The Influence of Relining or Implant Retaining Existing Mandibular Dentures on Health-Related Quality of Life: A 2-Year Randomized Study of Dissatisfied Edentulous Patients

Harald Gjengedal, DDS[a]/Einar Berg, BDS, Dr Odont[b]/Arne G. Grønningsæter, DDS[c]/Lisbeth Dahl, Dr Scient[d]/Marian K. Malde, Dr Scient[d]/Olav E. Bøe, DDS, MSc[a]/Tordis A. Trovik, DDS, MPH, PhD[e]

Purpose: The purpose was to assess and compare self-reported oral health and oral and general health related quality of life (OHRQoL and HRQoL) in two groups of edentulous adults who reported dissatisfaction with their mandibular dentures, and who were treated with a conventional relining of this denture or by having it converted into an implant-retained one. ***Materials and Methods:*** Sixty subjects were randomly allocated into two equal groups, a relined conventional denture (RCD) group and an implant-retained overdenture (IOD) group. Data on demographics, oral health, OHRQoL, and HRQoL were recorded by means of a self-administered questionnaire at baseline, 3 months, and 2 years. ***Results:*** Fifty-four subjects completed the protocol, 28 in the IOD-group and 26 in the RCD-group. The IOD group reported significant improvement in oral health and Oral Health Impact Profile (OHIP-20) sum score and all its domains after 3 months. The improvements remained stable at the 2-year control. The RCD group reported almost no significant improvements. Neither group reported improved HRQoL. ***Conclusion:*** The results of this study support the findings from other RCT studies that to implant-retain the mandibular denture significantly improves self-reported oral health and OHRQoL. This treatment modality should be a minimum standard of care in complete denture wearers dissatisfied with their mandibular denture. *Int J Prosthodont 2013;26:68–78. doi: 10.11607/ijp.3094*

In recent decades, the concept of quality of life (QoL) has evolved based on the World Health Organization's (WHO) definition of health.[1] QoL is now considered to be a multidimensional holistic construct containing both positive and negative attributes that can be applied to practically all important domains of life.[2] General health–related quality of life (HRQoL) and oral health–related quality of life (OHRQoL) refer to an individual's subjective assessment of his or her general and oral health and functional and emotional well-being.[3] These subjective values pose a challenge for measurement; nevertheless, HRQoL and OHRQoL are widely used as patient-reported outcome measures of medical and dental treatment.

Previous reports indicate that when complete denture wearers have their mandibular dentures replaced with implant-retained overdentures, their OHRQoL as measured by the Oral Health Impact Profile (OHIP-20) subsequently improves.[4–7] As a result of these and similar studies, it has been suggested that an overdenture retained by two implants should be the treatment of choice for the completely edentulous mandible.[8,9]

However, in all clinical trials comparing implant-retained overdentures and conventional dentures, the participants received new maxillary and mandibular dentures. This may complicate the interpretation of the results because several studies have also reported improved OHRQoL after treatment with new conventional dentures.[10–12] However, the

[a]*Researcher, Department of Clinical Dentistry, Centre for Clinical Dental Research, University of Bergen, Bergen, Norway.*
[b]*Professor Emeritus, Department of Clinical Dentistry, Section of Prosthodontics, University of Bergen, Bergen, Norway.*
[c]*Associate Professor, Department of Clinical Dentistry, Section of Oral Surgery and Medicine, University of Bergen, Bergen, Norway.*
[d]*Researcher, National Institute of Nutrition and Seafood Research, Bergen, Norway.*
[e]*Associate Professor, Department of Clinical Dentistry, University of Tromsø, Tromsø, Norway.*

Correspondence to: *Dr Harald Gjengedal, Department of Clinical Dentistry, Centre for Clinical Dental Research University of Bergen, N-5009 Bergen, Norway. Email: harald.gjengedal@iko.uib.no*

positive effect of denture renewal is relatively short-lived.[13] As pointed out by Emami et al,[14] the impact of inserting implant-retained dentures per se on treatment outcomes may be blurred when compared with the impact of new conventional dentures. However, a significant difference most likely develops over time. Although the actual treatment effect of implant-retained mandibular dentures versus conventional complete dentures still needs clarifying,[14] a recent longitudinal follow-up study showed that the difference between the two treatment modalities is stable over time and actually increases from year 1 to year 2 of follow-up.[15]

Patient satisfaction with dentures is another important factor. Studies have shown that most denture wearers are satisfied with their dentures[16–18] but also that the level of satisfaction is highly variable, especially in regard to mandibular dentures.[19,20] Satisfaction is relative, depending on patients' adaptation and acceptance of treatment as well as on their degree of resignation, potentially after years of wearing troublesome dentures. It is also recognized that predicting satisfaction with complete dentures is difficult.[21] In addition, there is a lack of agreement between patients' and dentists' evaluations of denture quality.[22,23] To complicate matters further, a patient's level of satisfaction and treatment preferences may influence the treatment outcome.[24,25] Therefore, a particularly challenging situation can arise in which the clinician regards the denture as technically acceptable but the patient is unsatisfied. In such cases, the denture itself may not be the problem. A more likely explanation is a lack of stability and retention at the denture-bearing area. Under these circumstances, providing the patient with yet another new denture is unlikely to succeed.

An effort to measure the effect size of technically acceptable implant-retained mandibular dentures in patients expressing dissatisfaction with their existing denture may offer valid information regarding the genuine effect of this treatment in patients expressing a subjective treatment need. This topic has not been studied before, and the results may provide additional data to support the superior treatment effect of implant-retained mandibular dentures.

This study was designed to control or at least reduce the impact of the methodologic problems described above. The aim of this study was to assess and compare the self-reported HRQoL and OHRQoL in two groups of edentulous adults who reported dissatisfaction with their mandibular dentures and who were treated with either a conventional relining of their mandibular denture or conversion of their denture into an implant-supported one.

