

Patients with Reconstruction of Craniofacial or Intraoral Defects: Development of Instruments to Measure Quality of Life

Jeff A. Sloan, PhD¹/Dan E. Tolman, DDS, MSD²/James D. Anderson, BSc, DDS, MScD³/
Adrian W. Sugar, BChD, FDSRCS⁴/John F. Wolfaardt, BDS, MDent, PhD⁵/Paul Novotny, MS⁶

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 (eg, 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) con-

ducting 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 a questionnaire is quality of life (QOL).

Instruments to measure general QOL have been available for many years.^{1,2} 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.³⁻⁵ Generally global QOL instrumentation should be supplemented with disease-specific tools⁶⁻⁹ 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 coworkers¹ and Reich.¹¹ Oulette¹² has discussed the psychologic ramifications of facial changes secondary to orthodontic treatment and orthognathic surgery

¹Associate Professor, Mayo Medical School; Senior Associate Consultant, Section of Biostatistics, Mayo Clinic, Rochester, Minnesota.

²Professor Emeritus, Mayo Medical School, Mayo Clinic, Rochester, Minnesota.

³Professor, Faculty of Dentistry, University of Toronto; Director, Craniofacial Prosthetic Unit, Toronto-Sunnybrook Regional Cancer Centre, Toronto, Ontario, Canada.

⁴Consultant Oral and Maxillofacial Surgeon, Morriston Hospital, Swansea, Wales, United Kingdom.

⁵Professor and Director, Craniofacial Osseointegration and Maxillofacial Prosthetic Rehabilitation Unit, Misericordia Hospital/Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta, Canada.

⁶Biostatistician, Mayo Clinic, Rochester, Minnesota.

Reprint requests: Dr Jeff A. Sloan, Section of Biostatistics, Charleston 6, Mayo Clinic, 200 First St SW, Rochester, MN 55905. Fax: +507 266 2477. E-mail: jsloan@mayo.edu

Blomberg and Linquist¹³ and Kiyak and associates¹⁴ 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.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.¹⁶⁻¹⁹ The functional assessment of cancer therapy/head and neck (H&N) scale,²⁰ European Organization for Research and Treatment of Cancer QOL questionnaire/H&N,^{13,21} performance status scale/H&N,²⁰ and McMaster H&N radiotherapy questionnaire²² 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.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.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 (pretreatment 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.^{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 Taylor³²), by Kapasi and Anderson,²⁵ and by Kiyak and associates,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.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.^{33,34} 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.^{39,40} Several studies have indicated that LASAs that use numeric anchors produce reliable and accurate data,^{40,41} 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 bene-

fits 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 fall 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 has been made operational, the draft questionnaire were 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 were subjected to a series of pilot tests.

Procedure

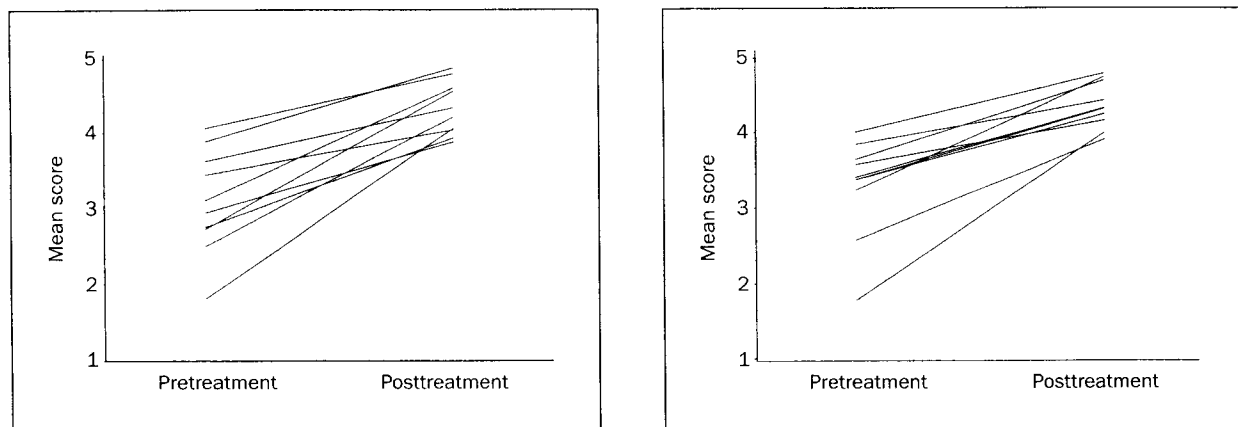
Patients from 4 medical centers (Edmonton, Alberta, Canada; Toronto, Ontario, Canada; Rochester, Minnesota, USA; and Morriston, Swansea Wales, UK) were given the set of questions relevant to the status of their treatment. Questionnaires were administered by para-professional support staff not directly 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 that required revision of any question 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, or 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



