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Development of an oral health-related quality of life questionnaire on neurosensory disturbances after orthognathic surgery – a pilot study

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ABSTRACT

Objective: Development of a new questionnaire, Oral Health-Related Quality of Life – Neurosensory Disturbances after Orthognathic Surgery (OHRQL-NDO), designed to measure the effects of neurosensory disturbance (NSD) on patients' oral health-related quality of life (OHRQL) and to evaluate reliability and validity of this questionnaire.

Materials and methods: A questionnaire including 11 items was constructed. Thirty patients with NSD affecting the lower lip and/or chin following orthognathic surgery were included. Convergent validity was assessed by comparing OHRQL-NDO with OHIP-14 and two global questions. Test-retest reliability was assessed by asking the patients to complete OHRQL-NDO at two different occasions with an interval of two to three weeks.

Results: The internal consistency, measured with Cronbach's alpha, was 0.84. The test-retest reliability, measured with ICC, was 0.89 (95% CI 0.77–0.95). The correlation between the mean sum score for the OHRQL-NDO and the mean sum score for the OHIP-14 was $r=0.75$, using Pearson correlation coefficient. The correlations between the mean total score for the OHRQL-NDO and the global questions 1 and 2 were $r=0.74$ and $r=0.72$, respectively.

Conclusions: The current instrument OHRQL-NDO is a promising test, but needs further development to better capture the different aspects of OHRQL. Further tests of the questionnaire must follow in other samples to finalize the instrument.

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Introduction

Bilateral sagittal split osteotomy (BSSO) is a standard procedure for surgical correction of mandibular skeletal deformity. Patients undergoing this treatment often have malocclusion and skeletal discrepancy, which affects their appearance. The treatment objective is to achieve good function, aesthetics and stability [1].

The surgery is performed close to the inferior alveolar nerve, which may cause direct or indirect damage to the nerve, and hence risk for neurosensory disturbance (NSD) of the lower lip and chin. Trauma to the nerve can occur during soft tissue dissection on the medial side of the ramus, the split itself, dissection of the nerve from the lateral fragment, mobilization of the medial and lateral osteotomized bone fragments, and fixation [2–4]. NSD is one of the significant drawbacks of the surgery, and the incidence ranges from 1.6 to 90%. The various results in the literature can be explained

by the lack of standardized diagnostic methods and the different follow-up periods [5].

The majority of patients have altered sensations initially after the surgery. However, this is temporary in many cases, and the patients regain their sensations. [6]. Patients with altered sensation in the lower lip and chin caused by BSSO experience different kinds of symptoms. Some describe the feeling as numb, rubbery, swollen, tingling, tickling, itching, tender or burning, and some might feel pain [7]. The majority of patients in a qualitative interview study reported that NSD affects their everyday lives to some extent and expressed difficulties when speaking, kissing, eating, drinking, putting on makeup and shaving [8].

There are different NSD assessment procedures, such as objective measurements, sensory testing and patient self-reports [9]. Patient-reported outcomes are an essential component of evaluating the success of surgical procedures such as orthognathic surgery [10]. Oral health-related quality of

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life (OHRQL) is one type of patient-reported outcome, reflecting the complex interactions between oral problems and psychosocial well-being, perceived function, aesthetics and social interaction [11]. According to Inglehart and Bagramian, OHRQL contains several dimensions, such as function, pain and discomfort, psychological factors and social factors [12]. There are a limited number of studies examining how and to what degree altered sensation in the lower lip and chin affects OHRQL [13]. A few questionnaires focus specifically on the perception of altered sensation and its problems [8,14–16].

However, these questionnaires have some limitations, such as covering a too narrow range of OHRQL aspects and mostly using only binary response formats thereby hampering the psychometric analyses.

There is a need to evaluate OHRQL in patients with NSD following BSSO, using a condition-specific measure. Therefore, this study aims to develop a new questionnaire, Oral Health-Related Quality of Life – Neurosensory Disturbances after Orthognathic Surgery (OHRQL-NDO), designed to measure the effects of NSD on patients' OHRQL and evaluate psychometric properties such as the reliability and validity of the proposed questionnaire. In contrast to available questionnaires, this instrument should cover a broader spectrum of OHRQL dimensions, where the patient also has the opportunity to grade each answer, to achieve a more detailed and profound description of the patient's discomfort.

Materials and methods

This study was approved by the Regional Ethics Committee in Gothenburg (Dnr: 567-18) and performed according to the Declaration of Helsinki.

