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ORIGINAL ARTICLE

Changes in oral health-related quality of life after three different strategies of implant therapy: a clinical trial

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Abstract

This research aims to evaluate changes in Oral Health-related Quality of Life (OHQoL) by means of the Oral Impacts on Daily Performances (OIDP) of patients treated with three distinct implant strategies. This clinical trial consisted of an oral examination and a questionnaire-based interview carried out before and after the definitive prosthetic rehabilitation in a consecutive sample of patients requiring dental implants. According to the clinical diagnosis and patient preference, patients were assigned to the one of the following groups: the conventional group (CGCL; $n=40$), where implants were inserted without guiding and conventionally loaded; to the guided surgery but conventional loading group (GSCL; $n=35$); or to the guided surgery and immediate loading group (GSIL; $n=29$). At baseline, the OHQoL was significantly greater among those assigned to CGCL (2.4 ± 1.3) than those assigned to GSCL (3.3 ± 1.3), which were both greater than those patients assigned to GSIL (4.6 ± 2.0). After implant therapy, the oral well-being was significantly better than at baseline, and patient satisfaction was greater when the implants were loaded immediately (8.7 ± 1.1) than if the prosthetic rehabilitation was delayed (8.3 ± 1.1). In the GSIL group, the effect size of the OIDP exceeded the threshold value of 0.8 for all of the OIDP domains and for the total OIDP score and patient satisfaction. A global improvement in the OHQoL scores and patient satisfaction was observed after implant therapy, but the change was markedly greater in the GSIL group.

Keywords Oral health-related quality of life · Dental implant · Immediate loading · Delayed loading · Guided surgery

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Introduction

Over the past 4 decades, the use of dental implants to support and stabilise oral prostheses has changed the prosthodontic management of the replacement of missing teeth. While the success of the clinical aspects of implant-stabilised prostheses has been reported [1], some doubt still remains concerning the impact of these procedures on oral health-related quality of life and patient satisfaction. Nowadays, clinicians are in need of clinical trials focused on the patient-centred outcomes of implant dentistry [2]. Hence, the use of standardized measures of oral health-related quality of life (OHQoL) is required [3].

Most of the studies that have been carried out found that implant therapy has a satisfactory effect on patients' OHQoL; however, some authors [4, 5] have suggested that the outcome of implant therapy is not always unequivocal or absolute. Therefore, further investigation is required to analyse the best approach for implant treatment. In addition, most research in the field of patient-based outcomes after dental implant treatment has mainly focused on edentulous patients, leaving the

other aspects of implant therapy with the need to be addressed [6].

The original protocol for dental implants included a load-free period of between 3 and 6 months for the lower jaw and maxilla, respectively [7]. The implants were inserted after elevating a flap to better visualize the bone support to minimize the risk of bone fenestration. However, nowadays, thanks to the incessant improvement of implant surface treatments, the conventional approach to implant placement only requires a load-free healing period of 2 months [8]. The use of Cone Beam Computed Tomography (CBCT) to plan the placement of implants and the use of surgical guides, together with specific software, preclude the use of a flap. Since flaps are associated with some degree of morbidity (pain/discomfort) and require suturing, several authors have suggested that guided surgery could help clinicians to minimize the risk of perforation and incorrect implant alignment [9], reducing the duration and intensity of post-operative pain [10].

Currently, there is still a lack of studies addressing the treatment outcomes (clinically based and patient-centred) of implant therapy with respect to the surgical procedure and loading protocols employed.

Cannizzaro et al. [11, 12] carried out two studies in which immediate loading or delayed loading of implants is compared using both clinical and subjective assessments. The authors conclude that immediately loaded implants increase patient satisfaction by decreasing treatment time and patient discomfort in both mandibular overdentures [11] and full-arch maxillary prostheses [12]. However, these studies only measured patient satisfaction retrospectively, 1 year after implant placement, ignoring the global effect on quality of life and the changes in well-being that occurred during the follow-up period.

Conversely, Vercruyssen et al. did not find significant differences in pain, OHQoL, or patient satisfaction between immediately and delayed loading protocols for the treatment of the edentulous maxilla with guided surgery [13]. Similarly, in another study, they did not find any significant differences between guided surgery and conventional surgery regarding both clinically based and patient-centred outcomes [14].

The aim of this study was to compare the effect of implant rehabilitation on oral health-related quality of life and satisfaction with three different clinical protocols: conventional (manual guided and delayed loading), guided surgery with delayed loading; guided surgery with immediate loading.