Figs 1a and 1b Stream plots of individual patient responses to pretreatment and to posttreatment questionnaires. (Left) Reconstruction of craniofacial defect (10 patients). (Right) Loss of specific intraoral structures (10 patients). Each line represents data from an individual patient.

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 approach⁴² was applied, combined with Sloan's empirical rule effect size estimation,⁴³ 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 dislocation 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**Craniofacial**

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

Intraoral

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

*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. Proxy 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.⁴⁴ 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.⁴⁵ It is important that these be combined with economic data, demonstrating that improved QOL translates into more efficient and superior patient care.⁴⁶

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REFERENCES

- Spilker B (ed). *Quality of Life and Pharmacoeconomics in Clinical Trials*. New York: Lippincott-Raven, 1996.
- Rosser R. The history of health related quality of life in 10 1/2 paragraphs. *J R Soc Med* 1993;86:315-318.
- Cox DR, Fitzpatrick R. Quality of life assessment: Can we keep it simple? *J R Stat Soc* 1992;155:353-393.
- Cella DF. Quality of life: The concept. *J Palliat Care* 1992; 8(3):8-13.
- Lepelge A, Hunt S. The problem of quality of life in medicine. *JAMA* 1997;278(1):47-50.
- Aaronson NK. Methodological issues in assessing the quality of life of cancer patients. *Cancer* 1991;67(Suppl):844-850.
- Donnelly S, Walsh D. Quality of life assessment in advanced cancer. *Palliat Med* 1996;10(4):275-283.
- Guyatt GH, Feeny D, Patrick D. Issues in quality of life measurement in clinical trials. *Control Clin Trials* 1991;12: 81S-90S.
- Nayfield SG, Ganz PA, Moinpour CM, Cella DF, Hailey BJ. Report from a National Cancer Institute workshop on quality of life assessment in cancer clinical trials. *Qual Life Res* 1992;1:203-210.
- Edgerton MT, Jacobson WE, Meyer E. Surgical-psychiatric study of patients seeking plastic (cosmetic) surgery: 98 consecutive patients with minimal deformity. *Br J Plast Surg* 1960;13:136-145.
- Reich J. The surgery of appearance: Psychological and related aspects. *Med J Aust* 1969;2:5-13.
- Oulette RL. Psychological ramifications of facial change in relation to orthodontic treatment and orthognathic surgery. *J Oral Surg* 1978;36:787-790.
- Blomberg S, Linquist LW. Psychological reactions to edentulousness and treatment with jawbone-anchored bridges. *Acta Psychiatr Scand* 1983;68:251-262.
- Kiyak HA, Beach BH, Worthington P, Taylor T, Bolender C, Evans J. The psychological impact of osseointegrated dental implants. *Int J Oral Maxillofac Implants* 1990;5:61-69.
- Tjellström A. Osseointegrated implants for replacement of absent or defective ears. *Clin Plast Surg* 1990;17:355-366.
- Padilla GV, Grant MM and Martin L. Rehabilitation and quality of life issues (Speech Rehabilitation Following Laryngectomy Workshop). *Head Neck Surg* 1988;10(Suppl II):S156-S160.
- Drettner B, Ahlborn A. Quality of life and state of health for patients with cancer in the head and neck. *Acta Otolaryngol* 1983;96:307-314.
- Epstein JB, Emerton S, Kolbinson DA, Le ND, Phillips N, Stevenson-Moore P, Osoba D. Quality of life and oral function following radiotherapy for head and neck cancer. *Head Neck* 1999;21(1):1-11.
