Patients with reconstruction of craniofacial or intraoral defects experience a profound impact on their quality of life (QOL). This impact on QOL is influenced by the patients' medical conditions and the treatment interventions. Instruments to measure general QOL have been available for many years. A major criticism of QOL instruments is that too often the questions are not specific to the particular problems of a disease or condition. A search of the literature regarding QOL measurement for patients with maxillofacial implant-supported prostheses produced a short list of instruments, none of which were sufficiently developed or suited to the patients involved in reconstructive treatment. This study was designed to develop pretreatment and posttreatment questionnaires for measuring QOL for patients with reconstruction of a craniofacial defect and patients with reconstruction of loss of specific intraoral structures utilizing an implant-supported prosthesis (e.g., severe resorption of the maxilla or mandible or both). The goal was to develop brief, targeted instruments for this specific patient population. The produced instruments were sensitive and easy to administer and score, and no disruption of clinical care occurred with the administration of the questionnaires. The instruments were used with equal success both in face-to-face interviews and via mail. (Int J Oral Maxillofac Implants 2001;16:225–245)

Key words: craniofacial abnormalities, implant-supported prosthesis, quality of life, questionnaire

To practice health care using the philosophy of evidence-based medicine requires (1) asking clinically relevant questions of the patient that will assist the clinician in providing better care, (2) conducting a systematic review of available scientific evidence that may answer clinically focused questions, and (3) using the evidence-based findings and conclusions to provide treatment. Asking clinically relevant questions (before and after treatment) is one of the methods to evaluate treatment outcome. One specific outcome that may be assessed by questionnaire is quality of life (QOL).

Instruments to measure general QOL have been available for many years. Literally hundreds of QOL instruments have been developed during the last decade. A major criticism of QOL tools is that too often the questions are not specific to the problems of a certain disease or condition. Generally, global QOL instrumentation should be supplemented with disease-specific tools because QOL is a multidimensional construct.

The psychologic aspects of QOL resulting from major changes after plastic surgery procedures have been investigated by Edgerton and coworkers and Reich.广告 has discussed the psychologic ramifications of facial changes secondary to orthodontic treatment and orthognathic surgery.
Blomberg and Linquist\textsuperscript{13} and Kiyan and associates\textsuperscript{14} have reported on the psychologic improvement of patients receiving osseointegrated implant-supported prostheses for treatment of edentulism.

Osseointegrated implant support for craniofacial prostheses, introduced in 1979, has improved the QOL for this group of patients, in comparison to support systems previously available for this type of prosthesis.\textsuperscript{15} However, specific instruments to measure this change in QOL for patients with craniofacial defects were not available. In caring for patients who have undergone reconstruction of craniofacial defects with an implant-supported prosthesis or specific intraoral conditions such as a severely resorbed maxilla or mandible or both, an instrument designed to evaluate that specific problem could provide help in the evaluation of QOL.

Quality-of-life instruments are available for head and neck cancer, and considerable research has been done investigating QOL in patients with head and neck cancer.\textsuperscript{16-19} The functional assessment of cancer therapy/head and neck (H\&N) scale,\textsuperscript{20} European Organization for Research and Treatment of Cancer QOL questionnaire/H\&N,\textsuperscript{13,21} performance status scale/H\&N,\textsuperscript{20} and McMaster H\&N radiotherapy questionnaire\textsuperscript{22} are but a few. Collectively, these instruments cover a broad range of symptoms and characteristics. However, none of these instruments deals specifically with issues of prostheses or craniofacial implants.

Recent research has indicated that patients with H\&N cancer have specific aspects of QOL that are not necessarily measured by more common global QOL instrumentation. An oral prosthesis has been seen to impact a number of general QOL domains.

Some work has been done in this area, but the instruments are still relatively new and untested.\textsuperscript{23-29} A tool has been developed and shown to be sensitive to change in assessing the QOL related to shoulder function after neck dissection. A study of the psychosocial aspects for patients with H\&N cancer indicated that the most important aspects of QOL involved function and symptoms and indicated that standard QOL questionnaires needed to be adapted for use in this population. Similarly, a head-to-head comparison of more generic QOL instrumentation with a targeted QOL tool indicated the use of the more sensitive instrument to uncover specific patient problems.\textsuperscript{29} Further, the instruments are somewhat lengthy, with each instrument being in excess of 20 items. The authors’ search for brief, specific, and validated instrumentation revealed that a need existed for the development of such tools for patients with craniofacial implants and prostheses.

