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First Phase Development of a Patient-reported Outcome Measure for Midface Oncology

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Background: Facial cancer surgery involving the midface (comprising the lower eyelids, nose, cheeks, and upper lip) can have debilitating life-changing functional, social, and psychological impacts on the patient. Midface symptoms are inadequately captured by existing patient-reported outcome measures (PROMs). PROMs are increasingly used for individual patient care, quality improvement, and standardized reporting of treatment outcomes. This study aimed to present our findings from the first phase of the development of a midface, specifically periocular and nasal, PROM.
Methods: After international guidance for PROM development, the first phase comprised identification of salient issues and item generation. Fifteen patients who had midface surgery and 10 clinicians from various specialties with more than 5 years' experience treating these patients were recruited. Semi-structured interviews explored aesthetic, functional, social, and psychological outcomes, with specific attention to deficiencies in current PROMs. Thematic analysis was used to develop an item pool, and group interviews with clinicians were carried out to create and refine PROM scales.
Results: Qualitative data from patient interviews were grouped into aesthetic, functional, and psychosocial domains for the eyelids and nose. Ninety-nine draft items were generated across these domains. Following focus group discussions, the final version of the midface-specific PROM contained 31 items (13 eye-specific, 10-nose-specific, eight general midface items).
Conclusions: This midface-specific PROM is valuable in assessing and comparing patient-reported outcomes in those who have undergone complex resection and reconstruction of the midface. This PROM is currently undergoing field testing.
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INTRODUCTION

The face defines one's identity and serves complex functions, including verbal communication, facial expression, breathing, and eating. Disfigurement due to congenital conditions, trauma, or surgery can so negatively affect self-esteem of an individual as to increase rates of suicide.[1] Unfortunately, the face is disproportionately affected by the major types of skin cancer, including basal cell carcinoma, squamous cell carcinoma, and melanoma, due to its greater exposure to the sunlight.[2–4] Excision with clear surgical margins is necessary to achieve satisfactory disease control.[5–10] Ensuing defects often warrant complex reconstruction, which can be challenging due to a combination of the high visibility of the face, and the complex anatomy and highly specialized functions of facial subunits. In particular, the midface, including the lower eyelid and nose, plays an important role in the senses of sight, smell, and taste, and restoration of these structures is especially vital.[11]

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Despite a systematic and sophisticated approach to reconstruction, complete restoration of cosmesis and function is near impossible, and significant physical and emotional morbidity can arise as a result.[12] Unlike rates of postoperative complications such as flap necrosis and wound infection, adverse functional and psychosocial effects are largely intangible and poorly quantifiable. Patients with suboptimal reconstruction of midface defects often report compromised function with vision, breathing, oral competence and speech, contributing to poor health-related quality of life (HRQL).[13] Given the importance of these functional and psychosocial outcomes, it has become increasingly clear that traditional quantitative survival and disease control endpoints do not entirely paint the complete picture of success of treatment, and must be supplemented with reports of treatment-associated morbidity. In this regard, there is ample evidence that clinicians underappreciate the incidence and severity of adverse symptoms impacting on HRQL related to treatment.[14–16] Patient-reported outcome measures (PROMs) have become the gold standard for assessing patient HRQL,[17] and their use in clinical practice has been advocated by many authors.[18–20]

Validated PROMs enable the structured and robust comparison of patient-reported outcomes between different treatment approaches and modalities.[18] Advances in technology (eg, virtual surgical planning, proton therapy), delivery, and sequencing (eg, neoadjuvant immunotherapy) in various specialties have narrowed disparities in disease control and survival endpoints between treatment modalities over time, translating into more treatment options.[21–28] In this context, documenting patient-reported outcomes in addition to assessing treatment related adverse effects have become even more important for patient engagement and empowerment in both informed consent and the treatment decision-making process.

Although some PROMs evaluating outcomes in facial surgery have been validated in small patient cohorts, many lack patient involvement in their development, creating concerns about content validity and relevance.[29,30] Furthermore, recent literature reviews suggest that few measure psychosocial aspects after surgery,[31] and even fewer have been evaluated with Rasch analysis, which improves the accuracy with which we can assess longitudinal clinical change.[30] The FACE-Q Head and Neck Cancer Module is a condition-specific, modular instrument that has been developed for surgery of the face using Rasch analysis, specifically for oncology patients.[31–39] This PROM was developed and validated in head and neck cancer patients with, predominantly, pathology originating in the aerodigestive tract.[29] There were inadequate data from the eye and nose scales, which led to a lack of questions pertaining to midface soft tissue structures in the FACE-Q Head and Neck Cancer Module (private communication). This gives impetus for the development of a scale focused on the midface that can be used in isolation or as an adjunct to the FACE-Q Head and Neck Cancer Module, to comprehensively characterize the full experience of patients who have undergone composite facial resection and reconstruction involving the midface, specifically periocular and nasal subunits. Our research group ultimately aims to develop such a midface-specific PROM.

