, 14-day study of 45 onabotulinumtoxin A-naïve female patients (Beer et al., 2011). At all time points, scores on the FLO-11 improved ($p = .008$). In a randomized study of patients who received either onabotulinumtoxin A 44U ($n = 101$) or placebo ($n = 96$), three questions from the FLO-11 were used to assess the psychological impact of crow's feet lines. Thirty days after treatment, patients who received onabotulinumtoxin A showed a significantly greater response on the FLO-11 compared with those who received placebo (Carruthers et al., 2015).

Dermatology life quality index

The dermatology life quality index (DLQI) was the first dermatology-specific instrument to measure QoL. The index is a validated questionnaire composed of 10 items and was developed in the United Kingdom from the written responses of 120 patients detailing the ways in which their skin disease affected their lives (Finlay and Khan, 1994).

Test-retest reliability, validity, internal consistency, and responsiveness of the instrument have been confirmed in initial and subsequent studies (Basra et al., 2008; Finlay and Khan, 1994). The items on the DLQI inquire about skin disease effects on daily activities and interpersonal relationships (i.e., social activities, sports, working, friends and partners) on a scale from 0 (not at all) to 3 (very

Table 1
Summary of reviewed patient-reported outcome measures

Author, year	PROM	Validity	Reliability	Responsiveness	Number of questions	Use
Cox et al., 2003	FLSQ	Y	Y	N/A	14	Facial line treatment satisfaction (e.g., botulinum toxin treatment)
Fagien et al., 2007	FLO	Y	N/A	N/A	7 (FLO-7), 11 (FLO-11)	Patient concerns regarding upper facial lines (e.g., glabellar lines, crow's feet lines)
Klassen et al., 2010	FACE-Q	Y	Y	Y	Varies	Satisfaction with appearance, adverse effects, quality of life in facial esthetic patients undergoing elective procedures (e.g., botulinum toxin injection, soft tissue fillers, face lift, rhinoplasty, blepharoplasty)
Finlay and Khan, 1994	DLQI	Y	Y	Y	10	QoL impact in all skin conditions, including photo-aged skin, wrinkles, skin cancer, atopic dermatitis, psoriasis
Chren et al., 1996, 1997, 2001	Skindex	Y	Y	Y	16 (Skindex-16), 29 (Skindex-29)	QoL in all skin conditions, including radiation-induced breast telangiectasias, skin cancer, psoriasis, acne
Rhee et al., 2005	SCI	Y	Y	Y	15	QoL in patients with NMSC
Lee et al., 2018	FACE-Q Skin Cancer	Y	Y	Y	Varies	Satisfaction with appearance, QoL, cancer worry, patient experience in patients with facial skin cancer

DLQI, dermatology life quality index; FLO, facial line outcomes questionnaire; FLSQ, facial line satisfaction questionnaire; N, no; N/A, not available; NMSC, nonmelanoma skin cancer; PROM, patient-reported outcome measure; QoL, quality of life; SCI, skin cancer index; Y, yes

much). Subsequently, the individual scores are summed to calculate a total score that ranges from 0 to 30, with a higher score indicating greater QoL impairment. The DLQI has been translated into 55 languages, but cross-cultural adaptations have only been described for nine of them (Basra et al., 2008).

The DLQI was used to investigate patient expectation and satisfaction in 24 female patients undergoing fractional carbon dioxide laser resurfacing to treat wrinkles and photo-aged skin (Kohl et al., 2015). The mean DLQI score before laser treatment (4.3 ± 4.6) indicated slightly impaired QoL that was comparable to DLQI scores reported by patients with psoriasis and eczema. There was a significant difference in DLQI scores before and 3 months after the last laser treatment. Furthermore, the question with regard to how embarrassed or self-conscious the patient felt because of their skin showed the greatest improvement at follow up.

Using a PROM, this study quantified the emotional impact of wrinkles and photo-aged skin and demonstrated the impact of laser resurfacing on patients' QoL.

Skindex-16

The Skindex was created with the goal of comprehensively measuring the impact of skin disease on HRQoL and to distinguish between patients with different effects and evaluate changes in patients over time (Kirshner and Guyatt, 1985). A 61-item prototype version of Skindex was originally created, which was psychometrically tested and found to be both reliable and valid in patients with skin disease (Chren et al., 1996). This original conceptual framework was subsequently refined into the Skindex-29, with three domains in which skin disease affects patients' QoL: symptoms, emotions, and functioning. This version of Skindex retained its reliability and validity but decreased respondent burden and improved discriminative and evaluative capabilities (Chren et al., 1997).