Materials and Methods

Study Design and Sample

The study was designed as a randomized clinical study over 2 years. Two treatment modalities for the mandible in completely edentulous patients were compared: relining of the existing conventional denture (RCD) or conversion of the existing denture into an implant-retained overdenture (IOD). The existing denture had to be of acceptable technical quality for inclusion, ie, acceptable vertical dimension of occlusion and no defects of the teeth, denture base, fit, occlusion, or articulation. Further, there had to be no visible plaque on the dentures and no signs of irreversible stomatitis or tissue hyperplasia. The gums had to show only slight displacement by palpation. These criteria were assessed by four calibrated specialists in prosthodontics at the University Dental Clinic at the University of Bergen, Bergen, Norway. Verification of the calibration was performed prior to the study: Each prosthodontist separately assessed the prosthetic variables in 10 patients from the Section of Prosthodontics. When assessments differed, complete agreement was reached after reassessment and discussion. Further selection criteria included the following: the patients had to report acceptable general health, be ≤ 76 years of age, be cooperative and communicate easily, smoke fewer than 20 cigarettes per day, and present no general or local contraindications to the insertion of two mandibular intraosseous implants. Importantly, all selected patients had to report dissatisfaction with their existing mandibular denture. This was necessary to address the conclusion of Awad et al,[24] who argued that the level of satisfaction was a predictor of treatment preferences. The participants' personal treatment preference was not known to the researchers.

The participants were recruited during two periods. The first recruitment involved patients who were previously treated with complete dentures in one or both arches at the Section of Prosthodontics. The second recruitment involved advertising for participants in seven newspapers in Bergen and nearby regions and seeking referrals from dentists in Bergen.

All 201 eligible subjects completed a screening questionnaire containing 16 questions regarding satisfaction with their dentures. The responses were registered on a four-item scale: very satisfied, satisfied, unsatisfied, or very unsatisfied. Only respondents who were unsatisfied or very unsatisfied with their mandibular denture were invited for further examinations.

Sixteen patients from the first recruitment and 44 from the second satisfied the selection criteria and constituted the final sample. To ensure even treatment distribution in each of the two treatment modalities, the patients from the first recruitment blindly drew a ticket with the treatment allocation from an original stack of 16, with 8 tickets for each of the two treatment modalities. The same procedure was followed for patients from the second recruitment; each patient drew a ticket from an original stack of 44, with 22 tickets for each treatment modality.

To avoid specific treatment expectations, the patients were first only generally informed about the aim of the study. Subsequently, they were informed in full about the treatment to which they were assigned. All treatment was offered at no cost, and the patients were guaranteed free treatment with the alternative treatment modality after the study period of 2 years if they so desired. The patients could withdraw from the study at any time without consequences. Informed consent was provided by all patients. The study was approved by the Norwegian Committee for Medical Research Ethics in Norway, Health Region West, and registered at the Norwegian Social Science Data Services. Further details regarding the study design and study sample are described in a previous report.[26]

Assessments

The participants filled out a self-administered questionnaire at baseline, 3 months, and 2 years after the completion of prosthetic treatment. The questionnaire contained items regarding demographics, QoL, overall perceived general and oral health, health status (The Medical Outcomes Study Short-Form 36-Item Health Survey [SF-36]), general well-being (WHO-Five Well-Being Index), coping strategies (Brief Approach/Avoidance Coping Questionnaire [BACQ]), denture experience, and the impact of oral health (OHIP-20).

Overall QoL was registered by patients' responses to a global question on a five-point Likert scale ranging from excellent (1) to bad (5). Overall perceived general and oral health was registered by responses to separate global questions on a five-point Likert scale ranging from very good (1) to very bad (5). For further analyses, oral health was dichotomized into the two most positive responses as score 1 and the three most negative as score 0.

The SF-36 is a generic multipurpose health survey designed to measure self-perceived health status.[27] The 36 items are divided into eight domains, which are in turn collected in either a physical or mental component. Calculations of the SF-36 scores were made using the Health Outcomes scoring software (version 4.0, QualityMetric) by transforming the scores of each domain and dimension into a 100-point scale, where 0 represents the most negative score and 100 the most positive.

The WHO-Five is a five-item modification of the Positive General Well-Being Scale that measures positive well-being.[28] Each item is registered on a six-point Likert scale ranging from all of the time (1) to at no time (6). A greater sum score represents greater problems.

The BACQ is a 12-item index designed to measure a general concept of approach- versus avoidance-oriented coping of illness or problems.[29] Responses are registered on a five-point Likert scale ranging from completely agree (1) to completely disagree (5). A lower sum score represents better coping ability.

Denture experience was recorded as years of complete edentulousness, how many times maxillary and mandibular dentures had been renewed, and how many years had passed since the patients received their current dentures.

The questions from the OHIP-20 are grouped in seven domains and assess specific oral health problems associated with wearing dentures. Responses are registered on a six-point Likert scale ranging from at no time (1) to all of the time (6). For each subject, the OHIP-20 sum score ranges from 20 to 120; a high figure indicates that oral health problems have a negative impact on OHRQoL. For estimation of clinical impact, the OHIP-20 domain scores were dichotomized so that the two most positive answers were registered as score 1 and the four most negative as score 0. The total OHIP-20 score was dichotomized as follows: code 0 = sum score > 40 and code 1 = sum score ≤ 40.

Statistical Analysis

The statistical analyses were carried out using the statistical package PASW (version 18, IBM). Standard descriptive statistics (mean and standard deviation) were used to describe the main outcome variables OHIP-20 and SF-36. Calculations were made at each time point (baseline, 3 months, and 2 years) for the two groups (RCD and IOD) separately. Further, each domain of the two variables was described similarly.