PROM development can be divided into three phases. In the first phase, the conceptual model for the PROM is defined, and concepts are identified for item generation. The second and third phases involve field-testing and validation using psychometric measures, respectively.[33,40] This study aimed to present our findings from the first phase of the development of this midface-specific scale.

Takeaways

Question: Midface symptoms are inadequately captured by existing patient-reported outcome measures (PROMs). This study aimed to conduct the first phase of the development of a midface-specific PROM.

Findings: A 31-item midface-specific PROM was created, covering aesthetic, functional, and psychosocial domains for the eyelids and nose.

Meaning: This PROM, which is currently undergoing field testing, is valuable in assessing and comparing patient-reported outcomes in those who have undergone complex resection and reconstruction of the midface.

METHODS

Patient Recruitment

Eligible participants were identified from patient records maintained by treating surgeons at two tertiary hospitals in Sydney, Australia. Patients who had undergone an operation involving the midface (especially the eyelids and nose) between 2012 and 2018, and were older than 18 years at the time of surgery were eligible. Exclusion criteria included patients who were still undergoing treatment for the specific disease at the time of review, those who did not speak English as a primary language (to eliminate any language barrier), and the presence of cognitive impairment, intellectual disability, or mental illness precluding first-person informed consent.

Patients were recruited by their treating surgeon during clinic consultations. Interested patients received documents describing the study and subsequently discussed participation with the research team. Patients were given a period of up to 3 months to consider participation. Patients who agreed to participate provided informed consent before being interviewed and were free to withdraw from the study at any time. Patients were recruited and interviewed until data saturation was achieved, as indicated by contemporaneous data analysis to determine the point at which no new themes were identified.

Patient demographic and clinical data were collected, including information on age; sex; disease etiology; facial subunit(s) resected; type of reconstruction; surgical complications, including need for unplanned surgery; adjuvant therapy; and disease status at follow-up. These data were de-identified before analysis to ensure patient confidentiality.

Clinician Recruitment

Clinician inclusion criteria included consultant surgeons who were involved in either the ablative or reconstructive component of midface operations or radiation oncologists who were involved in postoperative care of patients who had undergone midface operations. They were required to have more than 5 years' experience with treating patients with midface disease, and speak English as a primary language. Clinicians were identified from two tertiary hospitals and invited via email to participate in the study. They were given three months to consider the invitation. Clinicians who agreed to participate provided informed consent before interview, and were recruited and interviewed until data saturation was achieved. Contemporaneous data analysis was conducted to assess the point at which no new themes were identified.

Patient Interviews

Patients participated in semistructured interviews exploring aesthetic, functional, social, and psychological satisfaction after surgery, lasting approximately 15 minutes, with a member of the research team (higher degree research student, J.L.). An interview guide (Table 1) was developed based on a review of relevant literature on surgery to the midface and covered treatment-related morbidity and satisfaction. Patients were given the opportunity to raise any other issues or concerns not covered before completion of interviews. Similarly, clinicians underwent a semistructured interview (Table 2) developed based on a review of relevant literature. Interview audio was recorded with consent and transcribed.

Development of a Conceptual Framework

Inductive content analysis was performed on the transcripts using a "line-by-line" approach in Microsoft Word (Microsoft Corp, Redmond, Wash.). Participants' quotes were tabulated according to the theme identified. Constant comparison was used to identify recurring or common themes. The data were categorized into themes, which were further grouped into domains based on the facial subunit affected (nose or eye) and subdomains (aesthetic, functional, and psychological). As data collection and analysis were conducted concurrently, sample size was determined by data saturation, ie, when no new themes surfaced. Data saturation was reached following 10 individual clinician interviews and 15 patient interviews.

Item Development

For each theme identified, a multi-item scale was created by generating one or more items from patient statements made during interviews. Where there was ambiguity about item wording, multiple items were drafted. Each item was written with efforts made to retain the participants' language as much as possible. To ensure that items were clear and easy to understand, we avoided double-barreled items and technical wording. These items were collated to form the first draft of the PROM.

Clinician Interviews

Clinician participants were recruited to two rounds of small-group Delphi-style focus group discussions to provide input and feedback on drafted items. The drafted items were compiled into a survey for distribution to clinicians to receive feedback. During clinician focus group discussions, a consensus-based approach was used to facilitate group discussion for feedback on each item. Items that were not supported by group consensus were excluded.