Patients were consecutively recruited from the Department of Oral & Maxillofacial Surgery at Sahlgrenska Academy in Gothenburg, the Unit of Cranio- & Maxillofacial Surgery at Karolinska University Hospital in Stockholm, and the Department of Oral and Maxillofacial Surgery at Örebro University Hospital. All patients received a letter of information and signed a consent form before participating in the study. Inclusion criteria were: neurosensory disturbance affecting the lower lip and/or chin following BSSO or bimaxillary surgery, with or without genioplasty. The majority of patients were included prior to surgery. If the patients did not experience NSD postoperatively they were excluded.

Excluded were patients with craniofacial syndromes, cleft lip and palate, or previous facial trauma; patients undergoing vertical ramus osteotomy; and patients undergoing genioplasty or Le Fort 1 osteotomy alone. Patients who recently had undergone surgery did not receive the questionnaire until six weeks postoperatively.

Development of the new questionnaire OHRQL-NDO

A questionnaire including 11 items was constructed based on a previous study by Lee et al. [8] and suggestions made by some of the authors (MA, FB, CC, HK) of this article. Some of the items in the questionnaire (items 1,2,3,5,9,10) were constructed based on interpretations of the interviews and questionnaire items presented by Lee et al. [8], in combination with the authors' clinical experience regarding this patient group. Further, items 4, 6 and 11 were incorporated to the questionnaire from the Lee et al. study [8]. Items 7 and 8 were based on the authors' clinical experience and they have extensive experience of treating orthognathic patients, both pre- and postoperatively.

The items included the following dimensions: function (e.g. difficulty controlling your intake of food), psychological impact (e.g. affected your facial expression negatively), social impact (e.g. negative impact on your social life) and pain/discomfort (e.g. burnt yourself on the lip when eating or drinking). The items are presented in Table 1. Each item is scored from 0 to 4, where 0 = never, 1 = hardly ever, 2 = occasionally, 3 = often and 4 = very often. The sum of scores ranges from 0 to 44, where a higher score indicates a lower OHRQL.

The questionnaire was evaluated by five maxillofacial surgeons involved in orthognathic surgery (experience between 5 and 10 years), five general dentists and five laypersons. Their comments were systematically collected and were used to improve the wordings and sentences of each item. The questionnaire was translated into English by a bilingual professional translator whose native language was English. It was then back-translated into Swedish by a bilingual professional translator whose native language was Swedish. Minor changes to the text were made after the translations.

Two single, global questions were included to assess the validity of the questionnaire: (i) Do you perceive that your quality of life is negatively impacted by your changed sensation in the lower lip/chin? and (ii) Do you perceive that your daily life is negatively impacted by your changed sensation

Table 1. Description of the new questionnaire.

Item number	Description of the item
1	Do you feel that your changed sensation has had a negative impact on your social life?
2	Do you experience difficulty controlling your intake of food because of your changed sensation?
3	Do you avoid eating/drinking among people because of your changed sensation?
4	Have you, because of your changed sensation, burnt yourself on the lip when eating or drinking warm food or beverages?
5	Have you, because of your changed sensation, burnt yourself on the tongue when eating or drinking warm food or beverages?
6	Have you, because of your changed sensation, bitten yourself on the lip by mistake
7	Have you, because of your changed sensation, bitten yourself on the cheek by mistake?
8	Have you, because of your changed sensation, bitten yourself on the tongue by mistake?
9	Do you feel that your changed sensation has had a negative impact on your love life?
10	Do you feel that your changed sensation has affected your facial expression negatively (e.g. when you smile/laugh/talk, etc.)?
11	Do you have difficulties shaving yourself or applying makeup because of your changed sensation?

in the lower lip/chin? These questions are scored on a scale from 0 to 6, where 0 = not at all, and 6 = very much.

The Oral Health Impact Profile 49 (OHIP-49) may be viewed as a generic scale of OHRQL [17]. OHIP-14, a short version of the original OHIP-49, was used in this study for validation purposes [18]. Individuals were asked to complete the Swedish version of OHIP-14, which has demonstrated good reliability and validity [19]. The scale consists of 14 items divided into seven dimensions: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The items are scored from 0 to 4, where 0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often and 4 = very often. The sum of the scores ranges from 0 to 56, where a higher score indicates a poorer OHRQL [18].