For variables on nominal or ordinal scales, a chi-square test or Fisher exact test was used to compare the distributions in the two groups. The Mann-Whitney *U* test was used to compare the two groups at each time point for ordinal scale variables. To evaluate the overall change in each group separately, the Friedman test was applied. If the overall change was

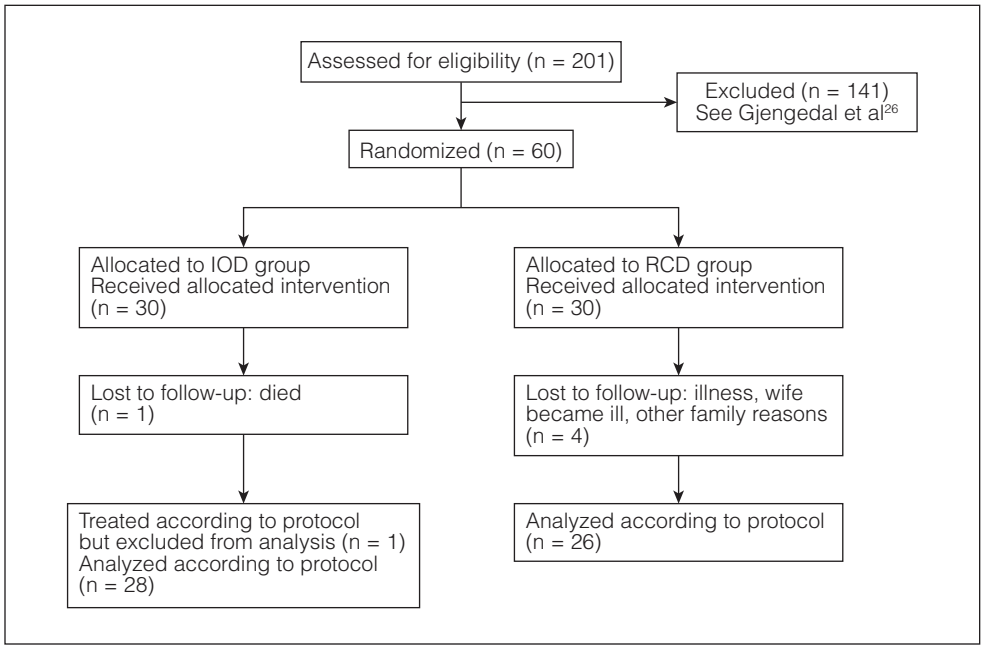

Fig 1 Flowchart showing the study sequence.

significant at the 5% level, the Wilcoxon signed rank test was applied to make multiple comparisons.

The two-sample *t* test was applied to assess any differences in ratio scale variables between the two groups. Repeated-measure analysis of variance with one within factor (time) and one between factor (group) was performed separately for each variable and its domain. If the calculated *P* values were less than .05, multiple comparisons were made using the Bonferroni adjustment.

The change within the different variables from baseline to 2 years was assessed by calculating the effect size (ES), which was defined as the mean of the change divided by the standard deviation of the baseline values. An ES < 0.2 is described as a small change, while an ES > 0.8 is described as a large change.[30]

Stepwise multiple linear regression analysis was carried out with the change of OHIP-20 score between the baseline and 2-year assessments as the outcome variable. Before including the baseline value of OHIP-20 as a possible predictor variable, the Oldham method was used to evaluate the presence of any correlation between the baseline value and the change.[31] If no such correlation was found, the baseline value was not included as a possible predictor variable in the stepwise procedure. In addition, stepwise multiple logistic regression analysis with the dichotomized change of self-perceived oral health as the outcome variable was performed. In both regression analyses, the included variables were considered of clinical interest and the predictive variables revealed a statistically significant association at the 5% level. Age and sex were included in the final analyses to adjust the other coefficients in the analyses with regard to these two variables.

A power calculation was made to detect a treatment effect of 20 points on the OHIP-20 scale. An estimated standard deviation of 25 points, sample size of 28, and significance level of .05 were used in the calculation.

Results

Between-Group Comparisons at Baseline

Six patients, all men, were excluded from analysis; three patients withdrew from the study, one patient lost one implant and was retreated, one patient died, and one patient was lost to follow-up (Fig 1). This left a study sample of 54 patients: 28 in the IOD group (18 women and 10 men; mean age: 68 years; range: 48 to 78 years) and 26 in the RCD group (17 women and 9 men; mean age: 67 years; range: 52 to 78 years). There were no significant differences between the groups regarding sex ($P = .93$), age ($P = .85$), or mean time of experience wearing complete dentures ($P = .40$). Likewise, there were no significant differences between the groups for any of the other variables (range: $P = .06$ to .89) (Tables 1 to 3).

Table 1 Analysis of Mean (Standard Deviation) OHIP-20 Scores

	RCD group			IOD group		
Domain	Baseline	3 mo	2 y	Baseline	3 mo	2 y
Functional limitation	12.3 (3.4)	11.2† (3.7)	11.2† (4.3)	12.6 (3.6)	7.0*† (2.7)	6.2*† (2.0)
Physical pain	13.1 (4.5)	12.6† (5.1)	13.2† (5.1)	14.4 (4.8)	7.6*† (2.6)	7.4*† (3.9)
Psychologic discomfort	6.1 (2.8)	5.1 (2.9)	6.1 (3.4)	7.4 (3.2)	3.8* (1.7)	4.1* (1.9)
Physical disability	11.1 (3.7)	10.5† (5.2)	11.3† (5.5)	12.8 (5.0)	6.5*† (2.7)	6.9*† (3.0)
Psychologic disability	5.7 (2.9)	5.3 (3.1)	5.8 (3.4)	6.4 (3.2)	3.5* (1.4)	3.7* (2.0)
Social disability	4.5 (1.8)	4.8 (2.9)	5.1 (3.5)	6.6 (4.1)	4.2* (1.5)	4.0* (1.4)
Handicap	4.6 (2.1)	4.3 (2.9)	4.3 (2.8)	5.7 (3.4)	3.0* (1.0)	3.1* (1.8)
Sum score	57.9 (16.8)	54.1† (21.9)	57.3† (24.7)	66.1 (22.7)	35.8*† (11.4)	35.6*† (12.3)

*Significant difference between baseline and 3 months and baseline and 2 years within treatment groups (repeated-measures analysis of variance, $P < .05$, Bonferroni adjusted).
†Significant difference between RCD and IOD groups (repeated-measures analysis of variance, $P < .05$, Bonferroni adjusted).
RCD = relining of existing conventional denture; IOD = implant-retained overdenture.