This project was designed to develop 2 sets (pre-treatment and posttreatment) of brief but specific instruments for measuring QOL issues related to craniofacial implants and prostheses. Separate tools were constructed for patients who had reconstruction of a craniofacial defect with an implant-supported prosthesis and for patients who had reconstruction of loss of specific intraoral structures, such as severe resorption of the maxilla or mandible or both. The 2 sets of instruments can be used separately or together (for the patient with a complex defect).

The purpose of the questionnaires on the craniofacial instrument is to assess the stability, ease of placement and removal, care, and appearance of the prosthesis and to evaluate patient apprehension, self-consciousness, difficulty associated with hygiene of the defect, limitation of activities, discomfort associated with wearing the prosthesis, and patient perception of their prosthesis (as viewed by others). The purpose of the questionnaires on the intraoral instrument is to assess fit, function, and discomfort with wearing of the prosthesis and the effect of the prosthesis on patient activities.

**METHODS**

**Instrument Development**

The present measuring instruments were developed using established and standard procedures for constructing QOL instrumentation.\textsuperscript{30,31} After a comprehensive review of the literature on QOL measurement for patients with H\&N conditions, various measuring instruments were collected and a list of constructs to be measured was developed. The list included tools created by Nobel Biocare AB (Göteborg, Sweden) (as used in the multicenter study reported by Tolman and Taylor\textsuperscript{32}), by Kapasi and Anderson,\textsuperscript{25} and by Kiyan and associates,\textsuperscript{14} with the requisite approvals from the tool authors. The construct list was not exhaustive, and only constructs were included that either were considered important to the patient or were expected to show moderate shifts (or both).

Once the list of constructs was developed, the “keep it simple and straightforward” principle for implementation was followed, as advised by numerous QOL tool developers.\textsuperscript{33-38} To obtain global measures on each specific construct related to patient QOL, one guiding principle rather than a litany of individual constructs was used. For example, the construct of social interaction was suggested as vitally important to patient QOL. Only one question specific to this construct was included—“How often does your implant affect your socializing?”—instead of asking patients to respond to a list of
social activities. In this approach, the goal was to obtain from the patients a gestalt response regarding the impact of the implant/prosthesis on social activities. Experience and the literature have demonstrated that summation of individual social activities is difficult owing to variability across individuals in social patterns and the number of items necessary to cover all forms of social activity. Although this approach does lose detail as to which aspects of social QOL have been affected, the precise pattern of impact is less important than the perception of the patient that, on the whole, there has been an impact on his or her social activity.

The use of simple linear analog self-assessment (LASA) items has long been validated in the psychometric literature. Several studies have indicated that LASAs that use numeric anchors produce reliable and accurate data, similar to simple Likert scales. Because some items were mere incidence variables, questions requiring a simple “yes” or “no” were used. The LASA format was adapted, and a series of items derived from the construct list previously compiled was constructed. This construct list was sent to the other tool authors, clinicians, nurses, and patients for input, and a subsequent revised set of instruments was produced.

The resulting instruments are a combination of QOL considerations as related to surgical and prosthodontic procedures. The level of detail of the instruments is targeted to identify those areas of concern that should stimulate further investigation into QOL. The items are intended to stand alone rather than to be used as a summative scale. Thus, the instruments are intended to serve as clinical practice facilitators as well as research tools. This approach requires that the instruments be shorter than the more detailed instruments currently available.

Clinical significance of the individual item scores directed the item selection process—a difference from typical approaches, which are more concerned with producing summative scores and assessing clinical relevance indirectly. Each item is intended as a trigger to clinical intervention. By definition, a number of items for any person are expected to reflect satisfaction, lack of a problem, or a problem that is not of concern. The present instruments cover the major constructs in fewer than 20 items. This decision was made so that patients could complete the questionnaire in less than 10 minutes. One of the disadvantages of this approach is that some details may be missed. This approach is an appropriate compromise between data detail and patient burden. The instruments cannot be considered a substitute for a complete clinical visit, in which the care provider can delve into the important details regarding the benefits or difficulties that the patients have encountered with the implants. The instruments should provide gross measures of the QOL constructs that are most likely to be affected by the placement of the implant and provide details for more involved or clinical interventions (Appendices 1 and 2).