- List MA, Siston A, Haraf D, Schumm P, Kies M, Stenson K, Vokes EE. Quality of life and performance in advanced head and neck cancer patients on concomitant chemoradiotherapy: A prospective examination. *J Clin Oncol* 1999;17(3): 1020-1028.
- List MA, D'Antonio LL, Cela DF, Siston A, Mumby P, Haraf D, Vokes E. The performance status scale for head and neck cancer patients and the functional assessment of cancer therapy-head and neck scale. A study of utility and validity. *Cancer* 1996;77(11):2294-2301.
- Bjoridal K, Hammerlid E, Ahlner-Elmqvist M, de Graeff A, Boysen M, Evensen JF, et al. Quality of life in head and neck cancer patients: Validation of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire—H&N 35. *J Clin Oncology* 1999;17(3):1008-1019.
- Browman GP, Levine MN, Hodgson DJ, Sathya J, Russell R, Skingley P, et al. The head and neck radiotherapy questionnaire: A morbidity/quality of life instrument for clinical trials of radiation therapy in locally advanced head and neck cancer. *J Clin Oncol* 1993;11:863-872.
- Huguenin PU, Tausky D, Moe K, Meister A, Baumert B, Lutolf UM, Glanzmann C. Quality of life in patients cured from a carcinoma of the head and neck by radiotherapy: The importance of the target volume. *Int J Radiat Oncol Biol Physics* 1999(Aug 1);45(1):47-52.
- Moroi HH, Okimoto K, Terada Y. The effect of an oral prosthesis on the quality of life for head and neck cancer patients. *J Oral Rehabil* 1999;26(4):265-273.
- Kapasi A, Anderson JD. Quality of life with implant-retained facial prostheses. A pilot study [abstract]. Presented at the First International Congress on Maxillofacial Prosthetics, Palm Springs, California, 1994.
- Kuntz AI, Weymuller EA Jr. Impact of neck dissection on quality of life. *Laryngoscope* 1999;109(8):1334-1338.
- Rogers SN, Lowe D, Brown JS, Vaughan ED. The University of Washington head and neck cancer measure as a predictor of outcome following primary surgery for oral cancer. *Head Neck* 1999;21(5):394-401.
- Hammerlid E, Persson LO, Sullivan M, Westin T. Quality-of-life effects of psychosocial intervention in patients with head and neck cancer. *Otolaryngol Head Neck Surg* 1999; 120(4):507-516.
- Rogers SN, Lowe D, Brown JS, Vaughan ED. A comparison between the University of Washington Head and Neck Disease Specific Measure and the Medical Short Form 36, EORTC QOQ-C33 and EORTC Head and Neck 35. *Oral Oncol* 1998;34(5):361-372.
- Cella DF. Quality of life outcomes: Measurement and validation. *Oncology* 1996;10(1):233-246.
- Ware JE. Standards for validating health measures: Definition and content. *J Chron Dis* 1987;40(6):473-480.
- Tolman DE, Taylor PF. Bone-anchored craniofacial prosthesis study. *Int J Oral Maxillofac Implants* 1996;11(2):159-168.
- Osoba D. Lessons learned from measuring health-related quality of life in oncology. *J Clin Oncol* 1994;12(3):608-616.
- Testa MA, Simonson DC. Assessment of quality of life outcomes. *N Engl J Med* 1996;334(13):835-840.
- Gill TM, Feinstein AR. A critical appraisal of the quality of life measurements. *JAMA* 1994;272:619-626.
- Nelson EC, Landgraf JM, Hays RD, Wasson JH, Kirk JW. The functional status of patients: How can it be measured in physicians' offices? *Med Care* 1990;1111-1126.
- Nou E, Aberg T. Quality of survival in patients with surgically treated bronchial carcinoma. *Thorax* 1980;35:255-263.
- Giorgi F, Cellerino R, Gramazio A, Tummarello D, Menichetti ET, Giordani P, et al. Assessing quality of life in patients with cancer: A comparison of a visual-analogue and a categorical model. *Am J Clin Oncol* 1996;19(4):394-399.