A single-page version, Skindex-16, was also created and tested in 541 dermatology patients and found to be reliable, valid in content and construct, and responsive (Chren et al., 2001). Items asked how bothered the patient is about various symptoms (i.e., itching, burning, and irritation), emotions (i.e., frustration and embarrassment), and functioning (i.e., daily activities, work, and interactions with others). Responses were transformed into a linear scale from 0 (best) to 100 (worst). The Skindex-16 has been used in studies for many different dermatologic conditions.

The Skindex-16 was administered to 22 female patients with radiation-induced breast telangiectasias undergoing treatment with laser therapy (Rossi et al., 2018). Although the efficacy and safety of this treatment had been previously assessed, this was the first study to

use a validated PROM to assess HRQoL in patients. The emotional domain (questions on embarrassment about their skin condition) showed the greatest QoL impairment prior to treatment. Patients showed a statistically significant improvement in the emotional and functional domains of Skindex-16 as well as total Skindex score after treatment. This study demonstrates the value of using a PROM because it underscores the psychosocial burden of radiation-induced breast telangiectasias on breast cancer survivors.

FACE-Q

The FACE-Q is a multimodule, patient-reported outcome instrument that consists of more than 40 independently functioning scales and was developed to measure important concepts and symptoms for patients undergoing elective esthetic procedures (Klassen et al., 2010). The scales may be administered to facial esthetic patients to measure their perspective on appearance, QoL, adverse effects, and process of care. Each scale provides a score from 0 (worst) to 100 (best), and physicians may choose to administer scales that are relevant to a patient or procedure. Separate scales have been developed for different parts of the face (e.g., nose, forehead, cheek, chin, and eyes), and the different scales have been validated in several studies (Klassen et al., 2014, 2015, 2016a, b, 2017; Schwitzer et al., 2015).

The Satisfaction with Appearance scale of the FACE-Q was administered to almost 1000 facial esthetic patients, of whom 87% were female. In patients undergoing botulinum toxin injection, facial filler, rhinoplasty, face lift, or blepharoplasty, the mean Satisfaction with Appearance scores were significantly higher in the posttreatment group compared with pre-treatment (Klassen et al., 2016a, b). Another study administered the FACE-Q to 50 patients, 44 of whom were women, who were treated with botulinum toxin injection and/or soft tissue filler in a resident cosmetic clinic. The study found significantly improved scores in all domains that were assessed, with a large magnitude of change for Psychological Well-Being, Social Functional, and Satisfaction with Facial Appearance scales (Qureshi et al., 2017). In another study of 31 patients undergoing laser resurfacing or injectable treatment with neurotoxin or fillers, scores on the Satisfaction with Facial Appearance and Satisfaction with Facial Skin scales significantly improved after treatment (Hibler et al., 2016).

Skin cancer

Skin cancer incidence has been steadily increasing over recent years, with a disproportionate increase in women. A large population-based cohort study found an increased incidence of basal cell carcinoma in younger women and cutaneous squamous cell

carcinoma in older women (Muzic et al., 2017). The same trend has also been observed in melanoma where in women age <44 years, the incidence of melanoma is 8.2 per 100,000 compared with 5.3 per 100,000 in men in the same age group (Howlader et al., 2011). This increasing incidence has been thought to be related to the increased use of tanning beds by young women (Little and Eide, 2012).

However, a recent study found that female sex may be an independent risk factor for early-onset melanoma, independent of ultraviolet radiation exposure (Liu-Smith and Ziogas, 2017). Furthermore, nonwhite female subjects aged <40 years were found to have an elevated risk of melanoma compared with male subjects of the same age, which suggests that tanning bed usage alone may not explain this increased risk (Yuan et al., 2018).

Given the increasing incidence of skin cancer in women, unique considerations for its management are critical. Detection and treatment of skin cancer can cause discomfort, scarring, and significant distress, particularly in young women (Al-Dujaili et al., 2015). Furthermore, women are more likely to have NMSCs in the central facial region (e.g., forehead and nose), and are more likely to seek reconstruction by a plastic surgeon following Mohs micrographic surgery (MMS) compared with men (Lee et al., 2014). Thus, minimizing scarring and considering esthetic concerns are crucial for physicians. PROMs are particularly useful in this respect because they capture the concerns that are the most important to patients.

Skindex

Skindex-16, as previously discussed, has also been used to assess HRQoL in patients with NMSC. In a prospective cohort study of 633 patients with NMSC, Skindex-16 was used to quantify and compare QoL outcomes of electrodesiccation and curettage, surgical excision, and MMS for basal and squamous cell carcinomas (Chren et al., 2007). The study found that patients who were treated with excision or MMS improved in all QoL domains after treatment; however, scores did not improve after electrodesiccation and curettage. In addition, there was no difference in the amount of QoL improvement after excision compared with MMS.