Materials and methods

Sampling

Any patient seeking dental implants who was 18 years or older and able to sign a written informed consent form was eligible for inclusion in this study, which had been previously approved by the Bioethics Committee of Jaime I University of Spain (Clinical Trial Registration Number: CEIC/60-11).

Eligible patients needed to have sufficient bone dimensions, a diameter of at least 3.7 mm and a length of 10 mm, to allow the placement of the required implants.

During 2008–2010, a consecutive sample of 105 individuals agreed to participate in the study and, in total, 399 implants were placed. Patients were recruited and treated by one single operator (JD), with a great deal of experience in implant therapy, at a private dental surgery in Spain. Depending on the patients' preferences, and as long as the clinical diagnosis permitted it, the subjects were assigned to one of the following three treatment protocols: the conventional treatment (CGCL), in which implants were inserted after flap elevation without guiding templates; the guided surgery/conventional loading group (GSCL), and the guided surgery/immediate loading group (GSIL).

The study consisted of an oral examination and a questionnaire-based interview, which were carried out at baseline and 3 months after the delivery of the definitive prosthetic rehabilitation (5–6 months after surgery).

The effect of implant therapy on quality of life was assessed by comparing the preoperative and post-treatment summary scores and patient satisfaction. The tested null hypotheses were that there were no statistically significant differences in the oral health-related quality of life (OHQoL) within the subjects and between the groups, or in satisfaction. The modulating factors subject to change were analysed by exploring the relationship between subjective measures and sociodemographic, clinical, and behavioural variables, using multivariate logistic regression analyses.

The main clinical criteria for a patient to belong to the GSCL or to the GSIL groups were: the patient was in need of the replacement of multiple missing teeth in a given saddle of the same jaw, had a sufficient quantity of bone (5 mm width and 12 mm height), showed sufficient bone quality (D1–D3) after Computed Tomography scanning (CT), and a sufficient vertical mouth opening (> 55 mm). All patients were informed about the advantages, shortcomings, and costs of each procedure before being assigned to a group, which was dependent on their treatment preference and clinical situation. The guided surgery was planned using the MozoGrau Guided Surgery Software (MG_Fidelis, Mozograu, Valladolid, Spain) for optimal implant placement according to the outline of the permanent prosthesis. Since the digital data from the surgical plan are transferred to a computer-milled surgical template for guiding implants to the preplanned position, a flapless surgical procedure was applied in all of the patients. A single surgical template was affixed to the bone by three transversal pins, and sleeves of increasing diameter were connected to drills. In addition,

within the GSIL group, a pre-fabricated hybrid-fixed prosthesis was manufactured for immediate functioning of the inserted implants by transferring the exact position of the implants from the presurgical plan to the dental laboratory. In the other groups, the implants were left submerged and free of loading, and the patients remained in the same condition as when they came to the clinic, i.e., without prostheses or with their removable prostheses, until 3 month post-surgery, at which time a fixed definitive prosthesis was placed onto the implants. An experienced dentist (JD) performed all the surgical and prosthetic interventions using the implants (MG-Osseus and MG-Inhex) and the proper abutments provided by the same manufacturer (MozoGrau SL, Valladolid, Spain). An interviewer (JS) collected the data on quality of life and satisfaction, assuring that all the items were properly understood and coherently filled in by the patients.

Clinical protocol

All patients were first examined clinically and then by means of intraoral radiographs and panoramic orthopantomographs. Computerized tomography scans were taken when deemed necessary and for all patients in which a guided surgery was planned (GSCL and GSIL). Patients received professional oral hygiene prior to surgery and were instructed to rinse with a 0.2% chlorhexidine mouthwash for 1 min, twice a day, during the 3 days before surgery and 10 day post-surgery. All patients took an antibiotic for 7 days, starting the treatment the day before implantation (in general amoxicillin 1 g/8 h was prescribed, except for penicillin-allergic individuals who took erythromycin 500 mg/8 h instead). Local anaesthesia was obtained using articaine with 1:100,000 adrenaline. In addition, the patients treated by guided surgery were subjected to a mild-to-moderate sedation by intravenous infiltration of midazolam (up to a maximum of 10 mg). In these patients, a single intravenous dose of dexketoprofen (50 mg) was administered half an hour before the end of the surgical procedure.

Implant rehabilitation followed the standard prosthetic procedures recommended by the manufacturer (MOZO-GRAU SL, Valladolid, Spain) for fixed implant-supported restorations. The type of prosthetic rehabilitation was selected by the operator, based on widely accepted recommendations for screwed or cemented restorations [15].