Procedure

Participants were provided with a web link to gain access to OHRQL-NDO, OHIP-14 and questions about their background (age, gender, civil state, level of education). The web link was sent to their phone number and email address. Participants were asked if they experienced an NSD in the lower lip/chin. If any altered sensation was present, they could continue to complete the questionnaires.

After completing the questionnaires, the participants were asked to complete the OHRQL-NDO again, two to three weeks following the first occasion, to assess test-retest reliability. This time interval was chosen to avoid carryover effects. If the participant had not completed the questionnaire, a reminder was sent.

Statistical analysis

Descriptive statistics such as mean values, standard deviations and percentages were used. Cronbach's alpha and item-total correlation were used to measure the internal consistency of the OHRQL-NDO. Test-retest reliability was calculated with the intraclass correlation coefficient (ICC). Convergent validity was assessed by comparing the OHRQL-NDO with the OHIP-14 and the global questions 1 and 2 using the Pearson correlation coefficient (r). Specifically, with regard to OHIP-14, Spearman correlation analysis (r_s) was also performed due to some skewness in the distribution of the data. Statistical analysis was performed with SPSS software (version 25, IBM Corp., Armonk, NY, USA).

Results

Sample characteristics

A total of 34 individuals were asked to participate in the study. One individual did not respond, despite several reminders. Two individuals were excluded because they had regained their sensation the second time they completed the questionnaire. One individual did not experience altered sensation. The number of participants in the study was $n = 30$, and Table 2 illustrates the individuals' characteristics according to age, gender, education, civil status and type of surgery.

Table 2. Demographic characteristics of the patients.

	<i>n</i> (%)
Gender	
Female	17 (56.7)
Male	13 (43.3)
Age mean $\pm$ SD	25.4 $\pm$ 8.8
Range	18–46 years
Highest education	
Elementary school	1 (3.3)
Senior high school	16 (53.3)
University/University college	13 (43.3)
Civil state	
Single	21 (70)
Cohabiting/partner/married	9 (30)
Type of surgery	
Bimaxillary	18 (60)
BSSO	11 (36.7)
BSSO and genioplasty	1 (3.3)

Table 3. Mean score and standard deviation (SD) for each item in OHRQL-NDO and total score (after completing the questionnaire the first time).

Item	Mean	SD
1. Social life	1.5	1.0
2. Intake of food	1.9	1.2
3. Avoid eating/drinking	1.6	1.3
4. Burnt lip	0.6	0.9
5. Burnt tongue	0.9	1.0
6. Bitten lip	2.1	1.5
7. Bitten cheek	1.6	1.5
8. Bitten tongue	0.8	1.0
9. Love life	1.3	1.3
10. Facial expression	1.7	1.4
11. Shaving or applying makeup	1.5	1.3
Total score	15.5	8.5

OHRQL-NDO

Mean values and standard deviations for each item in the OHRQL-NDO (for the first assessment) are presented in Table 3. The mean sums of scores for the first and second assessments were 15.5 (8.5) (range 1–34) and 14.0 (8.7) (range 2–32), respectively. At the first assessment, the two items with the highest mean scores were bitten lip and intake of food, whereas the items with the lowest mean scores were burnt lip and bitten tongue.

The correlations between the items in the OHRQL-NDO (the first assessment time) are presented in Table 4. The correlation matrix explicitly revealed high correlations between the items social life, intake of food, avoiding eating/drinking, love life, and facial expression. The following items had low correlations with the other items in the questionnaire: shaving or applying makeup, burnt lip and burnt tongue. The same pattern of correlation coefficients was found at the second assessment (data not shown for the second assessment). Very low correlations were found between the items bitten tongue and avoiding eating/drinking ($r = 0.08$) and between love life and bitten tongue ($r = -0.02$).

Reliability

The internal consistency of the OHRQL-NDO, measured with Cronbach's alpha, was 0.84 at the first assessment and 0.88 at the second assessment. The item-total correlation ranged between 0.21 and 0.79. The test-retest reliability, measured

Table 4. Correlation between the items in OHRQL-NDO, the first time the patients ($n = 30$) completed the questionnaire.

