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Patient- and clinician-reported outcomes of lower jaw contouring using patient-specific 3D-printed titanium implants

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Abstract. The main aim of this study was to assess patient-reported outcomes of jawline contouring with patient-specific three-dimensional (3D) -printed titanium alloy implants using validated Face-Q questionnaires. Four FACE-Q questionnaires (Appearance Appraisal Scale, Quality of Life Scales for Psychological and Social Function, and Adverse Effects Scale) were sent to 21 patients consecutively operated on by the same surgeon between 2014 and 2019. Thirteen patients responded. Mean Rasch Transformed Scores for Satisfaction, Psychological Function and Social Function (0–100) were 70.6, 73.2, and 71.1, respectively. These values are difficult to interpret, however, as comparative literature and prospective follow-up scores are lacking. The second objective was to correlate clinician-reported morphology improvement by panel scoring (Likert scale) with patient-reported appearance appraisal. As for satisfaction, we can conclude that an objective acceptable result does not corroborate patients' perceptions (Spearman Rho test r_s = -0.021). Psychological factors and results from previous surgeries probably modulate patients' views. The mean score for the Adverse Effect Scale (15–45) was low (18.6), indicating that the intraoral drop-in fit of customized titanium implants does not cause major side effects.

Key words: patient satisfaction; maxillofacial prosthesis implantation; maxillofacial abnormalities; titanium.

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Facial contouring or sculpting is an elective aesthetic procedure that aims to improve the general appearance of the face. Mandibular contouring to produce a smaller, slender, V-shaped lower face (V-line surgery) has become popular in East Asia. In Europe, mandibular contouring surgery to increase jaw line definition, jaw angle prominence and mandibular symmetry is increasing in popularity, because current technology of computer-aided design and manufacturing of the implants theoretically guarantee perfect and symmetrical outcomes. However, both patient and clinician still worry about the size and shape of the implant. Soft-to-hard tissue ratios are not available. The preoperatively presented design render [virtually three-dimensional (3D), computer-generated picture] does not guarantee postoperative satisfaction. Patient

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Table 1. Patient-reported outcome questionnaire results.

Chronological patient no.	Type of problem	FACE-Q satisfaction with lower face and jawline	RTS	FACE-Q psychological function	RTS	FACE-Q social function	RTS	FACE-Q adverse effects: cheeks, lower face and neck
1	Hemifacial microsomia	No		No		No		No
2	Postorthognathic	12	46	30	62	24	62	17
3	Masculinization	No		No		No		No
4	Hemifacial microsomia	15	66	36	80	27	73	17
5	Postorthognathic	12	46	31	65	31	92	26
6	Transgender	10	34	32	68	18	44	16
7	Postorthognathic	No		No		No		No
8	Postorthognathic	20	100	37	84	27	73	17
9	Postorthognathic	No		No		No		No
10	Hemifacial microsomia	17	78	32	68	22	55	22
11	Postorthognathic	16	72	34	74	27	73	18
12	Postorthognathic	No		No		No		No
13	Hemifacial microsomia	19	92	36	80	25	66	19
14	Postorthognathic	No		No		No		No
15	Parry-Romberg disease	20	100	39	93	32	100	17
16	Beautification	No		No		No		No
17	Beautification	15	66	30	62	24	62	15
18	Masculinization	No		No		No		No
19	Hemifacial microsomia	13	52	36	80	29	81	21
20	Beautification	15	66	No		29	81	No
21	Hemifacial microsomia	20	100	30	62	24	62	No
	Mean score		70.6		73.2		71.1	18.6

RTS, Rasch Transformed Score. Satisfaction with lower face and jawline: minimum is 5, maximum is 20. Psychological function: minimum is 10, maximum is 40. Social Function: minimum is 15, maximum is 32. Adverse effects: cheeks, lower face and neck: minimum is 15, maximum is 45. No = no response obtained.

satisfaction can be rated using validated measurement instruments.

A patient-reported outcome (PRO) is ''a measurement based on a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else''[1]. As literature on patient satisfaction after computer-aided design and manufacturing augmentation of the lateral mandibular border is sparse[2,3], the aim of this study was to assess PROs of patient-specific 3D-printed titanium alloy jawline contouring implants[4]. We also found it interesting to compare the PROs with the opinion of a clinician panel about the results achieved in the flawed jawline. The methods of investigation were validated questionnaires sent to patients and panel scores given to pictures of patients' faces, before and after implantation.