Operationally, any score on any item that falls into 1 of the 2 “problem categories” of the LASA (for example, a 1 or a 2 on the discomfort item) is defined as an indication of a problem needing clinical attention. Once the initial list of constructs had been made operational, the draft questionnaire was sent to a number of clinical experts for feedback. These experts included oral and maxillofacial surgeons, prosthodontists, physicians, nurses, patients, and researchers (internal and external to the authors’ institutions). The subsequent feedback was incorporated into revised versions and was subjected to a series of pilot tests.

Procedure
Patients from 4 medical centers (Edmonton, Alberta, Canada; Toronto, Ontario, Canada; Rochester, Minnesota, USA; and Morriston, Swansea Wales, UK) were given the set of questions relevant to the status of their treatment. Questionnaires were administered by para-professional support staff no directly involved in the patient’s care. After the questionnaires were completed, the questions and comments were reviewed. Several questions were modified early in the pilot testing on the basis of comments received from the patients. After these early revisions, no additional responses or comments were received. In essence, the design process was complete.

Pilot Testing
The population from which participants were drawn were English-speaking persons who underwent treatment of craniofacial or intraoral defects or patients with complex defects requiring both craniofacial and intraoral reconstructions. The intention was to determine whether the questions were clear, confusing, relevant to the patient’s problem, important, and whether additional questions should be asked. The patients were given the opportunity to provide comments (Appendix 3).

RESULTS AND DISCUSSION
A convenience sample of 27 patients (16 with craniofacial defects, 11 with intraoral defects) was given the questionnaires. Of the 16 patients with craniofacial defects, 4 completed both the pretreatment and
posttreatment questionnaires and 12 completed 1 of the 2. Of the 11 patients with intraoral defects, 3 completed both questionnaires and 8 completed a pretreatment or a posttreatment questionnaire. To obtain answers to pretreatment and posttreatment questionnaires on each of the 27 patients would have required a lengthy period of time. Thus, only pretreatment questionnaires were given to those patients beginning treatment and only posttreatment questionnaires were given to these patients having previously completed treatment.

Responses indicated no missing data on any of the questionnaires and no confusing or unclear questions. Seven items were identified as not being relevant to a patient's particular situation, but no more than 2 items per patient were classified by patients as being inapplicable to their situation. Responses by the 7 patients completing both sets of questionnaires generally revealed moderately positive shifts. No patient in this group of 7 patients indicated a negative shift on any question. Scatter plots of each item were developed for each of the 2 patient groups at the pretreatment and posttreatment assessments (Figs 1a and 1b). The 7 patients who completed both sets of instrumentation showed notable improvement in a number of areas. Overall, patients moved from an average score of 3 on the visual analog scale to an average of 4.5 (on a scale of 1 to 5, low/worst to high/best). Discomfort and eating showed the largest amount of improvement.

Posttreatment scores were uniformly high (Table 1). Most important, however, shifts in the pretreatment to posttreatment scores were notable. If Cohen's effect size approach was applied, combined with Sloan's empirical effect size estimation, patient responses moved more than 0.5 standard deviation on a number of items.

All 27 patients understood the questions, and all 27 stated the belief that the questions were relevant and important to their problems. The following represent comments of individual patients:

- "I would have welcomed these questions for each generation of prosthesis I have worn."
- "The questions are a very good way to help you think about your prosthesis and how you are affected by it."
- "The questions were very clear."
- One patient (given posttreatment questions only) stated, "Pre-surgery (10 years ago) I would have answered all questions very negatively—at the lowest end of the scale. Posttreatment, it is a pleasure to be able to smile again, to eat, talk, yawn, or even sneeze without any discomfort or any concern as to whether or not my dentures are going to fall out of my mouth. Truly a new lease on life!"
- "The questionnaire is a good one and hopefully it will assist with future patients."
- "The questionnaire could certainly give a clear understanding of how a patient is managing with or without a denture."