Item	1. Social life	2. Intake of food	3. Avoid eating/ drinking	4. Burnt lip	5. Burnt tongue	6. Bitten lip	7. Bitten cheek	8. Bitten tongue	9. Love life	10. Facial expression	11. Shaving or applying makeup
1. Social life											
2. Intake of food	0.68**										
3. Avoid eating/drinking	0.61**	0.73**									
4. Burnt lip	0.27	0.21	0.20								
5. Burnt tongue	0.28	0.39*	0.23	0.69**							
6. Bitten lip	0.53**	0.52**	0.55**	0.22	0.22						
7. Bitten cheek	0.47**	0.54**	0.45*	0.21	0.22	0.65**					
8. Bitten tongue	0.26	0.35	0.08	0.44*	0.26	0.46*	0.45*				
9. Love life	0.56**	0.40*	0.44*	0.11	0.11	0.20	0.36	−0.02			
10. Facial expression	0.67**	0.70**	0.55**	0.18	0.14	0.46*	0.24	0.31	0.25		
11. Shaving or applying makeup	0.05	0.20	0.12	0.27	0.47**	0.10	−0.06	0.10	0.20	0.13	

* $p < 0.05$, ** $p < 0.01$.**Table 5.** Mean score and standard deviation (SD) for each item in OHIP-14 and in total.

Item	Mean	SD
1. Trouble pronouncing words	1.8	1.4
2. Sense of taste worse	1.0	1.2
3. Painful aching in mouth	1.6	1.2
4. Uncomfortable to eat foods	1.9	1.3
5. Been self-conscious	1.8	1.5
6. Felt tense	1.3	1.3
7. Diet has been unsatisfactory	1.8	1.4
8. Had to interrupt meals	1.1	1.3
9. Difficult to relax	0.9	1.1
10. Been embarrassed	0.9	1.2
11. Been irritable with others	0.9	1.3
12. Difficulty doing usual jobs	1.1	1.0
13. Felt life less satisfying	1.1	1.1
14. Totally unable to function	0.1	0.4
Total score	17.4	10.6

with ICC, was 0.89 (95% CI 0.77–0.95), and the Pearson correlation coefficient between the mean total score for the OHRQL-NDO at the first and second assessment was 0.80.

Validity

Table 5 presents the mean values of the items and the mean sum of scores for the OHIP-14. The items with the highest mean values were trouble pronouncing words, painful aching in mouth, uncomfortable to eat foods, been self-conscious and diet has been unsatisfactory (Mean score range 1.6–1.9). The mean sum of scores was 17.4 (10.6). The correlation between the mean sum score for the OHRQL-NDO and the mean sum score for the OHIP-14 was $r = 0.75$ and $r_s = 0.70$.

The mean score and standard deviation (SD) for global question 1, after completing the questionnaire at the first and second assessment, were 2.4 (1.7) and 2.2 (1.8), respectively, whereas the corresponding results for global question 2 were 2.5 (1.5) and 2.3 (1.6). The correlations between the mean total score for the OHRQL-NDO and the global questions 1 and 2 at the first assessment were $r = 0.74$ and $r = 0.72$, whereas the analysis for the second assessment showed $r = 0.73$ and $r = 0.73$, respectively.

Further development

Due to low inter-correlations within the OHRQL-NDO for three items (items 4, 5, 11), a reanalysis was performed

excluding these items. Thus, for the eight-item questionnaire, the internal consistency measured with Cronbach's alpha was 0.86. The item–total correlation for the eight-item questionnaire ranged from 0.37 to 0.80. Moreover, the correlation between the OHRQL-NDO and the OHIP-14 was $r = 0.70$, whereas for the global questions 1 and 2 the coefficients were $r = 0.76$ and $r = 0.73$, respectively.

Discussion

A new questionnaire was developed to evaluate the effects of NSD on OHRQL after mandibular surgery in orthognathic patients. The 11-item OHRQL-NDO questionnaire showed promising results concerning properties of reliability and validity.

There are some previous scientific reports concerning patient-reported outcomes after orthognathic surgery; however, the instruments used lack some important aspects of OHRQL, and psychometric analyses. Lee et al. created a questionnaire that covered different aspects of sensory disturbance: description, effects, feelings/expectations, and advice/opinions [8]. Likewise, Al-Bishri et al. developed a questionnaire where patients were asked to describe the altered sensation and answer questions regarding the duration of the disturbance, effects on everyday life, satisfaction with the result of the surgery and whether they would recommend this treatment [14]. August et al. [15] modified a questionnaire from Zuniga and Essick [20]. The questionnaire focused on the presence, distribution and description of NSD and function [15]. The above questionnaires do not allow the patients to grade their answers for each difficulty they may experience, thus limiting the amount of information obtained and the possibility to evaluate some of the psychometric properties. Phillips et al. used a questionnaire containing questions about the problems related to altered sensation and difficulties associated with function [16]. However, the items in this questionnaire cover only a narrow range of OHRQL aspects.

