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Clinical Significance Unveiled: Understanding the Meaning of FACE-Q Skin Cancer Scores for Improved Patient Care

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Abstract

Objective: The FACE-Q Skin Cancer Module is a Patient-Reported Outcome Measure (PROM) utilized to assess outcomes following facial skin cancer resection. However, the lack of Minimal Important Difference (MID) estimates hinders the interpretability of the PROM scores. This study established MID estimates for the four outcome scales from the FACE-Q Skin Cancer Module using distribution-based methods.

Methods: A prospective cohort study at four hospitals in the United States, enrolled participants who underwent Mohs Micrographic Surgery (MMS) for facial skin cancer between April 2020 and April 2022. Participants completed the Satisfaction with Facial Appearance, Appearance-related Psychosocial Distress, Cancer Worry, and Appraisal of Scars scales at four time points: pre-operatively, 2-weeks, 6-months, and 1-year post-surgery.

Results: A total of 990 patients participated in the study, with completion rates of 98.4% for the pre-operative assessment, 70.8% at 2 weeks, 59.3% at 6 months, and 60.4% at 1 year. MID estimates, calculated using 0.2 standard deviation and 0.2 standardized response mean, were determined for the four scales. The mean MID estimates, based on a Rasch transformed score ranging from 0 to 100, were 5 for the Appraisal of Scars scale and 4 for the remaining three scales.

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Conclusion: This multicenter study provides valuable MID estimates for the FACE-Q Skin Cancer Module, specifically for the MMS patient population, enabling clinicians and researchers to better interpret scores, determine appropriate sample sizes, and apply the findings in clinical care.

Keywords

Minimal important difference; Mohs micrographic surgery; Patient-reported outcome

Introduction

Patient satisfaction and quality of life after surgery are important metrics of treatment success, yet they are highly subjective. To quantify these experiences, researchers have developed patient-reported outcome measures (PROMs), such as the FACE-Q Skin Cancer Module, to assess outcomes in patients undergoing surgical treatment for facial skin cancer.^{1,2} As skin cancer is the most prevalent type of cancer among fair-skinned individuals, with incidence and treatment rates increasing annually,³ the need for PROM research in this field is growing. While extensively evaluated, the FACE-Q Skin Cancer has yet to establish a minimal important difference (MID).⁴

Calculating the MID is critical for PRO research, as it enables accurate interpretation of changes in PRO scores and assists in treatment decision-making.^{5,6,7} Moreover, regulatory agencies mandate evidence of MIDs to approve new drugs or treatments.^{8,9} Nonetheless, the MID is not universally applicable and may differ based on disease context, severity, population characteristics, and outcome instruments.¹⁰ Therefore, it is critical to estimate MIDs specific to the clinical setting.

The objective of this study was to establish a MID estimate for the 4 outcome scales in the FACE-Q Skin Cancer Module using distribution-based methods. This study will provide clinicians and researchers with a benchmark for determining the sample size required for clinical trials or observational studies, aid in making treatment decisions, and demonstrate the effectiveness of new interventions and their impact on the patient's quality of life.

Methods

Study Population and Methods

We conducted a multicenter prospective cohort study at four hospitals in the United States, selected based on their location and surgical experience with facial skin cancer (UT Southwestern, UC Davis, the University of Nebraska Medical Center, and Memorial Sloan Kettering Cancer Center (MSKCC)). From April 2020 to April 2022, eligible participants who underwent Mohs Micrographic Surgery (MMS) for facial skin cancer were enrolled. The study excluded patients who underwent multiple facial skin cancer resection on the same day, patients under the age of 18, and patients who were unable to complete the study questionnaires. Participants provided written informed consent at the hospital where they received treatment, following the provision of both oral and written information about the study. This study was coordinated by MSKCC and approved by the Institutional Review

Board (IRB). Each of the participating centers (UT Southwestern, University of Nebraska and UC Davis) also obtained IRB approval.