Issues and concerns were raised for each of the 27 patients. In particular, scores for the individual items ranged over the entire 5-point scale. The instruments identified 10 different problems among the 27 patients, with clear indications for intervention in 5 patients. Problems identified included 3 patients expressing difficulties chewing or biting foods, 2 patients reporting mandibular denture looseness or discomfort, and 2 patients reporting worry about looseness and potential dislodgement of the prosthesis, thereby making them self-conscious and causing them to limit their socializing and other routine activities.
Table 1  Pretreatment and Posttreatment Responses of Patients with Craniofacial and Intraoral Defects

<table>
<thead>
<tr>
<th>Craniofacial</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfortable with appearance while using prosthesis or covering?</td>
<td>2.7</td>
<td>1.79</td>
<td>4.5</td>
</tr>
<tr>
<td>How well does your prosthesis or covering stay in place?</td>
<td>3.1</td>
<td>1.75</td>
<td>4.6</td>
</tr>
<tr>
<td>Are you apprehensive that prosthesis or covering will become loosened or displaced when not at home?</td>
<td>2.8</td>
<td>1.69</td>
<td>3.9</td>
</tr>
<tr>
<td>How noticeable is your prosthesis or covering?</td>
<td>1.8</td>
<td>1.53</td>
<td>4.0</td>
</tr>
<tr>
<td>How self-conscious are you about your prosthesis or covering when in public?</td>
<td>2.9</td>
<td>1.86</td>
<td>3.9</td>
</tr>
<tr>
<td>How difficult is it to put on your prosthesis or covering?</td>
<td>3.9</td>
<td>1.51</td>
<td>4.9</td>
</tr>
<tr>
<td>How difficult is it to remove your prosthesis or covering?</td>
<td>4.1</td>
<td>1.72</td>
<td>4.8</td>
</tr>
<tr>
<td>How difficult is it keeping the tissue under prosthesis or covering clean?</td>
<td>3.4</td>
<td>1.41</td>
<td>4.0</td>
</tr>
<tr>
<td>How limited are your activities because of your prosthesis?</td>
<td>2.5</td>
<td>1.23</td>
<td>4.2</td>
</tr>
<tr>
<td>How much discomfort with your prosthesis or covering in place?</td>
<td>3.6</td>
<td>1.16</td>
<td>4.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intraoral</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Extent of discomfort under your upper denture?</td>
<td>3.8</td>
<td>0.29</td>
<td>4.4</td>
</tr>
<tr>
<td>Extent of discomfort under your lower denture?</td>
<td>3.6</td>
<td>1.45</td>
<td>4.1</td>
</tr>
<tr>
<td>Difficulty speaking when you are wearing your denture(s)?</td>
<td>3.4</td>
<td>0.46</td>
<td>4.3</td>
</tr>
<tr>
<td>Do you avoid activities because of possibly being embarrassed by your denture(s)?</td>
<td>3.4</td>
<td>0.42</td>
<td>4.2</td>
</tr>
<tr>
<td>How often do your denture(s) affect your socializing?</td>
<td>3.4</td>
<td>0.71</td>
<td>4.3</td>
</tr>
<tr>
<td>How often do your denture(s) affect your work?</td>
<td>3.6</td>
<td>0.78</td>
<td>4.7</td>
</tr>
<tr>
<td>How difficult is it for you to bite into soft foods?</td>
<td>3.2</td>
<td>1.56</td>
<td>4.7</td>
</tr>
<tr>
<td>How difficult is it for you to bite into hard foods?</td>
<td>1.8</td>
<td>0.72</td>
<td>4.0</td>
</tr>
<tr>
<td>How difficult is it for you to chew soft foods?</td>
<td>4.0</td>
<td>0.47</td>
<td>4.8</td>
</tr>
<tr>
<td>How difficult is it for you to chew hard foods?</td>
<td>2.6</td>
<td>1.45</td>
<td>3.9</td>
</tr>
</tbody>
</table>

*Scores ranged from 1 (low) to 5 (high).*

Two other patients identified problems with prosthesis placement. Individual concerns raised by 1 patient each dealt with difficulty in speaking, inadequate healing, and noticeability of the prosthesis.

**CONCLUSION**

The questionnaires are a systematically developed set of measurements of QOL of patients undergoing treatment for craniofacial or intraoral or complex defects. This study represents the first stage in the development of these instruments. Preliminary indications show sensitivity to changes in clinical problems that will need replication with further study. Those studies are presently underway. The tools are recommended for clinical intervention/assessment more than for research. The instruments, similar to measures of H&N QOL, would require supplementation by standard global QOL instruments. The tools performed well in terms of ease of administration and scoring. Reports from the clinical area indicated no disruption of clinical practice by administration of the tools. The tools were used both in person and via mail with equal success. Prox responses may be usable, although further study is needed to fully resolve this issue.