Table 2 Analysis of Mean (Standard Deviation) SF-36 Scores

	RCD group			IOD group		
Domain	Baseline	3 mo	2 y	Baseline	3 mo	2 y
Physical function	75.7 (20.6)	77.1 (22.4)	72.7 (21.9)	78.3 (22.0)	77.5 (22.3)	72.5 (26.2)
Role-physical	69.9 (29.1)	69.4 (25.1)	66.3 (29.5)	73.6 (27.1)	72.5 (28.3)	62.5* (27.4)
Bodily pain	58.6 (27.0)	60.5 (23.9)	58.1 (23.5)	74.2 (24.9)	66.9 (30.3)	67.2 (28.1)
General health	66.2 (21.5)	63.6 (20.9)	63.7 (22.5)	70.4 (19.6)	68.6 (19.6)	62.6** (21.2)
Vitality	53.6 (21.2)	52.1 (17.9)	46.6 (23.1)	60.9 (20.6)	63.6 (19.6)	56.7 (19.9)
Social function	83.1 (20.3)	82.2 (20.6)	76.4 (25.3)	77.6 (26.4)	84.8 (19.3)	79.9 (21.6)
Role-emotional	82.3 (21.6)	79.8 (26.2)	73.3 (29.4)	81.2 (24.4)	82.7 (21.2)	76.1 (27.5)
Mental health	81.7 (11.7)	80.0 (13.5)	76.5 (17.5)	82.3 (12.2)	83.5 (11.6)	83.3 (13.8)
Physical component	44.3 (10.8)	44.7 (9.7)	44.0 (8.5)	47.8 (8.5)	46.1 (10.5)	43.7** (10.3)
Mental component	52.0 (7.4)	50.5 (9.2)	48.0 (11.4)	51.1 (8.3)	53.3 (6.8)	51.5 (8.6)

*Significant difference between 3 months and 2 years.
**Significant difference between baseline and 2 years.
RCD = relining of existing conventional denture; IOD = implant-retained overdenture.

Table 3 Analysis of the Median Values for the Variables for Oral Health, QoL, BACQ, and WHO-Five

	RCD group			IOD group		
	Baseline	3 mo	2 y	Baseline	3 mo	2 y
Oral health	3.0	3.0	3.0	3.0	2.0*	2.0*
QoL	3.0	3.0	3.0	3.0	2.5	3.0
BACQ	37.5	38.5	37.5	38.0	38.0	39.0
WHO-Five	12.0	13.0	14.0	11.5	11.0	12.0

*Significant difference from baseline and between groups. Mann-Whitney: $P = .004$ at 3 months and $P < .001$ at 2 years. Friedman: $P = 0.166$ from baseline to 2 years (RCD group) and $P < .001$ from baseline to 2 years (IOD group). Wilcoxon signed rank test: $P < .001$ from baseline to 3 months, $P < .001$ from baseline to 2 years, and $P = .096$ from 3 months to 2 years (IOD group).
QoL = quality of life; BACQ = Brief Approach/Avoidance Coping Questionnaire; WHO-Five = World Health Organization-Five Well-Being Index; RCD = relining of existing conventional denture; IOD = implant-retained overdenture.

Between-Group Comparisons After 3 Months

Three months after prosthetic treatment, the IOD group reported significantly better self-perceived oral health than the RCD group (median: 2 vs 3, $P = .001$). The IOD group had a significantly lower OHIP-20 total score than the RCD group (35.8 vs 54.1, $P < .001$) and also showed significantly lower scores regarding

Table 4 Effect Size (ES) After 2 Years for the SF-36 and OHIP-20

		RCD group		IOD group	
Instrument	Domain	Difference of means	ES	Difference of means	ES
OHIP-20	Functional limitation	1.0	0.3	6.4	1.7
	Physical pain	0.0	0.0	7.0	1.4
	Psychologic discomfort	0.0	−0.1	3.2	1.0
	Physical disability	−0.1	0.0	5.9	1.1
	Psychologic disability	0.0	0.0	2.6	0.8
	Social disability	−0.6	−0.3	2.6	0.6
	Handicap	0.3	0.1	4.6	0.7
	Total	0.5	0.0	30.5	1.3
SF-36	Physical function	3.0	0.1	5.8	0.2
	Role-physical	3.6	0.1	11.1	0.4
	Bodily pain	0.4	0.0	7.0	0.2
	General health	2.5	0.1	7.7	0.3
	Vitality	6.9	0.3	4.2	0.2
	Social function	6.7	0.3	−2.2	0.0
	Role-emotion	9.0	0.4	5.0	0.2
	Mental health	5.1	0.4	−1.0	0.0
	Physical component	0.3	0.0	4.0	0.4
	Mental component	3.9	0.5	−0.4	0.0

RCD = relining of existing conventional denture; IOD = implant-retained overdenture.

the domains functional limitation, physical pain, and physical disability (Table 1). There were no significant differences between the groups regarding the global question of QoL, BACQ, or WHO-Five (range: $P = .04$ to .91; significance level = .016 according to the Bonferroni adjustment). There were no significant differences regarding SF-36 summary components or any of its domains (Table 2).

Between-Group Comparisons After 2 Years

Two years after treatment, the IOD group reported significantly better self-perceived oral health than the RCD group (median: 2 vs 3, $P = .007$). The IOD group reported a significantly lower OHIP-20 total score than the RCD group (35.6 vs 57.3, $P < .001$) as well as a significantly lower score for the same three OHIP-20 domains as after 3 months (functional limitation, physical pain, and physical disability) (Table 1). A comparison of the clinical impact of OHIP-20 using the Fisher exact test showed that the IOD group had a significantly higher proportion of the two most positive responses for the OHIP-20 total score and five of the domains (range: $P = .001$ to .027), indicating a difference in clinical impact between the IOD and RCD groups. Two domains (psychologic discomfort and social disability) did not have significantly different proportions of responses between the two groups ($P = .09$ and .08, respectively) after 2 years. There were no significant differences between the groups regarding SF-36 summary components or any of its domains (Table 2).