Clinical variables

The clinical examination involved counting the number and position of missing teeth before surgery, and the bone quality [16] observed during surgery. When the sutures were removed (usually 7–10 days after surgery), the presence of some immediate post-surgical side-effects was recorded as dichotomous variables, i.e., severe pain, haematoma, facial inflammation, wound dehiscence, or long-lasting wound bleeding.

Patient-centred variables

Sociodemographic information (age, gender, education, and marital status) and brushing habits were gathered at baseline. Patients were interviewed face-to-face using validated questionnaires to collect data on oral health-related quality of life (OIDP) and self-rated oral health satisfaction (OSS) at both baseline (before treatment) and 3 months after placement of the new prostheses.

The OHRQoL was measured by the Spanish version of the (Oral Impacts on Daily Performances) OIDP [17]. This instrument contains eight items that capture a person's perception about the frequency and severity of the impact of oral conditions on eight daily performances (eating, pronouncing, hygiene, occupational, social relations, sleeping/relaxing, smiling, and emotional state). The impact is quantified by multiplying the frequency and severity scores of each of the eight items to obtain the performance scores for each dimension. The frequency and severity scores are Likert-type scale, but a zero score is only possible for severity. Hence, severity is weighted and can produce a zero score for an impact if the individual considers that there is no effect on their daily life activities. The number of items with impact is considered the total OIDP score. The impact scores are quantitative variables proportional to the perceived impact on the oral health-related quality of life (i.e., the higher the score, the greater the impact on quality of life). Furthermore, the global oral satisfaction was determined using a 0–10 visual analogue scale (OSS) [17], in which 10 is the highest satisfaction state and 0 is the worst.

Several methods for assessing the responsiveness to change in the quality of life measures have been reported and discussed elsewhere [18]. Although none of these methods are universally accepted, we estimated the "effect size" (ES), which is a distribution-based measure of change calculated by dividing the mean difference between the baseline and follow-up scores by the standard deviation of the baseline score [18]. Effect sizes (ES) were interpreted according to the following benchmarks: ES of < 0.5 was considered to be low, 0.5–0.8 was moderate, and > 0.8 was high [19]. As suggested by Locker [18], ES can be used to assess the relative responsiveness of different health indicators but also to compare the amount of change resulting from different therapeutic interventions.

Paired *t* tests were used to compare the within-subject change scores (from baseline to the final follow-up). ANOVA tests were used to compare quantitative variables between groups. Chi-square tests were used to compare the distribution of data between groups according to nominal variables. A forward step-wise logistic regression analysis

was performed to predict the risk of having impact after treatment. All statistical procedures were performed with the SPSS v.21 (Statistical Package for Social Sciences; Chicago, IL), using a p value of 0.05 as the threshold for statistical significance.

Results

The sample comprised 104 patients distributed within the following groups: CGCL (38.5%), GSCL (33.7%), and GSIL (27.9%). During this study, 4 out of the 399 implants failed in 4 patients (2 belonging to the CGCL group, 1 to the GSCL group, and 1 to the GSIL group), which implied an overall implant survival rate of 99%. As depicted in Table 1, the majority of participants were females (55.5%), married (80.8%), aged 55.5 years on average, and reported an optimal brushing habit (86.5%). A similar distribution of patients was observed, regarding sex, marital status, and tooth-brushing habits, for the three groups, although the GSIL group was significantly older and had a lower level of education than the other two groups (Table 1).

Table 2 shows the distribution of the main anatomical and surgical characteristics of the treatment groups. The average bone quality and the implant location were similar among the three groups, but the GSIL group needed a more extensive rehabilitation, which involved the use of more implants for the replacement of both anterior and posterior teeth on both sides. Facial inflammation and bleeding were the most common post-operative complications.

At baseline, the GSIL was the most disabled group as the patients suffered from a significantly higher impact on the eight daily performances of the OIDP and were the least satisfied, in comparison to groups CGCL or GSCL (Table 3). However, upon final observation, all groups were comparable in terms of impact on the OIDP and patient satisfaction, although the GSCL group tended to perceive a greater impact on oral hygiene ($F = 2.66$; $p = 0.75$) and the GSIL perceived greater satisfaction than their counterparts after receiving treatment (8.7 ± 1.1 versus 8.3 ± 1.1). Regarding the intra-group comparisons, a significant improvement on daily performances and patient satisfaction was observed for all three groups. Figure 1 shows that most of the patients felt that all the quality-of-life domains had improved or remained the same after implant therapy, although 15% of patients perceived that the ability to perform oral hygiene had worsened after treatment.