A recent review article demonstrated that specific aspects of QOL for patients with H&N cancer are particularly important. A further review article supported this hypothesis and provided a detailed list of generic and disease-specific instrumentation that is available for patients with head and neck cancer. It is important that these be combined with economic data, demonstrating that improved QOL translates into more efficient and superior patient care.
ACKNOWLEDGMENT

This project was supported by Nobel Biocare, USA, Inc., Yorba Linda, CA.

REFERENCES


APPENDIX 1

CRANIOFACIAL TISSUE-INTEGRATED PROSTHESIS

The following information should be available to abstract from the patient’s medical/dental records. Check (√) the appropriate response or answer.

Patient ID number: ____________________ Date: ____________________

Sex: Male ☐ Female ☐

Date of Birth: Month __________ Day __________ Year __________

Site of defect: Ear ☐ Eye ☐ Nose ☐

Cause of defect: Congenital ☐ Trauma ☐ Tumor ☐

Wearing prosthesis: Yes ☐ No ☐

Support for present prosthesis:

Glue ☐ Tape ☐ Eyeglass frame or headband ☐

Other type of covering:

Patch ☐ Support: Glue ☐ Tape ☐ Eyeglass frame or headband ☐

Gauze ☐ Support: Glue ☐ Tape ☐

Combing or styling your hair over defect: Yes ☐ No ☐

THIS COVER SHEET TO BE COMPLETED BY COORDINATOR BEFORE TREATMENT BEGINS.
CRANIOFACIAL PROSTHESIS
PATIENT PRETREATMENT QUESTIONNAIRE

The purpose of this questionnaire is to obtain your opinion, information, and experiences about your prosthesis or covering you currently may be wearing. The responses to the questions will not affect your treatment in any way. You may leave any question blank that does not apply to you. Place an “X” on the line after each question.

Example: I like my prosthesis:

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>X</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

1. How comfortable are you with your appearance while using your prosthesis or covering? (No prosthesis or covering ☐)

Very uncomfortable

| 1 | 2 | 3 | 4 | 5 |

Very comfortable

2. How well does your prosthesis or covering stay in place?

Not well

| 1 | 2 | 3 | 4 | 5 |

Very well

3. How apprehensive are you that the prosthesis or covering will become loosened or dislodged when you are not at home?

Very apprehensive

| 1 | 2 | 3 | 4 | 5 |

Not apprehensive

4. How noticeable is your prosthesis or covering?

Very noticeable

| 1 | 2 | 3 | 4 | 5 |

Not noticeable

5. How self-conscious are you about your prosthesis or covering when in public?

Very self-conscious

| 1 | 2 | 3 | 4 | 5 |

Not self-conscious
6. How difficult is it for you to put on your prosthesis or covering?

<table>
<thead>
<tr>
<th>Very difficult</th>
<th>Not difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

7. How difficult is it for you to remove your prosthesis or covering?

<table>
<thead>
<tr>
<th>Very difficult</th>
<th>Not difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

8. How difficult is it for you to keep the tissue under your prosthesis or covering clean?

<table>
<thead>
<tr>
<th>Very difficult</th>
<th>Not difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

9. How limited are your activities because of your prosthesis?

<table>
<thead>
<tr>
<th>Many activities are limited</th>
<th>No activities are limited</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

10. How much discomfort do you have with your prosthesis or covering in place?

<table>
<thead>
<tr>
<th>Extreme discomfort</th>
<th>No discomfort</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

11. On average, how often do you remove your prosthesis or covering because of discomfort?

- Never □
- Once a day □
- 2 to 3 times a day □
- 4 to 5 times a day □
- More than 5 times a day □

12. Do you think your prosthesis causes you to be viewed typically by others:

- Just like everyone else □
- As handicapped □
CRANIOFACIAL PROSTHESIS
PATIENT POSTTREATMENT QUESTIONNAIRE

The following questions relate to your recently completed implant-supported prosthesis. Place an “X” on the line after each question.