Within-Group Comparisons

In the RCD group, no significant changes occurred for any variable during the 2-year follow-up period. In the IOD group, there were no significant changes regarding the variables global QoL, BACQ, or WHO-Five (range: $P = .24$ to .98) (Table 3).

In the IOD group, significant improvement was found for the OHIP-20 sum score and all seven domains from baseline to 3 months, and these significant changes remained at the 2-year follow-up (range: $P < .001$ to $P = .002$) (Table1). The calculated power of the study for the change in OHIP-20 after 2 years was 0.988.

Analyses of the SF-36 showed that in the IOD group, the role-physical ($P = .017$) and general health ($P = .003$) domains and the physical component ($P = .002$) significantly decreased after 2 years (Table 2). For role-physical, the significant change occurred from 3 months to 2 years after treatment; for general health and the physical component, the changes occurred from baseline to 2 years. All significant changes involved decreased SF-36 values, indicating a worsened situation.

In the IOD group, self-perceived oral health significantly improved from baseline to 2 years ($P < .001$) (Table 3). The primary change occurred from baseline to 3 months after treatment ($P < .001$). There was no further change from 3 months to 2 years ($P = .132$).

ES calculations for OHIP-20 changes in the IOD group showed definite positive effects for the sum score and most of the domains (ES > 1.0) (Table 4).

Table 5 Multiple Linear Regression Analysis Predicting OHIP-20 Change After 2 Years of Follow-up

Model	R^2	F	B	95% CI	*P*
Summary	0.35	9.35			< .001
Treatment			30.45	18.72–42.19	< .001
Age			−0.56	−1.44–0.321	.208
Sex			0.09	−12.21–12.409	.987
Constant			37.27		

R^2 = explained variance; F = test statistic; B = regression coefficient; CI = confidence interval.

Table 6 Multiple Logistic Regression Analysis Predicting Oral Health After 2 Years of Follow-up

Model	B	SE	OR	95% CI	*P*
Treatment	1.85	0.91	6.36	1.05–38.56	.044
OHIP-20 change	0.07	0.02	1.07	1.01–1.13	.010
WHO-Five	−0.33	0.14	0.71	0.53–0.94	.019
Age	0.53	0.06	1.05	0.93–1.19	.403
Sex	0.14	0.86	1.15	0.21–6.33	.865
Constant	−0.71				

B = regression coefficient; SE = standard error; OR = odd ratio; CI = confidence interval.

Psychologic disability was at the borderline with an ES of 0.8, while social disability and handicap showed medium ES scores (0.6 and 0.7, respectively). Only the domain functional limitation showed a definite positive effect for the RCD group, with an ES of 1.0. The other domains showed no or mediocre ES values (range: −0.3 to 0.6) (Table 4). For the SF-36, all ES values were small (range: 0.0 to 0.4).

Multiple Regression Analysis

Multiple linear regression analyses for the change in OHIP-20 (baseline to 2 years) were performed with both groups combined (Table 5). The Oldham method showed no correlation between OHIP-20 change and mean OHIP-20 [(baseline + 2 years)^2]; therefore, baseline OHIP-20 was not entered into the analyses. In the stepwise multiple linear regression analyses, nine baseline variables either showing significant correlation with OHIP-20 or of clinical interest were included: treatment, number of years edentulous, QoL (global question), self-perceived oral health, general health, BACQ, WHO-Five, SF-36 physical health dimension, and SF-36 mental health dimension. In addition, age and sex were included in the analysis. However, only the variable treatment showed a significant *P* value and was thus included in the final multiple regression analysis (enter option). Age and sex were also included even though they were not significantly associated with the outcome variable. In the final model, only treatment was statistically significant, recording a B value of 30.45 ($P < .001$). As shown in Table 5, the total variance explained by the final model was 35% (F [3, 50] = 9.354, $P < .001$).

Multiple logistic regression analysis for oral health 2 years after prosthetic treatment was performed with both groups combined (Table 6). In the forward stepwise logistic regression analysis (step 1), the baseline variables treatment, number of years edentulous, QoL, general health, WHO-Five, BACQ, SF-36 summary components physical health and mental health, and OHIP-20 change from baseline to 2 years after treatment were included. The variables mental health component and WHO-Five were highly correlated, and since the variable mental health component had the smaller correlation with oral health of the two, it was not included in the final model. The final model included five variables: treatment, OHIP-20 change, WHO-Five, age, and sex. The model correctly classified 83.3% of the patients and explained 64.6% of the variance in reporting oral health (Nagelkerke R^2). The results indicate that the model was able to distinguish between patients reporting good or poor oral health. As shown in Table 6, the treatment variable had the highest odds ratio of 6.4. This means that patients treated with implant-retained overdentures were 6.4 times more likely to report good oral health compared to those who were treated with a conventional relining.

Discussion

The gold standard for analyzing data in a randomized clinical trial (RCT) is based on the intention-to-treat (ITT) principle. This principle offers a complete strategy for the design, conduct, and analysis of a trial, rather than for analysis alone.[32] Ideally, all patients who receive their allocated treatment will adhere to that treatment throughout the trial period. In this study, all patients received and adhered to their allocated treatment, but six patients were lost to follow-up. In order to perform an ITT analysis, the missing data would have to be estimated. Different methods are available for this purpose (eg, the commonly used Last Observation Carried Forward method) but none are unbiased.[33] The reasons for dropouts in this study were likely not associated with the prognosis of treatment effect. Further, since the dropouts in the IOD group were limited in number, the authors decided to carry out a per-protocol analysis, even knowing that the estimated treatment effects may be larger than with an ITT analysis.