Table 1 Comparisons of sociodemographic and behavioural variables between implant-loaded groups using Chi-square and Student t tests

	All	Implant groups		
	$n = 104$	CGCL[A] ($n = 40$; 38.5%)	GSCL[B] ($n = 35$; 33.7%)	GSIL[C] ($n = 29$; 27.9%)
Sociodemographic and conductual variables	n (%)	n (%)	n (%)	n (%)
Gender				
Female	57 (54.8)	22 (55.0)	19 (54.3)	16 (55.2)
Male	47 (45.2)	18 (45.0)	16 (45.7)	13 (44.8)
Marital status				
Single	11 (10.6)	8 (20.0)	3 (8.6)	0 (0.0)
Married	84 (80.8)	29 (72.5)	28 (80.0)	27 (93.1)
Divorced/widow	9 (8.7)	3 (7.5)	4 (11.4)	2 (6.9)
Educational level				
Basic studies (compulsory school)*	32 (30.8)	7 (17.5)	8 (22.9)	17 (58.6)
High school studies*	33 (31.7)	19 (47.5)	11 (31.4)	3 (10.3)
University studies	39 (37.5)	14 (35.0)	16 (45.7)	9 (31.0)
Brushing habits				
At least 3 times/day	90 (86.5)	35 (87.5)	32 (91.4)	23 (79.3)
No more than twice/day	14 (13.5)	5 (12.5)	3 (8.6)	6 (20.7)
	Mean (sd)	Mean (sd)	Mean (sd)	Mean (sd)
Age (years)**	55.5 (11.2)	51.3 (13.1)	56.1 (9.6)	60.4 (7.9)

*Significant difference between groups ($p < 0.05$) after ANOVA or Chi-square tests

**Significant difference between groups ($p < 0.01$) after ANOVA or Chi-square tests

[A]Manually guided and conventionally loaded implant therapy

[B]Guided surgery and conventionally loaded implant therapy

[C]Guided surgery and immediately loaded implant therapy

Table 2 Comparisons of anatomical and surgical variables between implant-loaded groups using Chi-square and Student *t* tests

	All	Implant groups		
	n = 104	CGCL[A] (*n* = 40; 38.5%)	GSCL[B] (*n* = 35; 33.7%)	GSIL[C] (*n* = 29; 27.9%)
Anatomical–surgical variables	*n* (%)	*n* (%)	*n* (%)	*n* (%)
Bone intervened				
Maxilla	57 (54.8)	22 (55.0)	18 (51.4)	17 (58.6)
Mandible	36 (34.6)	15 (37.5)	14 (40.0)	7 (24.1)
Both jaws	11 (10.6)	3 (7.5)	3 (8.6)	5 (17.2)
Bone quality				
D1	8 (7.7)	3 (7.5)	3 (8.6)	2 (6.9)
D2	55 (52.9)	21 (52.5)	16 (45.7)	18 (62.1)
D3	36 (34.6)	14 (35.0)	13 (37.1)	9 (31.0)
D4	5 (4.8)	2 (5.0)	3 (8.6)	0 (0.0)
Missing teeth location				
Anterior teeth**	14 (13.5)	7 (17.5)	5 (14.3)	2 (6.9)
Posterior teeth**	48 (46.2)	29 (72.5)	18 (51.4)	1 (3.4)
Both anterior and posterior teeth**	42 (40.4)	4 (10.0)	12 (34.3)	26 (89.7)
Laterality of implant placements**				
One-side	47 (45.2)	27 (67.5)	18 (51.4)	2 (6.9)
Both sides	57 (54.8)	13 (32.5)	17 (48.6)	27 (93.1)
Prevalence of post-surgical side-effects				
Severe pain	9 (8.7)	4 (10.0)	4 (11.4)	1 (3.4)
Hematoma	12 (11.5)	4 (10.0)	3 (8.6)	5 (17.2)
Facial inflammation	81 (77.9)	30 (75.0)	27 (77.1)	24 (82.8)
Dehiscence	11 (10.6)	7 (17.5)	3 (8.6)	1 (3.4)
Wound bleeding	62 (59.6)	23 (57.5)	17 (48.6)	22 (75.9)
Implant failure rates	4 (3.9)	2 (5.0)	1 (2.9)	1 (1.4)
Quantitative variables	Mean (sd)	Mean (sd)	Mean (sd)	Mean (sd)
Number of implants inserted**	3.9 (2.7)	2.4 (2.0)	3.6 (2.0)	6.2 (2.7)
Number of replaceable missing teeth**	8.9 (9.5)	3.4 (6.0)	8.0 (8.9)	17.6 (8.1)
Number of replaced teeth on implants**	7.1 (8.9)	2.4 (6.0)	5.7 (7.1)	15.4 (8.6)