Example: I like my prosthesis:

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>

1. How comfortable are you with your appearance while using your prosthesis?

Very uncomfortable

<table>
<thead>
<tr>
<th>Not well</th>
<th>Very well</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
<td></td>
</tr>
</tbody>
</table>

2. How well does your prosthesis stay in place?

3. How apprehensive are you that the prosthesis will become loosened or dislodged when you are not at home?

Very apprehensive

<table>
<thead>
<tr>
<th>Not apprehensive</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
</tr>
</tbody>
</table>

4. How noticeable is your prosthesis?

Very noticeable

<table>
<thead>
<tr>
<th>Not noticeable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
</tr>
</tbody>
</table>

5. How self-conscious are you about your prosthesis when in public?

Very self-conscious

<table>
<thead>
<tr>
<th>Never self-conscious</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
</tr>
</tbody>
</table>
6. How difficult is it for you to put on your prosthesis?

Very difficult  Not difficult

7. How difficult is it for you to remove your prosthesis?

Very difficult  Not difficult

8. How difficult is it for you to keep the tissue under your prosthesis clean?

Very difficult  Not difficult

9. How limited are your activities because of your prosthesis?

Many activities are limited  No activities are limited

10. How much discomfort do you have with your prosthesis in place?

Extreme discomfort  No discomfort

11. On average, how often do you remove your prosthesis because of the discomfort?

Never □ Once a day □ 2 to 3 times a day □
4 to 5 times a day □ More than 5 times a day □

12. Do you think your prosthesis causes you to be viewed typically by others:

Just like everyone else □ As handicapped □
If this is your first prosthesis answer questions 13 and 14. If this is not your first prosthesis answer questions 15 and 16.

13. To what extent has your implant-supported prosthesis allowed you to increase your regular daily activities?

- No increase
- Greatly increased

14. To what extent has your implant-supported prosthesis allowed you to increase your ability to function at school or work?

- No increase
- Greatly increased

15. Compared with the method of support for your previous prosthesis, to what extent has your implant-supported prosthesis allowed you to increase your regular daily activities?

- No increase
- Greatly increased

16. Compared with the method of support for your previous prosthesis, to what extent has your implant-supported prosthesis allowed you to increase your ability to function at school or work?

- No increase
- Greatly increased
APPENDIX 2

INTRAORAL TISSUE-INTEGRATED PROSTHESIS

The following information should be available from the patient's medical/dental records. Check (√) the appropriate response or answer.

Patient ID number: __________________________ Date: __________________________

Name: ______________________________________

Sex: Male □ Female □

Date of Birth: Month __________ Day __________ Year __________

Edentulous:
   Maxilla: Yes □ No □
   Mandible: Yes □ No □

Date edentulous:
   Maxilla: Month __________ Day __________ Year __________
   Mandible: Month __________ Day __________ Year __________

Date first denture inserted:
   Maxilla: Month __________ Day __________ Year __________
   Mandible: Month __________ Day __________ Year __________

THIS COVER SHEET TO BE COMPLETED BY COORDINATOR BEFORE TREATMENT BEGINS.
INTRAORAL PROSTHESIS (DENTURE)

PATIENT PRETREATMENT QUESTIONNAIRE

The purpose of this questionnaire is to obtain your opinion and information about your dental/oral functioning (with or without dentures) after the loss of your teeth. Your response to the questions will not affect your treatment in any way. You may leave any question blank that does not apply to you. For those questions with numbers, place an "X" on the line after each question.

Example: I like my prosthesis:

<table>
<thead>
<tr>
<th>Not at all</th>
<th></th>
<th></th>
<th></th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

1. Do you have any numbness in the facial area or around your mouth? Yes □ No □

2. Are you:
   - Missing all your upper teeth? Yes □ No □
   - Missing all your lower teeth? Yes □ No □
   - Wearing an upper denture? Yes □ No □
   - Wearing a lower denture? Yes □ No □

3. If you are wearing a denture(s), how long have you worn:
   - An upper denture? _______ years
   - A lower denture? _______ years

4. Describe the extent of discomfort under your upper denture:

   Extreme discomfort | No discomfort
   | | | | |
   | 1 | 2 | 3 | 4 | 5 |

5. Describe the extent of discomfort under your lower denture:

   Extreme discomfort | No discomfort
   | | | | |
   | 1 | 2 | 3 | 4 | 5 |

6. How would you describe the fit of your upper denture?

   Very loose | No looseness
   | | | | |
   | 1 | 2 | 3 | 4 | 5 |
7. How would you describe the fit of your lower denture?