In a follow up study, Skindex-16 was used to identify the predictors of posttreatment skin-related QoL (Chen et al., 2007). Pretreatment skin-related QoL, comorbidities, and mental health status were found to predict posttreatment skin-related QoL, but sex was not related to QoL.

Skin cancer index

The skin cancer index (SCI) is a reliable disease-specific QoL instrument for patients with NMSC (Rhee et al., 2005). The instrument consists of 15 items across 3 subscales: (1) emotion (i.e., anxiety, frustration, worry), (2) social (i.e., meeting new people, not going out in public), and (3) appearance (i.e., size and visibility of scar, effects on attractiveness). A five-point Likert response is transformed to a scale from 0 (worst) to 100 (best). The instrument was validated in 228 patients with facial NMSC (Rhee et al., 2006) and found to demonstrate clinical responsiveness (Rhee et al., 2007).

The SCI was used in a prospective study of 211 patients with NMSC to evaluate baseline QoL, and assess risk perception and behavior modifications after surgery (Rhee et al., 2008). The study did not find a predictive relationship between disease-specific QoL and risk perception or sun protective behaviors. Another study administered a cross-sectional survey of the SCI to 136 patients with skin cancer and found that lower scores (worse QoL) were significantly associated with younger age and higher income. In addition, female patients had a significantly lower score, specifically in the Appearance domain (Sobanko et al., 2016).

A recent prospective study administered the SCI to 727 patients with skin cancer undergoing MMS immediately before and at 1 to 2 weeks and 3 months after surgery (Zhang et al., 2018). The authors

found that overall QoL remained impaired 1 to 2 weeks after surgery, mainly due to increased distress with regard to physical appearance and social interactions. Three months after surgery, patients had significant improvements with regard to skin cancer anxiety, social interactions, and concerns about scar appearance. Interestingly, this study also found that female patients had significantly worse SCI scores at all three time points ($p = .0001$).

Dermatology life quality index

The DLQI, as discussed previously, has also been used in several studies exploring QoL in patients with skin cancer. The DLQI was administered prospectively to 121 patients with NMSC before and after surgery (Rhee et al., 2004). The total scores did not greatly differ; however, two items statistically improved after treatment: decreased pain/itch/soreness of skin and decreased influence of skin on clothing choice. The DLQI was also used in a group of 58 patients with skin tumors to examine the relationships between QoL and different psychological coping mechanisms (Pereira et al., 2016). The study found that awareness of the patient's anxiety, emotional distress, and body image were all critical to identify patients at a higher risk for poor QoL.

Most recently, the DLQI was also used to assess the impact of treatment on HRQoL in 3846 patients from 13 European countries (Balieva et al., 2018). The study found a 6.8% reduction in QoL due to treatment in patients with skin cancer. In addition, higher DLQI scores (worse QoL) were found overall in female patients compared with male patients, but this includes other dermatologic conditions such as atopic dermatitis, psoriasis, and prurigo.

FACE-Q skin cancer

The FACE-Q Skin Cancer Module is a new validated PRO instrument that was developed from the need for a comprehensive PROM that addresses important attributes related to QoL that are specific in the facial skin cancer patient population (Lee et al., 2018). This multifaceted instrument was created after the development of the FACE-Q, with unique considerations for patients with facial skin cancers, such as cancer worry and scarring.

The FACE-Q Skin Cancer Module consists of five independently functioning scales. There are two scales related to appearance, two quality of life scales, and one patient-experience scale. Four Likert-style response options are provided for each item in the scale, and total scores are transformed to a Rasch equivalent score from 0 (worst) to 100 (best). The module was psychometrically tested in a cohort of 209 patients with NMSC or early melanoma of the head and neck. The validation demonstrated high reliability, construct validity, and responsiveness of the scales. Further validation for the module in a UK population is underway (Dobbs et al., 2017). In a pilot study assessing patient expectations and outcomes in 67 patients using the appearance scales of the FACE-Q Skin Cancer Module, women had lower facial and scar satisfaction after surgery compared with men (Blank et al., 2018).

Limitations

The limitations of this review include the use of a single database (PubMed) for our search, and the inclusion of a select number of PROMs. Studies that used PROMs and included findings pertinent to women were also chosen, which may have excluded other studies relevant to the dermatologic surgery and cosmetic dermatology literature.

Conclusion

PROMs in dermatologic procedures incorporate the patient's perspective of their outcome and is increasingly recognized as crucial to

the treatment process. Given the increasing popularity of cosmetic procedures and increasing incidence of skin cancer particularly in women, understanding the changing landscape of health care is of the utmost relevance to dermatologists. The use of PROMs allows physicians to achieve this goal, as disease-specific concerns and treatment outcomes can be reliably captured to improve the patient experience.

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