Ethics

Ethics approval for this study was granted by Sydney Local Health District Ethics Committee (HREC/18/

Table 1. Questions Asked to Patients in Semistructured Interviews

Eyelids	How do you feel about the appearance of your eyelids and eyes?
	Do you have any issues with the appearance of your eyes?
	Do you have any persistent or ongoing troubles and/or complications?
	Have you changed anything that you normally do because of the results of your surgery?
	Do you experience any negative emotions because of it?
Nose	How do you feel about the appearance of your nose?
	Do you have any issues with the appearance of your nose?
	Do you have any persistent or ongoing troubles and/or complications?
	Have you changed anything that you normally do because of the results of your surgery?
	Do you experience any negative emotions because of it?

These were used as a guide to explore how patients reported their experience.

Table 2. Questions Asked to Clinicians in Semistructured Interviews

In your experience, how satisfied are your patients with their appearance following surgery involving their eyelids?
Do patients have any common complaints about their eye appearance?
What persistent or ongoing troubles and/or complications do they experience? This includes problems from a physical, social and psychological perspective.
In your experience, how satisfied are your patients with their appearance following surgery involving any part of their nose?
Do patients have any common complaints about the appearance of their nose?
What persistent or ongoing troubles and/or complications do they experience? This includes problems from a physical, social and psychological perspective.

RPAH/349 and X18-0254) before study commencement. Throughout this study, steps were taken to ensure participant confidentiality, including the de-identification of data and safe storage of sensitive information as set out in the protocol approved by the ethics committee. No conflicts of interest were identified by the treating team.

RESULTS

Participants

Data saturation was reached following 15 patient interviews and two focus groups with 10 clinicians. Characteristics of the 15 patients interviewed are shown in Supplemental Digital Contents 1 and 2. (**See table, Supplemental Digital Content 1,** which displays the patient demographics and surgical/postoperative characteristics of the 15 patients interviewed. Data for surgical and postoperative characteristics are displayed as the number of patients. "Other malignancy" included sinonasal carcinoma, carcinoma ex pleomorphic adenoma, and microcystic adnexal carcinoma. **http://links.lww.com/PRSGO/D127**.) (**See table, Supplemental Digital Content 2,** which displays the conceptual framework of the midface-specific PROM with supportive participant quotes and examples. Quotes are from patients unless otherwise specified. **http://links.lww.com/PRSGO/D128**.)

Of the 15 patients interviewed, nine (60%) were women. The average age was 63.9 years, with the youngest patient aged 35 years. All but one patient underwent surgery to excise a malignant or premalignant lesion, with one patient undergoing excision of an arterio-venous malformation. The 10 clinician participants included consultant head and neck surgeons, plastic and reconstructive surgeons, ear nose and throat surgeons, radiation oncologists, and ophthalmologists.

Conceptual Framework

A conceptual framework for midface oncology symptoms was developed consisting of the following domains: eye-specific, nose-specific, cheek-specific (including speech and chewing), and general midface-related symptoms. For each domain, the following subdomains were identified: functional outcomes, and impact on (a patient's daily) activities. In addition, in the general midface-related domain, two additional subdomains were identified: aesthetic outcomes and psychosocial outcomes. Aesthetic outcomes were not identified as a subdomain for specific subunits (such as the eye or nose) as patients tended to focus on changes to their general appearance, as opposed to describing structure-specific defects.

PROM Development

This conceptual framework guided the development of the first draft of the PROM. A total of 99 draft items were generated to address the domains identified in the conceptual framework.

Psychosocial and aesthetic outcomes were identified as a subdomain, but items generated for these subdomains were found to be adequately covered in the FACE-Q Head and Neck Cancer Module, and were hence not included in the final PROM.[33] **Supplemental Digital Content 2** (**http://links.lww.com/PRSGO/D128**) presents the domains and subdomains of the conceptual framework that were included in our PROM, with supporting quotes from interview data.

After clinician focus group discussions, the final version of the PROM consisted of 31 items (13 eye-specific, 10 nose-specific, eight general midface items). Each item was given a five-point Likert scale. The items were compiled into a single document instructing readers to identify the degree to which they agreed with each item, such that this document could be easily distributed to patients for self-completion.

DISCUSSION

In this study, semistructured interviews conducted with patients and clinicians revealed unique aesthetic, functional, and psychosocial issues faced by patients after surgery to the eyelids and the nose. These data were used to develop a conceptual framework, which in turn informed the development of a PROM for patients who have undergone cancer-related surgery to the midface. For a comprehensive assessment of issues important to patients who have undergone composite facial resection and reconstruction involving the midface, this PROM should be used in combination with the FACE-Q Head and Neck Cancer Module, which covers cheek-specific, aesthetic, and psychosocial domains/subdomains not included in this new PROM.