39. Wewers ME, Lowe NK. A critical review of visual analogue scales in the measurement of clinical phenomena. *Res Nurs Health* 1990;13:227-236.
40. Hyland ME, Sodergren SC. Development of a new type of global quality of life scale and comparison of performance and preference for 12 global scales. *Qual Life Res* 1996;5:469-480.
41. Sriwatanakul K, Kelvie W, Lasagna L, Calimlim JF, Weis OE, Mehta G. Studies with different types of visual analog scales for measurement of pain. *Clin Pharmacol Ther* 1983;34(2):234-239.
42. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Hillsdale, NJ: Lawrence Erlbaum & Associates, 1998.
43. Sloan J, O'Fallon J, Suman V, Sargent D. Incorporating quality of life measurements into oncology clinical trials. *Proc Am Stat Assoc* 1998;1312-1317.
44. Terrell JE. Quality of life assessment in head and neck cancer patients [review]. *Hematol Oncol Clin North Am* 1999;13(4):849-865.
45. Rogers SN, Fisher SE, Woolgar JA. A review of quality of life assessment in oral cancer. *Int J Oral Maxillofac Surg* 1999;28:99-117.
46. Sherman EJ, Ruchlin HS, Holden JS, Pfister DG. Clinical economics of head and neck malignancies [review]. *Hematol Oncol Clin North Am* 1999(Aug);13(4):867-881.

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:

Not at all		Very much
1	2	5
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="flex-grow: 1; border-top: 1px solid black; position: relative;"> <div style="position: absolute; top: -5px; left: 35%; font-size: 2em;">X</div> </div> </div>		
1	2	4

