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Influence of minimally invasive implant-retained overdenture on patients' quality of life: a randomized clinical trial

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Abstract

Objectives: The aim of this prospective, randomized clinical trial was to evaluate the effect of a minimally invasive implant procedure for denture stabilization on patients' quality of life (QoL).

Materials and methods: Thirty totally edentulous patients were selected for this study. All prostheses were adjusted and relined before randomization and allocation to treatment either with two small diameter implants (SDI) – retained overdenture (study group) or non-intervention group (control group). Quality of life was assessed using the Oral Health Impact Profile-EDENT (OHIP-EDENT) questionnaire before intervention and at one-year follow-up. Between-group comparisons were carried out using the non-parametric Mann-Whitney test.

Results: Magnitude of change in the OHIP-EDENT total score at one-year follow-up was 25.4 ± 10.7 for the study group, revealing a statistically significant difference with the control group, that showed a change of 9.5 ± 8.3 ($P = < 0.001$).

Conclusions: After one-year follow-up, patients wearing mandibular overdentures with two minimally invasive splinted SDI, experienced more improvements in perceived oral health-related quality of life, than patients having conventional treatment.

People wearing complete dentures experience many difficulties on a daily basis, decreasing self-confidence and social contact (Bakke et al. 2002; Polzer et al. 2010).

Individual perceptions of oral health can be established in terms of oral health-related quality of life (OHRQoL). This parameter can also be used to show the advantages of treatment strategies (Strassburger et al. 2006), like the use of osseointegrated implants, which improve stability, retention, bite force, chewing efficiency, and oral health. (Bakke et al. 2002; Awad et al. 2003a,b; Emami et al. 2009).

A meta-analysis by Emami et al. (2009) concluded that although mandibular implant-retained overdentures may be more satisfying for edentulous patients than new conventional dentures, the magnitude of these effects remains uncertain, due to the studies heterogeneity.

It is difficult to compare related studies, because of the use of different QoL questionnaires (Awad et al. 2000, 2003a,b; Allen et al. 2001, 2006; Heydecke et al. 2003; Assuncao et al. 2007).

Several instruments exist to measure how oral health affects QoL, including the Oral Health Impact Profile (OHIP) (Slade & Spencer 1994). Shortened versions of this profile have been translated and validated in several countries. Among those smaller versions, OHIP-EDENT consists of 19 questions on masticatory capacity and other matters, making this specific inventory the most appropriate to be used with edentulous patients (Allen & Locker 2002).

Minimally invasive implant treatments have been suggested to reduce trauma for elderly patients when the use of standard-sized implants (>3 mm in diameter) would require bone reshaping or grafting (Flanagan 2006; Christensen 2008). The advantages of SDI include implant placement in narrow sites, minimally invasive surgery, and immediate loading (Cho et al. 2007; LaBarre et al. 2008).

No long-term studies have been carried out using OHIP-EDENT questionnaire to determine the impact of implants retaining overdentures on patients' QoL, not even for the use of minimally invasive procedures.

The hypothesis tested in this study was that SDI retaining overdentures improve QoL in edentulous patients compared with conventional dentures.

Material and methods

This clinical trial was developed following the guidelines of the Declaration of Helsinki. It was approved by the Ethics Committee of the University of Concepcion and the National Commission on Scientific and Technological Research in Chile. Written informed consent was obtained from all participants after the intervention had been fully explained.

Participants were recruited from December 2004 to April 2005 in a university hospital setting. Men and women between 45–90 years of age experiencing instability of conventional mandibular dentures, without temporomandibular disorders, were included.

Patients with uncontrolled systemic disease (e.g. hypertension, diabetes), with severe osteoporosis (BMD > 2.5 SD below the young adult reference mean, plus 1 or more fragility fractures) and/or taking bisphosphonates, patients with mental disorders, or medical history of psychological disorders or those receiving radiotherapy in the 18 months before the trial were excluded.

All dentures were made with anatomical teeth (Marche Ltda., Santiago, Chile). Prior to patients allocation, a specialist in prosthodontics controlled the vertical dimension, relined the prostheses, improved the prostheses fit using a low-exothermic acrylic resin (Tokuyama, J. Morita Corp., Tokyo, Japan), and created a balanced bilateral occlusal scheme with stable dental contacts.