At present, there is a dearth of literature investigating the prevalence, severity, and impact of such issues in patients who have undergone complex surgery to the midface for cancer. Multiple PROMs have been developed for aesthetic outcomes after cosmetic eye treatments, most prominently the FACE-Q Eye Module consisting of scales measuring the appearance of eyes, eyelids, and eyelashes.[32] Scales from FACE-Q Aesthetics such as satisfaction with appearance postsurgery have also been used to report aesthetic outcomes after double eyelid surgery.[41] However, these scales have not been designed for or validated in patients undergoing complex cancer resection and reconstruction, where aesthetic outcomes are seldom the primary consideration. Although the literature has reported complications after blepharoplasty, including dry eye, ocular irritation, epiphora, visual loss, lid retraction, and ptosis, consistent with the functional issues described by our patient cohort,[42] there are no validated PROMs for measuring these outcomes in midface cancer patients.

As with the eye, existing PROMs that address postoperative issues of the nose have been limited to those used in patients undergoing cosmetic procedures and are unsuitable for those undergoing cancer resection and reconstruction. FACE-Q Rhinoplasty, which assesses satisfaction with nasal appearance, is a subset of FACE-Q Aesthetics that has been validated in rhinoplasty patients.[35,43] Currently available PROMs addressing functional issues include the Nasal Surgical Questionnaire, Nasal Obstruction Symptoms Evaluation Scale, and Nasal Obstruction Septoplasty Effectiveness.[44,45] According to a systematic review by Barone and colleagues (2017), these

scales covered issues pertaining to breathing problems in different situations, including during sport, sleep, and in daily life, but did not address the more specific symptoms of nasal irritation and rhinorrhoea prevalent to the oncology patient cohort.[44] As such, these questionnaires are inadequate to measure the full spectrum of patient experience after midface surgery involving the nose.

Psychosocial issues faced by all patients who had undergone midface surgery included anxiety, depression, loss of self-confidence, and isolation from social interactions and relationships. Such psychosocial issues have been extensively reported in the literature and have been included in existing PROMs. Both the FACE-Q Skin Cancer Module and the FACE-Q Head and Neck Cancer Module include scales for cancer worry and appearance-related psychosocial distress.[29,46] The need for an improved preoperative discussion, as raised in our clinician interviews, has not been as well captured in PROMs as other psychosocial issues. Discrepancy between patients' preoperative expectations and the postoperative reality has previously been shown to exacerbate the severity of body image disturbance in patients who had undergone head and neck cancer surgery.[47]

This study adds to the current literature by identifying midface-specific issues faced by patients undergoing complex surgical resection and reconstruction. Midface-specific issues have been shown to be lacking in existing PROMs for this patient population.[31] A systematic review of PROMs used in patients with head and neck cancer identified dysphagia, saliva function, difficulty chewing and dental problems, dysphagia, oral mucositis, and voice and speech impairment to be the most common functional issues addressed.[48] These PROMs are often developed from patient populations where the majority have undergone surgery involving the aerodigestive tract.[31] For example, the Edmonton-33 instrument, a commonly used PROM in head and neck cancer patients, was designed and tested only in patients with squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, and larynx,[49] whereas OncoQuest, a PROM measuring HRQL in head and neck cancer patients, was validated in a patient population where 78% of patients had tumors of the pharynx, larynx, or oral cavity.[50]

The PROM developed in this study is the first to specifically address outcomes related to the midface. It addresses eye- and nose-specific issues that are not addressed in any other existing PROM. Moreover, unlike existing PROMs, this PROM focuses on issues experienced by patients undergoing cancer resection and reconstructive surgery, where cosmesis is often second to achieving an ideal oncological outcome. However, aesthetic and psychosocial subdomains were not duplicated, as they are already covered in the FACE-Q Skin Cancer Module and the FACE-Q Head and Neck Cancer, and such PROMs will need to be used in conjunction for a comprehensive assessment.

CONCLUSIONS

This study has identified specific aesthetic, functional, and psychosocial issues faced by patients who have undergone oncology surgery to the midface. This has enabled phase one development of new PROM scales for eyelid and nose symptoms, to act as an adjunct or in isolation to currently existing PROMs for head and neck cancer patients. In the current changing landscape of oncological treatment with multiple modalities becoming available, this PROM has the potential to be used in the assessment and comparison of different modalities for improved patient counseling and treatment decision-making. The next phase of the development of this PROM is field-testing and analysis to examine the psychometric properties of reliability and validity of this PROM.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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