We argue that this new questionnaire encompasses a better and fuller understanding of the effects on OHRQL (such as symptoms, functions, psychological aspects) that may arise due to NSD. However, this is the first phase in developing

the OHRQL-NDO, and further evaluations should follow in other samples and cultural settings.

In contrast to the majority of the questionnaires mentioned above, the OHRQL-NDO allows the patients to grade how they experience discomfort on an ordinal scale, which is a development, since more detailed information can be obtained and further psychometric evaluations can be performed, such as reliability and validity.

The reliability analyses of the OHRQL-NDO showed acceptable values for a psychometric scale according to Streiner [21]. For the internal consistency, Cronbach's alpha and item-total correlations were high for the 11-item version. However, omitting items 4, 5 and 11 improved both measures of internal consistency even further. In addition, the test-retest analysis revealed very high agreement using the intraclass correlation coefficient [21].

As previously mentioned, Inglehart and Bagramian's definition of OHRQL includes function, pain/discomfort, psychological factors and social factors [12]. The items in the OHRQL-NDO include these factors. For further development, although only a small proportion report NSD as painful [7], it could be valuable to incorporate an additional question concerning pain beyond the present items of burning and biting effects. Therefore, an item regarding pain could be added to the OHRQL-NDO, such as 'Do you feel that your changed sensation is painful?' Moreover, the psychological factor and functional domain could be more thoroughly investigated, and therefore a question concerning perceived worries about the NSD could be included and the patients may also be asked if they have difficulties doing their usual jobs. The questions regarding 'burnt' and 'bitten' could be condensed into two questions instead of five questions, to improve content validity and make the questionnaire more balanced.

Convergent validity was assessed by comparing the OHRQL-NDO with the OHIP-14 and the two global single questions. The correlation between the mean total score for the OHRQL-NDO and the mean total score for the OHIP-14 was 0.75, which is a strong correlation, and a similar strong correlation was found between the OHRQL-NDO and the two global questions. When assessing validity, one should compare instruments that are expected to be related. Therefore, the OHIP-14, a generic measure that evaluates OHRQL, was used [18]. It has previously been used on patients undergoing orthognathic surgery [13]. The OHRQL-NDO, on the other hand, is a condition-specific measure that addresses neurosensory disturbance. Thus, they do not fully measure the same aspects of oral health, and therefore, a perfect correlation cannot be expected.

The following items in the OHRQL-NDO had low correlations with the items in the OHIP-14: burnt tongue, bitten cheek, bitten tongue, love life and shaving or applying makeup. This could be explained by the fact that these questions are specifically related to NSD, and since the OHIP-14 evaluates general oral health, these aspects are not covered in that questionnaire.

The total mean score for the OHIP-14 in the present study was 17.4 (10.6), indicating a rather high level of affected OHRQL compared with normative values for the Swedish

adult population, having a total mean score of 4.3 (6.8) [22]. Since the OHIP-14 is more of a generic OHRQL instrument, which captures different and more general aspects of OHRQL, there is a need for more condition-specific instruments, and OHRQL-NDO may complement OHIP-14 by assessing more condition-specific aspects not covered by the OHIP-14.

Strengths and limitations of the present study

Development of the first version of the OHRQL-NDO followed, generally, the procedure for the advancement of a new psychometric test as outlined by Streiner [21]. Thus, suitable and adequate items were generated from a pool of questions, both from previous literature and from experts. This pilot study also evaluated and analysed the results by using adequate statistical tests such as internal consistency and intraclass correlation for reliability, and correlation analysis for judging validity aspects. The relatively small sample size could be considered a weakness. Importantly, since this evaluation is the first test of the new questionnaire, it is understood that more research is needed with larger sample sizes and in different settings, to better reveal the nature of the psychometric properties. One difficulty in developing a questionnaire as the present one is that a multi-professional team is needed. Thus, the group responsible for the new scale included surgeons, orthodontists, and researchers in psychometrics.

Conclusion

The current instrument OHRQL-NDO is a promising test, but needs further development to better capture the different aspects of OHRQL. It captures many of the difficulties experienced by the patients and has shown good psychometric properties. Further tests of the questionnaire must follow in other patient samples to further develop the instrument while possibly adding and/or omitting items.

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