Participants were randomly assigned to treatment groups following a simple randomization procedure (computer-generated list of random numbers). Allocation by telephone was carried out with an independent collaborator.

The study group (bar group, $n = 15$), received a splinted SDI-retained overdenture, while in the control group (CD group, $n = 15$), no intervention was applied. Neither the surgeon nor the prosthodontist participated in assigning patients to groups.

Patients from bar group received prophylactic antibiotics (2 g amoxicillin 1 h before and 500 mg 6 h after surgery) and a non-steroidal anti-inflammatory 1 h before and 24 h after surgery. An infiltrative technique was used for nerve blocking in the area, and an initial spiral drill of 1.1 mm was used to prepare the implant site with a transmucosal perforation.

Over the course of 3 days, 30 square-headed SDI-implants with sand-blasted treated surfaces (1.8 × 15 mm, Sendax® MDI; IMTEC Corp., Ardmore, OK, USA) were placed in the anterior mandibles of 15 completely edentulous patients selected from a public health center in Concepcion, Chile. In all cases, an electronic drilling device (Osseo-Care DEC600 motor, Nobel Biocare, Gothenburg, Sweden) was used. The standard protocol for this group required the use of a surgical guide to control the precise insertion of the implant into the jawbone when working blind with a flapless procedure.

Just after insertion, a pre-fabricated round bar was cemented over the two implants and immediately loaded with mandibular overdentures.

The demographic variables (gender, age, comorbidities) of each group were recorded.

Assessment

Each patient's quality of life was assessed using the OHIP – EDENT scale with 19 items (Allen & Locker 2002). This version addresses the same seven domains as the original OHIP-49: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap, with a five-point Likert response ranging from "never" (coded 0) to "very often" (coded 4). Lower scores indicate a better quality of life. The questions used for this study were obtained from the validated OHIP-49 Spanish (Lopez & Baelum 2006), which was adapted to our sample by consulting experts and edentulous patients prior to its application.

Reliability was assessed using Cronbach's alpha coefficient as a test of internal consistency.

The questionnaire was applied twice, face-to-face by raters blind to treatment groups, once before intervention (baseline, i.e. before relining) and again 1 year later (endpoint). The patients were asked how frequently they had experienced each item in the preceding 6 months.

The primary outcome was the comparison between groups of magnitude of changes in the OHIP-EDENT total score at the one-year follow-up. The secondary outcomes consisted of comparisons between groups of average endpoint in the OHIP-EDENT total scores. Also, a description of the averages OHIP-EDENT for each of the seven subscores from baseline to endpoint was performed.

Incidence of infection and implant failure were recorded. Presence of signs and symptoms of peri-implantitis and peri-implant mucositis (Mombelli & Lang 1994; Zitzmann & Berglundh 2008) were assessed at 24 h, 7 days, every 3 months, and at 1 year. The SDI failure was defined as loss and removal of the SDI, due to a lack of osseointegration observed in X-ray and/or presence of implant mobility, evaluated at the 3rd, 6th month, and at 1 year.

Statistical analysis

The unweighted OHIP-EDENT total score was calculated by adding the scores of the 19 items. The unweighted OHIP subscale scores were calculated by adding the scores of the items corresponding to each domain.

Data were analyzed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA).

The characteristics of the patients were compared using Chi-square or Fisher's exact test (categorical variables) and Mann-Whitney test (continuous variables). Differences were considered to be statistically significant if $P \leq 0.05$.

Between-group comparisons of magnitude of change in the OHIP-EDENT total score (difference between score at baseline and endpoint) were carried out using the non-parametric Mann-Whitney test for two independent samples. The same test was used to compare the average endpoint in the OHIP-EDENT total scores between groups. A statistically significant difference was considered if $P \leq 0.05$.

A description of magnitude of change in OHIP-EDENT subscores from baseline to endpoint was shown through mean, median, and standard deviation of the changes between baseline and endpoint.

For the study analysis, the intent-to-treat principle was applied.