The object of this RCT was to examine the true effect of treatment with implant-retained mandibular dentures on the outcome variables. Attempts were made to isolate the treatment factor from others that might confound the result. Previous RCTs have compared the treatment effect of new conventional dentures with new implant-retained mandibular dentures; in this study, a similar comparison was made based on the patients' existing mandibular denture. The IOD group reported significant improvement of the OHIP-20 total score and all of its domains, while the RCD group reported no significant changes in any of the OHIP-20 measures.

The findings indicate that implant retention of mandibular dentures significantly reduces oral health problems related to wearing complete dentures and that this effect is greater than reported in other studies.[4–7,15] As suggested earlier, it is possible that new dentures, which have well-documented positive effects on treatment outcomes,[10] obscure treatment effects related specifically to implant-retained overdentures. This hypothesis appears to be confirmed by the results and may partially explain the divergence between past and present results. It seems likely that the unchanged maxillary denture, arch relation, and esthetics canceled out the "newness" factor. Since the only substantial change involved implant retention of the existing mandibular denture, the patients did not need to adjust to new dentures.

Another factor that could partially explain the greater treatment effect found in this study is that all included patients, contrary to other RCT studies, were dissatisfied with their existing mandibular denture and thus had a subjective treatment need. In previous studies, mandibular implant-retained overdentures were constructed regardless of the patients' acceptance of the existing dentures.

The outcome measures in this study were assessed 3 months and 2 years after prosthetic treatment. It is interesting that all significant changes within and between the treatment groups were already present at 3 months. No further changes occurred during the rest of the trial period. In accordance with these findings, a recent report with a 2-year follow-up period showed that changes in OHRQoL 1 year after treatment were stable over a 2-year period.[15] The unchanged results seem to indicate that the impact of implant-retained mandibular dentures on oral health is so profound that reference shift (ie, the relative change of subjective evaluation) is very small over time. Two years after treatment, edentulous patients still remember the obstacles involved in wearing conventional complete dentures.

The magnitude of the treatment effect may be influenced by the baseline value because a high OHIP-20 baseline score indicates more oral problems and a greater potential for improvement. The baseline OHIP-20 values for the RCD group were the same as in previous studies (range: 54 to 59),[5,6,15] but the IOD group had somewhat higher scores. However, the ES for the OHIP-20 total score in the IOD group was larger than that found in other studies (1.3 vs 1.1 and 1.2).[6,7,15] This difference is so high that it cannot be explained merely by a larger baseline score. Similarly, the ES of the RCD group was much lower than in the conventional denture groups of those previous studies (0.0 vs 0.4 and 0.8). Since an ES greater than 0.8 indicates a substantial change, the effect of implant-retained mandibular dentures on OHRQoL may be more profound than previously reported.

The IOD group had significant positive changes in all OHIP-20 domains, with the strongest changes for the domains functional limitation, physical pain, and physical disability (Tables 1 and 3). The ES values for these domains in the IOD group were high, and these were also the only domains for which the IOD group was significantly different from the RCD group after 2 years. In previous studies, significant differences between the treatment groups were found in either all domains, four domains, or only one domain,[4–6] all of which were related to physical oral problems. This seems to confirm the idea that reduction of physical oral problems associated with implant-retained mandibular overdentures has clinical significance.

The clinical impact of the different OHIP-20 domains differed between the two groups after 2 years.

The IOD group reported significantly higher proportions of the two most positive responses in five of the domains. The results indicate that the reduction of physical oral problems is not only statistically significant, but also of clinical significance in regard to wearing complete dentures. Only the domains psychologic discomfort and social disability had equal proportions of responses in the two groups, suggesting that these domains are minimally affected by implant retention. A likely explanation regarding the differences between these results and those of other RCTs is that the present participants were experienced denture wearers who were dissatisfied with their dentures. After years of dissatisfaction, these patients may have resigned themselves to functional problems but without letting this resignation influence their social life and psychologic health, ie, a kind of psychologic robustness.

The multiple regression analyses showed that the only predictor variable for a change in OHIP-20 score was the treatment modality. Other studies have shown that pretreatment OHIP-20 values may also predict the posttreatment OHIP-20 values[4,6] because high pretreatment values indicate a greater potential for change. However, as explained by Tu et al,[31] the change may be biased because pretreatment OHIP-20 score is part of the change and should not be part of a regression analysis without being tested for mathematical coupling. Predicting a change in OHIP-20 is probably more clinically relevant than estimating a posttreatment value.

The pattern regarding self-perceived oral health was basically similar to that of OHIP-20. Three months after prosthetic treatment, the IOD group reported significantly better results than the RCD group, and this difference was even more evident after 2 years, indicating that the impact of reduced oral problems on function and well-being is consistent over time. Treatment was a strong predictive variable. The fact that change in OHIP-20 score was also predictive for changes in reported oral health underlines the importance of oral problems as part an individual's perception of oral health.

The finding that the WHO-Five index was predictive for reporting good oral health should be interpreted with caution; the odds ratio was low, and even though it is possible that positive well-being actually influences a patient's evaluation of oral problems in the context of oral health, it could also just be a statistical effect. Care should be taken not to overestimate the impact of this index based on small sample sizes, such as that of the present study.

In contrast to the significant improvement achieved for OHIP-20 measures, analyses of HRQoL (as measured by the SF-36) showed minor and mostly insignificant changes (Table 2). This is in accordance with another RCT reporting SF-36 measures, although the baseline scores for the physical component in the present study were lower than in the previous study (44.3 and 47.8 vs 51.0 and 52.9 for the RCD and IOD groups, respectively),[6] indicating a worse state of physical health. The ES values for the SF-36 were small and indicated a worsened situation for most measures. The presence of significant negative changes for three domains in the IOD group and none in the RCD group cannot be reasonably explained by the intervention procedures. This apparently low sensitivity to oral health conditions may be explained by the construct of the scale; it may not be obvious that oral treatment should have an impact on, for example, the ability to get dressed or climb stairs. In fact, Allen et al[34] stated that the SF-36 has limited construct validity for measuring oral health conditions.