Data collection

All participants underwent MMS for facial skin cancer. The reconstruction was performed by the Department of Dermatology or the Department of Plastic and Reconstructive Surgery at the same hospital. Participants were invited to participate in the study by email at home or in-person using a study-specific tablet device. They received the validated FACE-Q Skin Cancer questionnaire before, 2 weeks, 6 months, and 1-year post-surgery. At each timepoint, participants who did not respond received a total of three automatic reminders. If participants did not complete one of the time-point evaluations but did not withdraw from the study, they still received an invitation to participate in the subsequent time-point. Patients were included if they completed at least two time points, pre- and/or post-surgery. All participants were administered 4 scales of the FACE-Q Skin Cancer questionnaire. Relevant demographic and clinical information were collected from electronic medical records, including Fitzpatrick skin type,¹¹ history of facial skin cancer, location and size of the facial skin cancer, skin cancer type and reconstruction.

FACE-Q Skin Cancer

The FACE-Q Skin Cancer was published in 2018,² and is specifically designed to measure outcomes important to patients who undergo surgical resection of facial skin cancer. This PROM consists of 5 scales and 2 checklists measuring Facial Appearance, Quality of Life, Adverse Effects and Experience of Care. For this study, the four outcome scales were utilized: Satisfaction with Facial Appearance, Appearance-related Psychosocial Distress, Cancer Worry, and Appraisal of Scars (Table 1). Each scale consists of 8 to 10 questions, with 4 response options on a Likert-type scale. The responses are summed and converted to a Rasch score ranging from 0 to 100. Higher scores represented greater satisfaction with facial appearance, increased distress, greater cancer worry, and greater satisfaction with the scar.

Statistical Analysis

Descriptive statistics including relative frequencies, means, medians, standard deviations, and interquartile range were used to describe the sample, the underlying surgical procedure, and the quality of life measures. FACE-Q Skin Cancer scales' mean and standard deviation scores were calculated at each time-point. Subsequently, for each scale, the mean and standard deviation were calculated for the change scores for patients who had both pre-operative and post-operative FACE-Q Skin Cancer scores. To obtain estimates of the MID, we used a 0.2*standard deviation approach. In addition, Cohen's d was estimated as the effect size measure using the mean difference between each time point divided by the pooled standard deviation of the difference. All study data were collected using a common REDcap form. Analyses were performed using Stata v16.1, Stata Corporation, College Station, TX.

Results

A total of 990 patients were included in the analysis. Of these patients, 974 patients (98.4%) completed the pre-operative, 701 (70.8%) the 2-weeks, 587 (59.3%) the 6-months, and 598 (60.4%) the 1-year FACE-Q Skin Cancer scales. Demographic and clinical characteristics of the study population are presented in Table 2. The majority of these patients were white non-Hispanic patients, with skin type 1, who underwent MMS for basal cell carcinoma.

The mean FACE-Q Skin Cancer scale scores for all patients at all time-points and change in time-points with the MID estimates are presented in Table 3. The MID estimates were based on $0.2 \times \text{SD}$ presented for each time-point and every change in time-point. The final column in Table 3 displays the mean MID calculated from the values across all seven columns. The mean MIDs for the scales when using a Rasch transformed score (ranging from 0 to 100), was 4 for the Satisfaction with Facial Appearance scale, 4 for the Appearance-related Distress scale, 4 for the Cancer Worry scale, and 5 for the Appraisal of Scar scale.

Discussion

PROMs play a vital role in assessing patient satisfaction and quality of life after surgery. In the context of surgical treatment for facial skin cancer, the FACE-Q Skin Cancer Module has been developed as a PROM to evaluate outcomes in patients undergoing such procedures.^{1,2} This PROM is widely used for clinical research and as standard of care for patients following facial skin cancer resection with multiple translations available.^{12–18} In this multicenter study, we aimed to determine the MID estimates for the four outcome scales of the FACE-Q Skin Cancer using distribution-based methods. The inclusion of multiple study centers enhances the generalizability of our findings and strengthens the reliability of the MID estimates.