Results

Flow of participants through the phases of this prospective, randomized clinical trial of two groups is shown in Fig. 1.

The baseline characteristics were similar for the two groups ($P > 0.05$), as shown in Table 1 All patients completed the assessment.

Magnitude of change in the OHIP-EDENT total score from baseline to endpoint showed statistically significant differences between groups. Bar group presented a decrease in score of 25.4 ± 10.7 (median: 26) points while CD group decreased 9.5 ± 8.3 (median: 11) points ($P = < 0.001$) (Fig. 2).
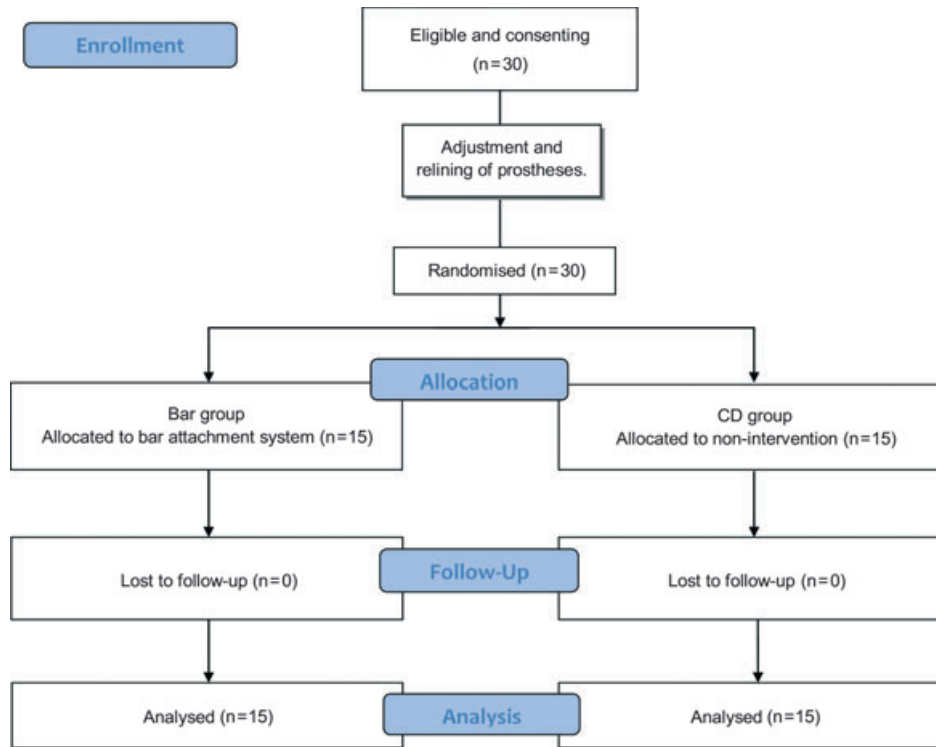
Fig. 1. Flow of participants during study.

Table 1. Demographic variables by treatment groups

	Bar group	CD group	Test for differences between groups
Gender (F/M)	10/5	7/8	0.270[*]
Age (years)	75.3 ± 12.1	75.5 ± 8.8	0.983[*]
Family income			
≤ Chilean minimum wage	12	13	>0.999[*]
> Chilean minimum wage	3	2	
Morbid condition			
Diabetes	3/15	3/15	0.999[*]
Osteoporosis	0/15	0/15	>0.999[*]
Smoking	0/15	0/15	>0.999[*]
BaselineOHIP-EDENT score	36.6 ± 8.2(median:37)	37.1 ± 10.0 (median:37)	0.755[*]

[*]: not significant.
Categorical variables were compared using Chi-Square test and continuous variables using the Mann-Whitney test. Differences were considered to be statistically significant if $P \leq 0.05$.
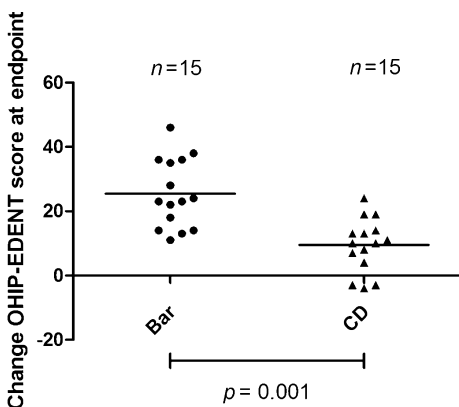

Fig. 2. Scatterplot comparing changes in the quality of life of patients in each group at the one-year follow-up.