Very loose

| 1 | 2 | 3 | 4 | 5 |

No looseness

---

8. Do you have difficulty speaking when you are wearing your denture(s)?

Almost always difficult

| 1 | 2 | 3 | 4 | 5 |

Almost never difficult

---

9. Are there activities that you avoid because of the possibility of being embarrassed by your denture(s)?

Almost always

| 1 | 2 | 3 | 4 | 5 |

Almost never

---

10. How often do your denture(s) affect your socializing?

Almost always

| 1 | 2 | 3 | 4 | 5 |

Almost never

---

11. How often do your denture(s) affect your work?

Almost always

| 1 | 2 | 3 | 4 | 5 |

Almost never

---

12. How difficult is it for you to bite into soft foods?

Extremely difficult

| 1 | 2 | 3 | 4 | 5 |

Not difficult

---

13. How difficult is it for you to bite into hard foods?

Extremely difficult

| 1 | 2 | 3 | 4 | 5 |

Not difficult
14. How difficult is it for you to chew soft foods?

Extremely difficult
1  2  3  4  5

Not difficult

15. How difficult is it for you to chew hard foods?

Extremely difficult
1  2  3  4  5

Not difficult

16. Do you have:

Popping or clicking of your jaw joint? Yes ☐ No ☐
Pain or soreness in front of your ear (jaw joint)? Yes ☐ No ☐
INTRAORAL PROSTHESIS (DENTURE)

PATIENT POSTTREATMENT QUESTIONNAIRE

The following questions relate to your recently completed tissue-integrated (implant-supported) prosthesis (denture). For those questions with numbers, place an "X" on the line after each question.

Example: I like my prosthesis:

<table>
<thead>
<tr>
<th>Not at all</th>
<th></th>
<th></th>
<th></th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

1. Do you have any numbness in the facial area or around your mouth? Yes □ No □

2. Describe the extent of discomfort under your upper denture:

<table>
<thead>
<tr>
<th>Extreme discomfort</th>
<th>No discomfort</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

3. Describe the extent of discomfort under your lower denture:

<table>
<thead>
<tr>
<th>Extreme discomfort</th>
<th>No discomfort</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

4. How would you describe the fit of your upper denture?

<table>
<thead>
<tr>
<th>Very loose</th>
<th>No looseness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

5. How would you describe the fit of your lower denture?

<table>
<thead>
<tr>
<th>Very loose</th>
<th>No looseness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

6. Do you have difficulty speaking when you are wearing your denture(s)?

<table>
<thead>
<tr>
<th>Always difficult</th>
<th>Never difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
7. Are there activities that you avoid because of the possibility of being embarrassed by your denture(s)?

Almost always

Almost never

8. How often do your denture(s) affect your socializing?

Almost always

Almost never

9. How often do your denture(s) affect your work?

Almost always

Almost never

10. How difficult is it for you to bite into soft foods?

Extremely difficult

Not difficult

11. How difficult is it for you to bite into hard foods?

Extremely difficult

Not difficult

12. How difficult is it for you to chew soft foods?

Extremely difficult

Not difficult

13. How difficult is it for you to chew hard foods?

Extremely difficult

Not difficult
14. Do you have:
   - Popping or clicking of your jaw joint?  Yes [ ] No [ ]
   - Pain or soreness in front of your ear (jaw joint)?  Yes [ ] No [ ]

15. How satisfied are you with the healing since your implant surgery?
   - Not satisfied
     1  2  3  4  5
   - Very satisfied

16. How satisfied are you with the results of having implants placed in your jaw?
   - Not satisfied
     1  2  3  4  5
   - Very satisfied

17. Do you think your implant-supported denture is actually a part of your own jaw?
   - Not at all
     1  2  3  4  5
   - Very much

18. To what extent has your implant-supported denture improved your social and work relationships with other people?
   - Not at all
     1  2  3  4  5
   - Very much

19. Considering that having implants is an elective procedure, would you recommend it to another person?  Yes [ ] No [ ]
APPENDIX 3

ACCOMPANYING QUESTIONS ASSESSING PATIENT’S RESPONSES TO PILOT QUESTIONNAIRE

1. Was any question unclear? If yes, describe lack of clarity.

2. Did any question confuse you? If yes, describe the confusion.

3. Do you think all questions were relevant to your problem? If not, please indicate which one(s) was (were) not relevant.

4. Do you think all questions were important to you? If not, please indicate which one(s) was (were) not important.

5. Is there any other question that needed to be asked? If yes, provide.

6. Do you have any other comment about this questionnaire? If yes, describe briefly.