The SF-36 is widely used as a measure of HRQoL.[6,35,36] In line with the present results, recent researchers have questioned the validity of the SF-36 in light of the multidimensional concept of QoL. These researchers argue that the SF-36 is simply measuring health status,[37] which may not provide an indication of an individual's evaluation of his or her QoL as included in the wider concept of the state of health.

The questionable connection and low sensitivity between generic health measures and oral conditions are illustrated by the analyses of the SF-36, BACQ, and WHO-Five indices. These measures showed no or minor changes after 2 years in both treatment groups. In fact, the data indicate that there was no correlation between general health as measured by the SF-36 and patients' reports of oral problems or perceived oral health. A single global rating of QoL is a useful supplement since it includes all individual components, evaluations, and values of a person's perception of life.[38,39] Individual weighting—unknown to us—makes it challenging to analyze global ratings, and despite the significant reduction in oral problems in the IOD group, there was no impact on reported overall QoL. Thus, the possible lack of association between oral problems and QoL is supported in the data.

Recent publications have questioned the validity of OHRQoL measurements based on the conceptual model of oral health[40–42] because they do not necessarily measure what they are intended to measure. Further, the dimensions of OHRQoL are perhaps more integrated than previously assumed, and it is difficult to interpret self-reported data. Finally, the causal process linking oral conditions to a patient-reported outcome is not established. The variability of these outcomes can be exemplified by tooth loss. For some

patients, tooth loss means loss of chewing ability; for others, it means relief of pain, with an inverse impact on OHRQoL. The OHIP-20 focuses on oral problems and not the subjective evaluation of those problems in terms of QoL. The main challenge in measuring QoL is its unique meaning for each subject.[43] Individual evaluations of the impact of symptoms and coping strategies, which are prerequisites for QoL, are therefore not measured by the OHIP-20.[44] For the same reason, it has not been clearly demonstrated that oral problems affect QoL.[41,45] However, for the purpose of comparing past and present results, the OHIP-20 remains useful because it is a validated measure of OHRQoL.

In clinical studies such as this, blinding is a problem. Even though patients were only informed about their allocated treatment modality, they may have become acquainted with and compared their own treatments against those of other patients over the course of repeated visits to the clinic for more than 2 years. This possibility raises the aspect of relative treatment effect. This effect is difficult to evaluate but must be taken into account when interpreting the results.

Conclusions

Within the limitations of this study's research design, the results suggest that provision of implant-retained mandibular dentures to dissatisfied denture wearers significantly reduces daily oral health problems and improves OHRQoL as measured by the OHIP-20. Further, the magnitude of this effect is larger than previously reported. Whether implant treatment has an impact on HRQoL or overall QoL could not be established by the generic measurements used in this study.

Acknowledgments

The authors express their gratitude to the study participants who made this paper possible. They also wish to thank Randi Sundfjord and Siren Hammer Østvoll at the Centre for Clinical Research for their help with the data collection and recording, as well as the staff at the Specialist Clinic, Institute of Clinical Dentistry, University of Bergen, Bergen, Norway, for all their goodwill and for use of the clinical premises. The authors thank Prof Kristina Arvidson Fyrberg for initiating this study and for her scientific advice and inspiration. Financial support from the University of Bergen and Astra Tech is gratefully acknowledged.

References

1. Definition of health. In: Basic Documents of the World Health Organization. Geneva, Switzerland: World Health Organization, 1948.
2. MacEntee MI. Quality of life as an indicator of oral health in older people. J Am Dent Assoc 2007;138(suppl):47S–52S.
3. Sischo L, Broder HL. Oral health-related quality of life: What, why, how, and future implications. J Dent Res 2011;90:1264–1270.
4. Awad MA, Locker D, Korner-Bitensky N, Feine JS. Measuring the effect of intra-oral implant rehabilitation on health-related quality of life in a randomized controlled clinical trial. J Dent Res 2000;79:1659–1663.
5. Awad MA, Lund JP, Shapiro SH, et al. Oral health status and treatment satisfaction with mandibular implant overdentures and conventional dentures: A randomized clinical trial in a senior population. Int J Prosthodont 2003;16:390–396.
6. Heydecke G, Locker D, Awad MA, Lund JP, Feine JS. Oral and general health-related quality of life with conventional and implant dentures. Community Dent Oral Epidemiol 2003;31: 161–168.
7. Allen PF, Thomason JM, Jepson NJ, Nohl F, Smith DG, Ellis J. A randomized controlled trial of implant-retained mandibular overdentures. J Dent Res 2006;85:547–551.
8. Feine JS, Carlsson GE, Awad MA, et al. The McGill Consensus Statement on Overdentures. Montreal, Quebec, Canada. May 24-25, 2002. Int J Prosthodont 2002;15:413–414.
9. Thomason JM, Feine J, Exley C, et al. Mandibular two implant-supported overdentures as the first choice standard of care for edentulous patients—The York Consensus Statement. Br Dent J 2009;207:185–186.
10. Ellis JS, Pelekis ND, Thomason JM. Conventional rehabilitation of edentulous patients: The impact on oral health-related quality of life and patient satisfaction. J Prosthodont 2007;16:37–42.
11. John MT, Slade GD, Szentpetery A, Setz JM. Oral health-related quality of life in patients treated with fixed, removable, and complete dentures 1 month and 6 to 12 months after treatment. Int J Prosthodont 2004;17:503–511.
12. Shigli K, Hebbal M. Assessment of changes in oral health-related quality of life among patients with complete denture before and 1 month post-insertion using Geriatric Oral Health Assessment Index. Gerodontology 2010;27:167–173.
13. Berg E. A 2-year follow-up study of patient satisfaction with new complete dentures. J Dent 1988;16:160–165.
14. Emami E, Heydecke G, Rompre PH, de Grandmont P, Feine JS. Impact of implant support for mandibular dentures on satisfaction, oral and general health-related quality of life: A meta-analysis of randomized-controlled trials. Clin Oral Implants Res 2009;20:533–544.
15. Jabbour Z, Emami E, de Grandmont P, Rompre PH, Feine JS. Is oral health-related quality of life stable following rehabilitation with mandibular two-implant overdentures? Clin Oral Implants Res 2012;23:1205–1209.
16. Gjengedal H, Berg E, Boe OE, Trovik TA. Self-reported oral health and denture satisfaction in partially and completely edentulous patients. Int J Prosthodont 2011;24:9–15.
17. Berg E. Acceptance of full dentures. Int Dent J 1993;43:299–306.
18. Carlsson GE. Clinical morbidity and sequelae of treatment with complete dentures. J Prosthet Dent 1998;79:17–23.
19. Redford M, Drury TF, Kingman A, Brown LJ. Denture use and the technical quality of dental prostheses among persons 18-74 years of age: United States, 1988-1991. J Dent Res 1996;75: 714–725.