SDI was lost (survival rate: 100%) nor peri-implantitis/mucositis was observed.

Discussion

Assessing QoL is an increasingly vital aspect of evaluating health care outcomes, including those of public health programs (Allen & McMillan 1999; Awad et al. 2000, 2003b).

To provide evidence of the effect of SDI-overdentures on patients' QoL, a randomized clinical trial was performed, assessing QoL through the OHIP-EDENT questionnaire.

Only a few studies have used OHIP-EDENT questionnaire, which is the most indicated version for edentulous patients wearing dentures. Zani et al. (2009) applied the OHIP-EDENT to evaluate the impact of overdentures and fixed prostheses on QoL, finding that both types of prostheses were perceived as being equally satisfactory by edentulous patients. Adam et al. (2007) showed that OHRQoL improved significantly in four (psychological discomfort and disability, social disability and handicap) of the seven domains after patients were provided with a new set of complete dentures. Recently, Pisani et al. (2011) applied the OHIP-EDENT and found improvement in the OHRQoL of edentulous patients after denture relining with a silicone-based soft liner. However, this result

The OHIP-EDENT total score at endpoint in bar group was lower (11.1) ± 7.1 (median: 11) than in CD group (27.7 ± 11.4 [median: 26]). This difference was statistically significant ($P = < 0.001$).

A description of magnitude of change for each of the seven domains of the treatment groups is shown in Table 2).

The reliability coefficient (Cronbach's alpha) of the OHIP-EDENT questionnaire was 0.70 before intervention and 0.85 after intervention.

Regarding the incidence of adverse effects, one patient reported slight soft tissue swelling 7 days after surgery that was immediately treated by readjusting the prosthesis. Neither

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Table 2. Magnitude of change in the OHIP-EDENT subscores of each treatment group

OHIP-EDENT domains	Bar group (n = 15)			CD group (n = 15)		
	Mean	Median	SD	Mean	Median	SD
Functional limitation	2.5	3	1.6	0.6	1	1.6
Physical pain	6.6	6	3.8	2.8	2	2.8
Psychological discomfort	2.7	3	2.7	1.3	2	3.1
Physical disability	1.9	2	2.3	1.1	0	2.2
Psychological disability	2.8	4	1.6	1.4	2	2.3
Social disability	4.6	4	2.5	1.6	1	2.4
Handicap	4.4	5	1.5	0.7	1	2.5

Positive value mean a decrease in score.

must be interpreted with caution, as it was a 3 months study and reliner effect decreases overtime.

In our study, OHIP-EDENT baseline was measured before relining the entire sample to avoid any influence of this procedure on the results.

Awad et al. (2003b) found in a two-months study, that patients wearing mandibular implant overdentures had improved their OHRQoL compared with patients wearing conventional dentures. Nevertheless, it is difficult to determine outcomes in short-term studies, as the implant group is likely to experience a reduced quality of life in the immediate postoperative period and may feel euphoric about their health after recovering from the surgery (McGrath 2000).

Previous studies have shown that bar attachment has better biomechanical and clinical behavior than ball attachment for overdentures (Assuncao et al. 2008; Tabata et al. 2010; Machado et al. 2011). No studies comparing attachment systems regarding QoL using OHIP-EDENT have been published.

In this study, an insertion guide was developed to control the precise insertion of the implant into the jawbone when working blind with a flapless procedure. This guide allows the use of a pre-fabricated bar, splinting the system, improving biomechanics and maintaining the advantages of SDI (cost and minimal trauma) (Jofre et al. 2010a, b,c)

Our finding indicates that after 1 year, patients wearing mandibular overdentures retained by two minimally invasive splinted SDIs significantly improve their quality of life compared with conventional dentures.

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