Analyzing the FACE-Q Skin Cancer scores, we found that the MID estimates are quite similar, with 1 point difference for the Appraisal of Scar scale. The MIDs we recommend, when using the Rasch transformed score ranging from 0 to 100, is 5 for the Scar Appearance scale, and 4 for the Facial Appearance scale, Appearance Distress, and Cancer Worry scales. These MID estimates indicate the minimum change in scores that would be considered clinically meaningful for each respective scale. For example, if a surgeon requests a patient to complete the Cancer Worry scale both at baseline and 1-year post-operative, observing a patients' increase of 3 points on the scale (1 MID), from 44 points (pre-operative) to 47 points (1-year post-operative), can serve as an important indicator for the physician. The 1 MID increase in cancer worry may prompt the physician to schedule a follow-up appointment with the patient to address their concerns.

Clinical Implications

Our findings have important implications for clinicians, researchers, and regulatory agencies. Clinicians can utilize the established MID estimates to interpret changes in FACE-Q Skin Cancer scores and make informed treatment decisions. Researchers can utilize these estimates to determine the sample size required for clinical trials or observational studies, thereby optimizing study design and resource allocation. Regulatory agencies can consider

the MID estimates as evidence when evaluating the effectiveness of new interventions and their impact on patients' quality of life.

Limitations

The demographic characteristics of our study population revealed that the majority of patients were white non-Hispanic individuals with skin type 1. This finding is consistent with the high incidence of skin cancer among fair-skinned Caucasians,¹⁹ making our findings particularly relevant for this population. Furthermore, non-responders may have affected the distribution and estimation of MIDs. While we observed a slight predominance of male non-responders and cases with larger defects, the overall large sample size supports the validity of our findings. Nevertheless, this study should be considered a foundational step, and future research should seek to validate these MID estimates in larger and more diverse patient populations. It is important to acknowledge that our study population mainly consisted of patients diagnosed with basal cell carcinoma and squamous cell carcinoma, the most common types of facial skin cancer.²⁰ Thus, our MID estimates are specifically applicable to this clinical context. It is important to acknowledge that MID estimates may not be universally applicable and can vary based on disease context, severity, population characteristics, and outcome instruments. Therefore, our MID estimates specifically apply to patients undergoing MMS for facial skin cancer using the FACE-Q Skin Cancer Module. In addition, we used a distribution-based method; a limitation is that the estimates of variability can differ from study to study.²¹ This study used Cohen's law for the effect sizes and standardized response mean values. Cohen's law suggests a 0.2 standard deviation as a small change, 0.5 as a moderate change, and 0.8 as a large change.²² However, there are authors proposing effect sizes of 0.5 as small.²³ When using 0.5 standard deviations as a small change, the mean MID for the scales would be 10 ± 1 . In our opinion, a smaller MID would be more applicable to this population based on prior studies and clinical relevance. Future studies should aim to replicate these findings in different clinical settings and with diverse patient populations to establish MID estimates with a distribution-based and with an anchor-based method that are more broadly applicable.

Conclusion

This study provides MID estimates for the four outcome scales of the FACE-Q Skin Cancer Module, specifically for the MMS patient population, allowing for a better understanding of the clinical significance of changes in scores. The high response rates and large sample size enhance the reliability and generalizability of our findings. The MID estimates can guide clinicians and researchers in interpreting FACE-Q Skin Cancer scores, determining sample sizes, and help in clinical decision making. Ultimately, these findings contribute to improving patient care and ensuring the successful implementation of new interventions in the field of surgical facial skin cancer treatment.

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Data availability statement:

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Table 1.

FACE-Q Skin Cancer scales

Scale	Items	Example	Answer options	Time-points
Satisfaction with Facial Appearance	9	Satisfied with facial contour	Very dissatisfied – Very satisfied	Pre-operative 2 weeks 6 months 1 year
Appearance-related Psychosocial Distress	8	Anxious when people look at you	Definitely disagree – Definitely agree	Pre-operative 2 weeks 6 months 1 year
Cancer Worry	10	Worry about dying	Strongly disagree – Strongly agree	Pre-operative 2 weeks 6 months 1 year
Appraisal of Scars	8	Bothered with scar length	Extremely bothered – Not at all bothered	2 weeks 6 months 1 year