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

Very uncomfortable

Very comfortable

1	2	3	4	5

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

Not well

Very well

1	2	3	4	5

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

Very apprehensive

Not apprehensive

1	2	3	4	5

4. How noticeable is your prosthesis or covering?

Very noticeable

Not noticeable

1	2	3	4	5

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

Very self-conscious

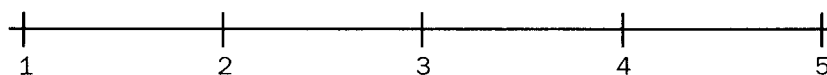
Not self-conscious

1	2	3	4	5

6. How difficult is it for you to put on your prosthesis or covering?

Very difficult

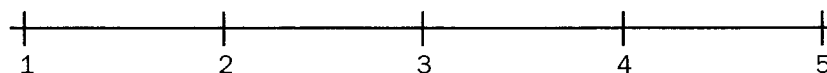
Not difficult



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

Very difficult

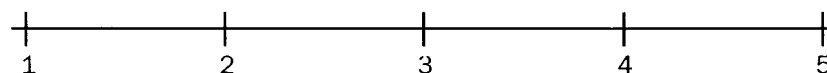
Not difficult



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

Very difficult

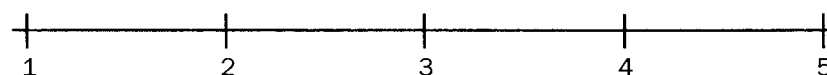
Not difficult



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

Many activities are limited

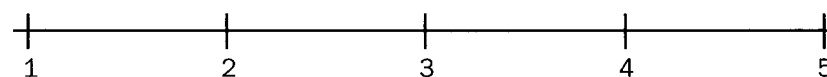
No activities are limited



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

Extreme discomfort

No discomfort



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 ☐

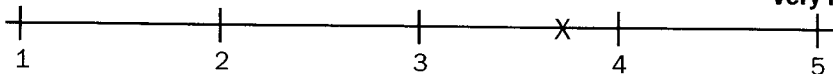
CRANIOFACIAL PROSTHESIS

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:

Not at all		Very much
1	2	5



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

Very uncomfortable

Very comfortable

1	2	5

2. How well does your prosthesis stay in place?

Not well

Very well

1	2	5

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

Very apprehensive

Not apprehensive

1	2	5

4. How noticeable is your prosthesis?

Very noticeable

Not noticeable

1	2	5

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

Very self-conscious

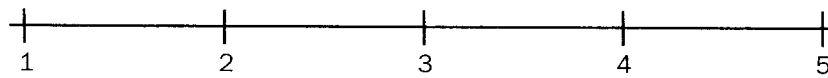
Never self-conscious

1	2	5

6. How difficult is it for you to put on your prosthesis?

Very difficult

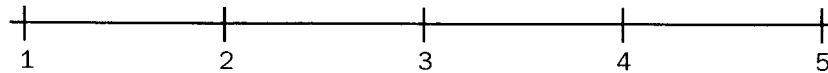
Not difficult



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

Very difficult

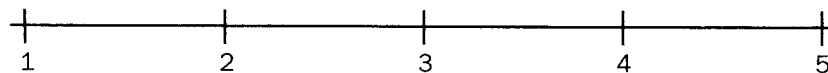
Not difficult



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

Very difficult

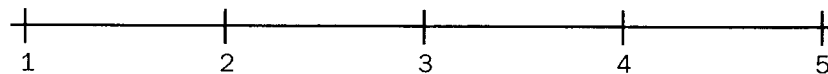
Not difficult



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

Many activities are limited

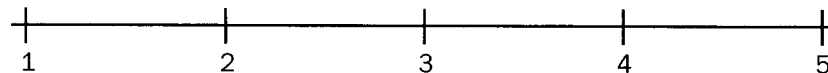
No activities are limited



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?

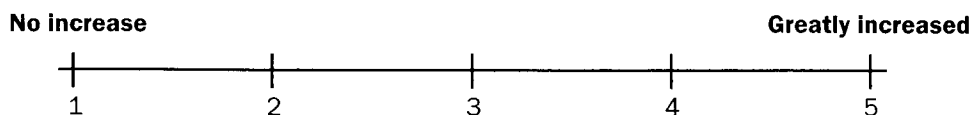
Never ☐ Once a day ☐ 2 to 3 times a day ☐
4 to 5 times a day ☐ More than 5 times a day ☐

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

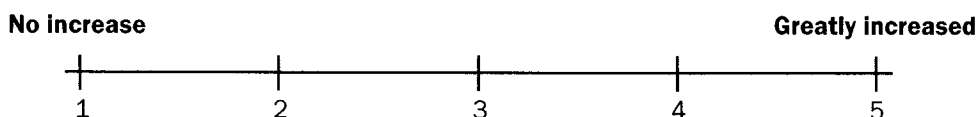
Just like everyone else ☐ As handicapped ☐

If this is your first prosthesis answer questions 13 and 14. If this is not your first prosthesis answer questions 15 and 16.

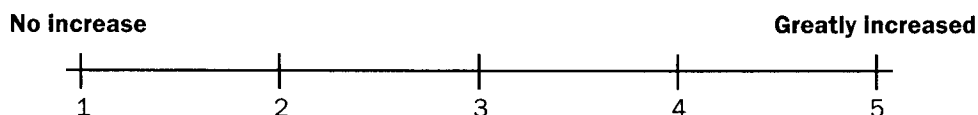
13. To what extent has your implant-supported prosthesis allowed you to increase your regular daily activities?