MATERIALS AND METHODS

This study was approved by the Medical Ethics Committee of the Universitair Ziekenhuis Brussel (#2019/131) and registered on www.clinicaltrials.gov (#NCT03932734).

Twenty-one consecutive patients underwent jawline contouring using patient-specific 3D-printed titanium alloy implants by the same surgeon between July 2014 and June 2019.

Patients were surveyed using a selection of validated scales belonging to a PRO instrument called FACE-Q©[5], including the Appearance Appraisal Scale, Quality of Life Scales for Psychological and Social Function, and Adverse Effects Scale. The Appearance Appraisal Scale assesses patients' perceptions of their lower face with items concerning the prominence and sculpted appearance of the jawline (Supplementary Fig. S1). The Quality of Life Scale for Psychological Function contains items pertaining to emotional heath constructs such as happiness, belief in oneself, confidence and feeling that one is in control (Supplementary Fig. S2). The Quality of Life Scale for Social Function contains items pertaining to social functions such as friendships, interactions with strangers, and first impressions (Supplementary Fig. 3S). The Adverse Effects Scale assesses morphological complications in the cheeks, lower face, and neck (Supplementary Fig. S4). Patients were asked to respond to items on a four-point scale while keeping their

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facial appearance in mind. Responses on each scale except the Adverse Effects Scale were summed and converted to a Rasch Transformed Score (RTS) from 0 to 100. For most FACE-Q scales except the Adverse Effects Scale, higher scores indicate better outcomes. There is no total score for the FACE-Q[6,7].

Questionnaires were sent to patients in July 2019, resent in August and September 2019, and February 2020 to non-responders. Questionnaire materials (i.e. the four FACE-Q scales, informed consent form and European Union General Data Protection Regulation form) were given to patients in Dutch, French or English as appropriate.

The FACE-Q instrument uses a psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PRO measure are conceptualized as 'rulers' with an ordered hierarchy of items from a low to high. For example, the Satisfaction with Facial Appearance scale measures a set of items that span a clinical arrangement from '' . . . how symmetric your face looks?'' to '' . . . how your face looks under bright lights?''[8]. RMT interval-level measurement allows for accurate tracking of change over time. However, the latter option was not used in this study.

Objective outcomes were rated by a panel. The panel comprised of six medical doctors in different stages of their training in oromaxillofacial surgery. The panel scored facial pictures in full face front, right and left oblique views before and at least 6 months postoperatively. A Likert scale of 1–5 (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree) was used, scoring the question ''Is the result of the jawline augmentation/correction acceptable?''

Statistical analysis

The numerical data showed normal distribution when tested with the Kolmogorov–Smirnov test of normality. Inter-rater reliability (parameters: two-way random-effects mode, mean of κ raters, agreement) and intra-rater reliability (two-way mixed-effects model) were calculated. For that purpose, the panel members were asked to score again 34 days after the first time. Correlation between the PRO's for satisfaction and the Likert scores of the clinicians was calculated using Spearman 's ρ-test. An alpha value of 0.05 was considered significant. The data were analysed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Of the 21 patients, 11 were females and 10 were males. Their mean age at surgery was 32.2 years (minimun 18 years, maximum 62 years). Thirty mandibular sides received an implant. Eight of the 21 patients did not complete the questionnaires. Of these non-responders, two stated that they were willing to complete the questionnaires but did not return the forms after four requests. The mean age of the 13 respondents (eight females, five males) was 32.5 years (minimum 18 years, maximum 62 years).

Table 1 shows the patient survey results. The patient with the lowest RTS was a trans woman (Fig. 1), and those with the highest RTSs were a gay man (Fig. 2) and a woman with Parry–Romberg syndrome (Fig. 3). The patients with the lowest psychosocial RTS had hemifacial microsomia (Fig. 4) and gender dysphoria (Fig. 1).