20. Boerrigter EM, Stegenga B, Raghoebar GM, Boering G. Patient satisfaction and chewing ability with implant-retained mandibular overdentures: A comparison with new complete dentures with or without preprosthetic surgery. J Oral Maxillofac Surg 1995; 53:1167–1173.
21. Critchlow SB, Ellis JS. Prognostic indicators for conventional complete denture therapy: A review of the literature. J Dent 2009; 38:2–9.
22. Magnusson T. Clinical judgement and patients' evaluation of complete dentures five years after treatment. A follow-up study. Swed Dent J 1986;10:29–35.
23. Pietrokovski J, Harfin J, Mostavoy R, Levy F. Oral findings in elderly nursing home residents in selected countries: Quality of and satisfaction with complete dentures. J Prosthet Dent 1995;73: 132–135.
24. Awad MA, Shapiro SH, Lund JP, Feine JS. Determinants of patients' treatment preferences in a clinical trial. Community Dent Oral Epidemiol 2000;28:119–125.
25. Fitzpatrick B. Standard of care for the edentulous mandible: A systematic review. J Prosthet Dent 2006;95:71–78.
26. Gjengedal H, Dahl L, Lavik Å, et al. Randomized clinical trial comparing dietary intake in patients with implant-retained overdentures and conventionally relined denture. Int J Prosthodont 2012;25:340–347.
27. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473–483.
28. Bech P. Health-related quality of life measurements in the assessment of pain clinic results. Acta Anaesthesiol Scand 1999;43:893–896.
29. Finset A, Steine S, Haugli L, Steen E, Laerum E. The Brief Approach/Avoidance Coping Questionnaire: Development and validation. Psychology Health Med 2002;7:75–85.
30. Kazis LE, Anderson JJ, Meenan RF. Effect sizes for interpreting changes in health status. Med Care 1989;27:178S–189S.
31. Tu YK, Baelum V, Gilthorpe MS. The problem of analysing the relationship between change and initial value in oral health research. Eur J Oral Sci 2005;113:271–278.
32. Lewis JA, Machin D. Intention to treat—Who should use ITT? Br J Cancer 1993;68:647–650.
33. Whittaker K, Sutton C, Burton C. Pragmatic randomised controlled trials in parenting research: The issue of intention to treat. J Epidemiol Community Health 2006;60:858–864.
34. Allen PF, McMillan AS, Walshaw D, Locker D. A comparison of the validity of generic- and disease-specific measures in the assessment of oral health-related quality of life. Community Dent Oral Epidemiol 1999;27:344–352.
35. Nemeth G. Health related quality of life outcome instruments. Eur Spine J 2006;15(suppl 1):44S–51S.
36. Inoue M, John MT, Tsukasaki H, Furuyama C, Baba K. Denture quality has a minimal effect on health-related quality of life in patients with removable dentures. J Oral Rehabil 2011;38:818–836.
37. Mooney A. Quality of life: Questionnaires and questions. J Health Commun 2006;11:327–341.
38. Locker D, Quinonez C. To what extent do oral disorders compromise the quality of life? Community Dent Oral Epidemiol 2011;39:3–11.
39. Prutkin JM, Feinstein AR. Quality-of-life measurements: Origin and pathogenesis. Yale J Biol Med 2002;75:79–93.
40. Baker SR. Testing a conceptual model of oral health: A structural equation modeling approach. J Dent Res 2007;86:708–712.
41. Locker D, Allen F. What do measures of 'oral health-related quality of life' measure? Community Dent Oral Epidemiol 2007;35: 401–411.
42. Baker SR, Gibson B, Locker D. Is the oral health impact profile measuring up? Investigating the scale's construct validity using structural equation modelling. Community Dent Oral Epidemiol 2008;36:532–541.
43. Carr AJ, Higginson IJ. Are quality of life measures patient centred? BMJ 2001;322:1357–1360.
44. Heydecke G, Tedesco LA, Kowalski C, Inglehart MR. Complete dentures and oral health-related quality of life—Do coping styles matter? Community Dent Oral Epidemiol 2004;32:297–306.
45. Hunt SM. The problem of quality of life. Qual Life Res 1997;6: 205–212.

Literature Abstract

The effects of poverty on children's development and oral health

This manuscript analyzes the impact of poverty on development and oral health in children. Based on the US Census Bureau, in 2010, there was an increase to 22% for the poverty rate of children below the age of 18 years. Harmful effects of poverty include impaired learning, psychosocial development, physical health, productivity, and family life. Countries should strive to combat poverty as it would help to prevent adverse health outcomes which would safeguard the most important national asset, its citizens. In addition, steps would also need to be taken to ensure worldwide accessibility to nutritious food. Children without secure access to nutrition have a higher risk of developing dental and overall health problems. Such problems can lead to the child having difficult and uncooperative behavior in the dental clinic. The author concluded that increasing awareness of the poverty culture would lessen the stereotypical attitude that pediatric dentists may feel when working with low-income patients, ultimately improving the quality of interaction.

da Fonseca MA. *Pediatr Dent* 2012;34:32–38. **Reprints:** Dr Marcioda Fonseca, Department of Pediatric Dentistry, University of Washington, Seattle, WA, USA. **Email:** marcio@uw.edu—*Sapphire Gan, Singapore*