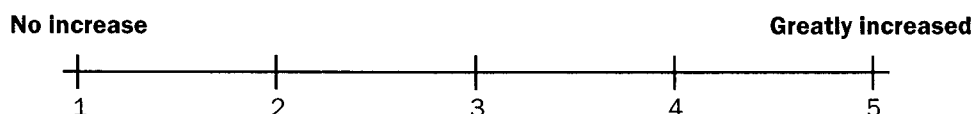
14. To what extent has your implant-supported prosthesis allowed you to increase your ability to function at school or work?



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?



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?



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:

Not at all		Very much
1	2	5
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="flex-grow: 1; border-bottom: 1px solid black; position: relative;"> <div style="position: absolute; top: -5px; left: 40%; font-size: 1.2em;">X</div> </div> </div>		
1	2	4
3		

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 <input type="checkbox"/>	No <input type="checkbox"/>
Missing all your lower teeth?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Wearing an upper denture?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Wearing a lower denture?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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	5
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="flex-grow: 1; border-bottom: 1px solid black; position: relative;"> <div style="position: absolute; top: -5px; left: 40%; font-size: 1.2em;">X</div> </div> </div>		
1	2	4
3		

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

Extreme discomfort		No discomfort
1	2	5
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="flex-grow: 1; border-bottom: 1px solid black; position: relative;"> <div style="position: absolute; top: -5px; left: 40%; font-size: 1.2em;">X</div> </div> </div>		
1	2	4
3		

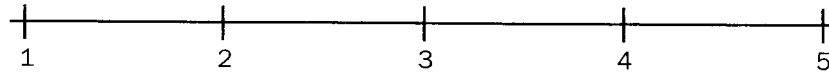
6. How would you describe the fit of your upper denture?

Very loose		No looseness
1	2	5
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="flex-grow: 1; border-bottom: 1px solid black; position: relative;"> <div style="position: absolute; top: -5px; left: 40%; font-size: 1.2em;">X</div> </div> </div>		
1	2	4
3		

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

Very loose

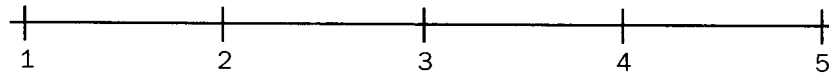
No looseness



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

Almost always difficult

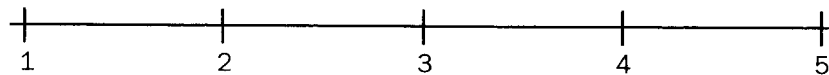
Almost never difficult



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

Almost always

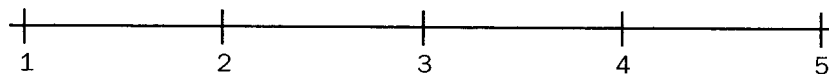
Almost never



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

Almost always

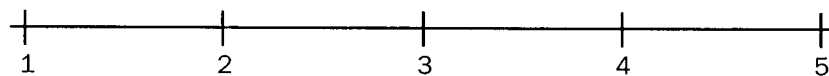
Almost never



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

Almost always

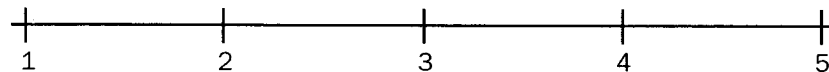
Almost never



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

Extremely difficult

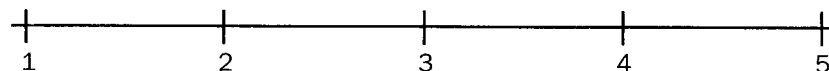
Not difficult



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

Extremely difficult

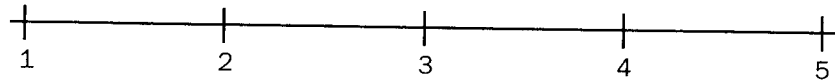
Not difficult



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

Extremely difficult

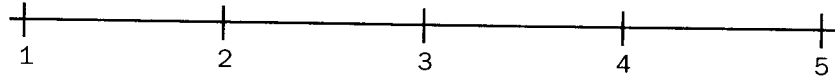
Not difficult



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

Extremely difficult

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:

Not at all		Very much
1	2 3 4 5	

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:

Extreme discomfort		No discomfort
	1 2 3 4 5	

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

Extreme discomfort		No discomfort
	1 2 3 4 5	

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

Very loose		No looseness
	1 2 3 4 5	

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

Very loose		No looseness
	1 2 3 4 5	

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

Always difficult		Never difficult
	1 2 3 4 5	

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

Almost always

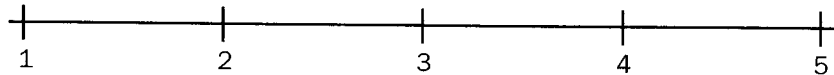
Almost never



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

Almost always

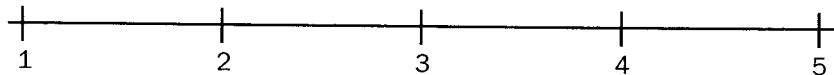
Almost never



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

Almost always

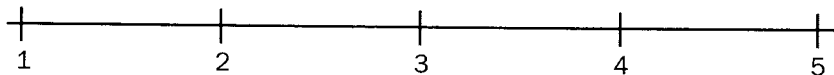
Almost never



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

Extremely difficult

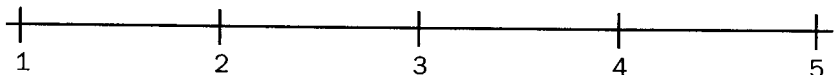
Not difficult



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

Extremely difficult

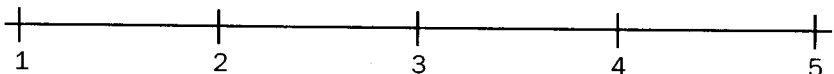
Not difficult



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

Extremely difficult

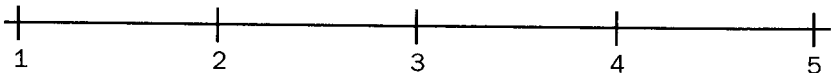
Not difficult



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

Extremely difficult

Not difficult



14. Do you have:

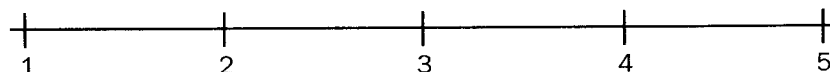
Popping or clicking of your jaw joint? Yes ☐ No ☐

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

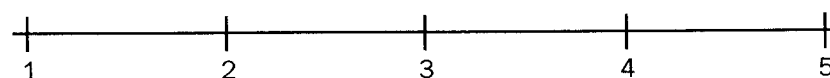
Very satisfied



16. How satisfied are you with the results of having implants placed in your jaw?

Not satisfied

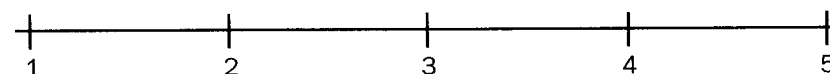
Very satisfied



17. Do you think your implant-supported denture is actually a part of your own jaw?

Not at all

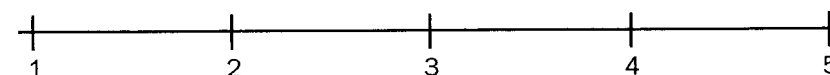
Very much



18. To what extent has your implant-supported denture improved your social and work relationships with other people?

Not at all

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.