The intraclass correlation coefficient (test–retest; two-way mixed effects model, type 'agreement') was 0.808, indicative for a good reliability of the assessors. Interclass correlation coefficient (two-way random, 95%interval, type 'agreement') allowed calculation of a Cronbach's alpha of 0.811, demonstrating good internal consistency of the panel survey.

Spearman's rank-order correlation r_s was −0.02128 (two-tailed $P = 0.95667$), indicative for a non-monotonic relationship between the PRO's for satisfaction and clinician's appraisal of the improve-

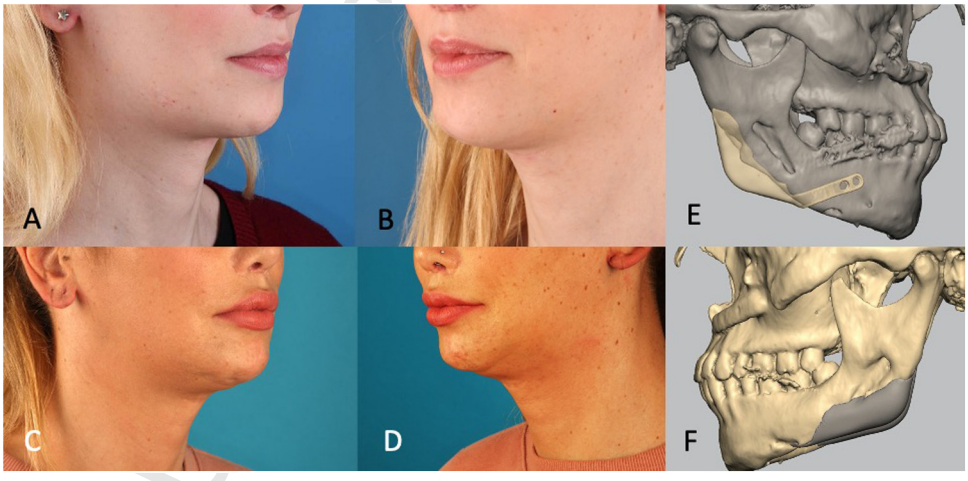

Fig. 1. Trans woman case with lowest Rasch Transformed Score. The jaw angles had been resected earlier, which is a typically recommended to remove a masculine aspect from the face, but when overdone, results in unaesthetic lack of projection in the posterolateral lower face. (A) Preoperative three-quarter profile right view; (B) preoperative three-quarter profile left view; (C) postoperative three-quarter profile right view; (D) postoperative three-quarter profile left view; (E) render of the patient-specific jaw angle implant on top of the gonial defect. A normal jaw angle was designed out of fear of obtaining a prominence that would look masculine to the patient. (F) Render of both jaw angle implants, demonstrating precision in symmetry. The preoperative photographs were taken 4 years prior to defect reconstruction. The postoperative photographs were taken 1.5 years after implantation. In the meantime, the patient had gained some weight. An exchange for larger implants is planned for, together with a midfacial height reduction.

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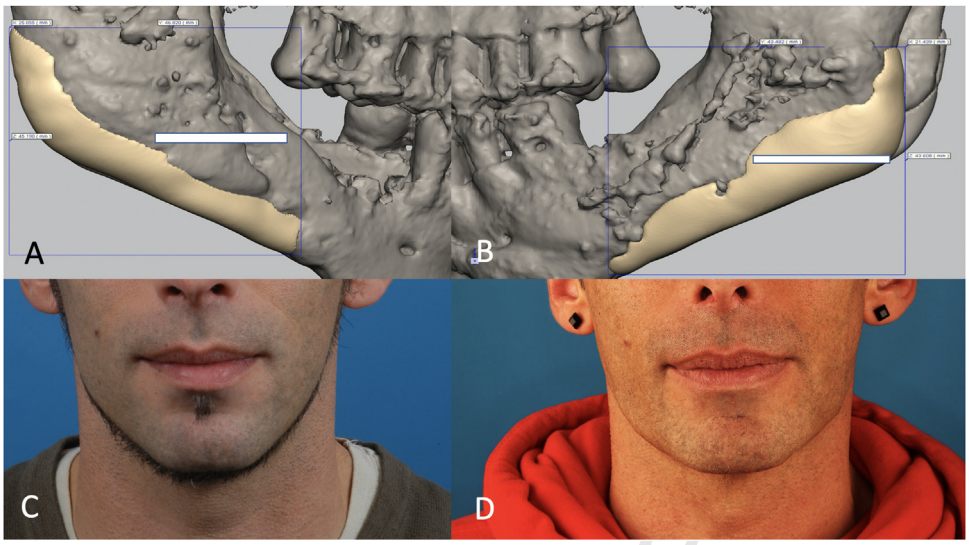