Table 2

Demographic Characteristics

Patient Characteristics		Value* (%)
Sex	Male	579 (58.5)
	Female	411 (41.5)
Mean age $\pm$ SD, yr		65.6 $\pm$ 12.4
Race [‡]	White Non-Hispanic	971 (97.7)
	Hispanic	9 (0.9)
	Asian or Pacific Islander	3 (0.3)
	Native American	3 (0.3)
	Black/African-American	1 (0.1)
	Other (e.g., mixed, unknown, white Hispanic)	7 (0.7)
Skin type [‡]	1	199 (19.9)
	2	562 (56.1)
	3	225 (22.5)
	4	15 (1.5)
	5	0 (0.0)
	6	0 (0.0)
Facial skin cancer history	Yes	535 (54.0)
	No	445 (46.0)
Cancer type	Basal cell carcinoma	680 (68.7)
	Squamous cell carcinoma	266 (26.9)
	Other (e.g., Sebaceous carcinoma, melanoma, dermatofibrosarcoma)	37 (3.7)
	Unknown	7 (0.7)
Tumor status	Primary tumor	940 (95.0)
	Local Recurrence	39 (3.9)
	Unknown	11 (1.1)
Mean defect diameter $\pm$ SD, cm		1.6 $\pm$ 1.3
Location surgery ^x	Peripheral	610 (61.6)
	Central face	373 (37.7)
	Unknown	7 (0.7)
Reconstruction	Second intention healing	105 (10.6)
	Primary closure	465 (47.0)
	Flap	287 (27.6)
	Graft ^{\$}	106 (10.7)
	Other (e.g., combination repair)	27 (2.7)

* Values are No. (%) unless otherwise indicated.

[‡] multiple options possible.

^x Peripheral defined as forehead, ears, cheek, and chin, Central defined as eyes, nose, upper and lower lip.

^{\$} Graft is defined as either full-thickness, split-thickness skin grafts, synthetic, or free cartilage grafts.

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Table 3.

FACE-Q Skin Cancer Mean Scores, Standard Deviation, Effect Sizes, and Minimal Important Difference Estimates for each time point and change in time points.

	Before Surgery			2 Weeks post-surgery				6 months post-surgery				1-year post-surgery			
	Mean	σ	0.2σ	Mean	σ	d	0.2σ	mean	σ	d	0.2σ	mean	σ	d	0.2σ
Satisfaction	72.1	21.3	4.3	71.4	22.6	0.03	4.5	75.8	25.7	0.15	5.1	78.5	24.8	0.28	5.0
Psychosocial	18.3	20.8	4.2	23.5	26.2	0.22	5.2	15.6	23.5	0.12	4.7	12.9	21.3	0.25	4.3
Worry	40.6	18.6	3.7	30	22.1	0.52	4.4	28.3	21.8	0.6	4.4	26.1	21.1	0.73	4.2
Scar	--	--	--	74.2	24.6	--	5	84.9	21.5	0.46	4.3	87.2	20.7	0.58	4.1
Change from pre-surgery to 2 weeks after surgery				Change from pre-surgery to 6 months after surgery				Change from pre-surgery to 1 year after surgery				Mean MID			
	Mean	σ	d	0.2d	Mean	σ	d	0.2d	Mean	σ	d	0.2d	0.2σ		
Satisfaction	0.9	23.6	0.03	4	3.5	28.3	0.15	5	7.0	28.0	0.28	5	4		
Psychosocial	5.8	25.4	0.22	5	1.8	23.3	0.12	4	4.1	22.5	0.25	4	4		
Worry	9.4	17.3	0.52	4	11.5	19.0	0.6	4	14.0	17.6	0.73	4	4		
				Change 2 weeks to 6 months				Change 2 weeks to 1 year							
Scar	--	--	--	--	12.0	21.5	0.46	5	13.9	23.6	0.57	5	5		

Satisfaction, Satisfaction with Facial Appearance scale; Psychosocial, Appearance-related Psychosocial Distress scale; Worry, Cancer Worry scale; Scar, Appraisal of Scars scale; MID, minimal important difference; SD, standard deviation; d, effect size