Fig. 2. Gay man case with maximal Rasch Transformed Score. Bilateral jaw angle implantation combined with genioplasty. (A) Render of right-sided patient-specific jaw angle design; (B) render of left-sided patient-specific jaw angle design (the software allows for perfect symmetry); (C) preoperative frontal view; (D) postoperative frontal view.

Fig. 3. A 35-year-old woman with Parry–Romberg syndrome (A) before any correction, (B) after right-sided jaw augmentation, (C) after patient-specific orbital floor implantation and microlipofilling in the chin and malar region, and (D) after another session of malar, infraorbital and chin microlipofilling.

ment brought by the patient-specific jaw implant(s).

DISCUSSION

A PRO is a measurement of a patient's perception of their own health status or quality of life[9]. The FACE-Q is a PRO instrument that can be used to assess the outcomes of aesthetic facial procedures and products from the patient's perspective.

However, patient satisfaction with the outcome (70.6 on a scale from 0 to 100) was difficult to judge due to several reasons not relevant to symmetry (as determined using mirroring software) or surgeon planning for ideal shape[10,11]. First, FACE-Q scores were not determined prior to implantation. Second, some patients were in the midst of sex reassignment surgery, some had marked birth defects precluding full satisfaction (e.g., hemifacial microsomia), some cannot discriminate between the outcomes of present and previous/subsequent surgical corrections, some exhibit perfectionism or body dysmorphic behavior and some have a high motivation to please, or suffer from iatrogenic damage, which can bias their responses. As such, the RTS for the Appearance Appraisal Scale should be interpreted with caution. Literature with which to compare PROs for mandibular patient-specific implants is non-existent. Previously reported patient dissatisfaction rates for stock silicone[12] and porous polyethylene[13] jaw angle implants (6% and 18.2%, respectively) were ''retrieved from notes taken by clinicians in the outpatient clinic'' and hence cannot be compared with that in the present study.

The results of this study indicate that adverse effects resulting from jawline contouring with patient-specific 3D-printed titanium alloy implants were low (18.6 on a scale from 15 to 45). This finding is consistent with a previous report that the intraoral route to drop-in fit a patient-specific implant causes minimal harm and complications[14].

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Fig. 4. Hemifacial microsomia case, with the lowest psychosocial RTS. Although the patient is satisfied (17/20), he feels socially (Rasch Transformed Score 55) insufficiently engaged. (A) Preoperative frontal view, before facial rotation osteotomies; (B) preoperative three-quarter profile view, before jaw angle reconstruction; (C) postoperative frontal view, after jaw angle reconstruction; (D) postoperative three-quarter profile view, after jaw angle reconstruction; (E) patient-specific 3D-printed titanium jaw angle implant in three parts, lateral view (sandblasted and acid etched finish); (F) implant of (E), medial view, demonstrating the scaffolding.

A limitation of this study is that the response rate was only 62%. Thus, non-response bias should be considered because as the missing data may not be random[15], even though surveys with a low response rate can yield statistically indistinguishable results from those with high response rates[16]. Furthermore, this study was retrospective in nature and single-authored.

When prioritizing that the morphological results were as can be expected from mirroring software, precision printing techniques and intraoperative cone beam computer tomography evaluation, a conclusion can be that patients ' perception of outcomes were markedly influenced by their psychological state, expectations, previous surgeries and underlying dysmorphology. An important message is that patients' level of satisfaction does not correspond with clinician's judgment.

Funding

None.

Competing interests

The author is a co-owner of the company (CADskills BV, Ghent, Belgium) that produces the patient-specific implant used in this study.

The author declares that he is innovation manager at CADskills bvba

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Patient consent

Informed consent was obtained from all individual participants included in the study.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijom.2020.07.008.

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