*Significant difference between groups ($p < 0.05$) after ANOVA or Chi-square tests

**Significant difference between groups ($p < 0.01$) after ANOVA or Chi-square tests

[A]Manually guided and conventionally loaded implant therapy

[B]Guided surgery and conventionally loaded implant therapy

[C]Guided surgery and immediately loaded implant therapy

As depicted in Table 4, the GSIL group experienced a great improvement in all of the OIDP domains in comparison to CGCL and GSCL (being significantly different except for smiling). All of the OIDP domains appeared to be sensitive enough to detect changes after implant therapy.

The major change in daily performances after implant therapy was observed for eating. Table 4 shows that the effect of the implant treatment on OHQoL domains was high (ES > 0.8) when the GSIL procedure was applied, and moderate (ES above 0.5) when GSCL or the conventional approaches were used. In terms of satisfaction, the three treatment strategies produced a great effect (ES > 1.5).

The logistic regression model (Table 5) revealed that the risk of having post-operative impact was significantly higher when patients suffered from inflammation after surgery (OR 1.7–22.8), which was significantly lower in males (OR 0.2–0.9), but the implant treatment protocol was not found to be a significant predictor of having post-operative impact. No other sociodemographic, clinical, or behavioural variables were found to modulate the risk of having impact after implant therapy.

Table 3 Comparisons of the oral health-related quality of life and oral satisfaction at baseline and follow-up assessments

OIDP domains	Baseline			Final follow-up		
	CSCL	GSCL	GSIL	CSCL	GSCL	GSIL
Eating	9.4 (6.9)*[a]	14.0 (6.1)*[b]	16.2 (7.4)*[c]	0.7 (2.5)[a]	1.3 (3.9)[b]	1.1 (0.2)[c]
Pronouncing	2.6 (5.8)*[a]	3.5 (6.5)*[b]	10.2 (10.1)*[c]	0.5 (2.1)[a]	0.4 (1.9)[b]	0.7 (2.3)[c]
Hygiene	4.7 (7.0)*[a]	3.7 (6.5)*	8.9 (9.2)*[c]	2.4 (4.8)[a]	4.4 (6.5)	1.4 (3.8)[c]
Occupational	1.5 (4.6)*[a]	2.3 (5.9)*[b]	6.6 (9.7)*[c]	0.0 (0.0)[a]	0.0 (0.0)[b]	0.0 (0.0)[c]
Social relations	1.4 (4.2)*[a]	5.0 (7.5)*[b]	11.1 (10.7)*[c]	0.0 (0.0)	0.0 (0.0)[b]	0.0 (0.0)[c]
Sleep–relax	1.2 (3.2)*[a]	2.9 (6.1)*[b]	6.6 (9.2)*[c]	0.0 (0.0)	0.0 (0.0)[b]	0.0 (0.0)[c]
Smiling	4.0 (6.9)[a]	6.3 (8.5)[b]	8.1 (9.8)[c]	0.0 (0.0)	0.0 (0.0)[b]	0.0 (0.0)[c]
Emotional	4.0 (6.3)*[a]	9.5 (8.9)*[b]	10.4 (9.3)*[c]	0.4 (2.0)[a]	0.4 (2.5)[b]	0.4 (1.9)[c]
OIDP total	2.4 (1.3)*[a]	3.3 (1.3)*[b]	4.6 (2.0)*[c]	0.5 (0.8)[a]	0.6 (0.6)[b]	0.4 (0.7)[c]
OSS (Oral Satisfaction Scale)	5.8 (1.3)*[a]	4.8 (1.0)*[b]	4.2 (2.0)*[c]	8.3 (1.1)[a]	8.3 (1.1)[b]	8.7 (1.1)[c]

Inter- and intra-group comparisons made by ANOVA and paired Student's t tests, respectively

*Significant differences between groups within the same period of observation after ANOVA tests

[a,b,c]significant differences within the three groups during follow-up after paired *t* tests

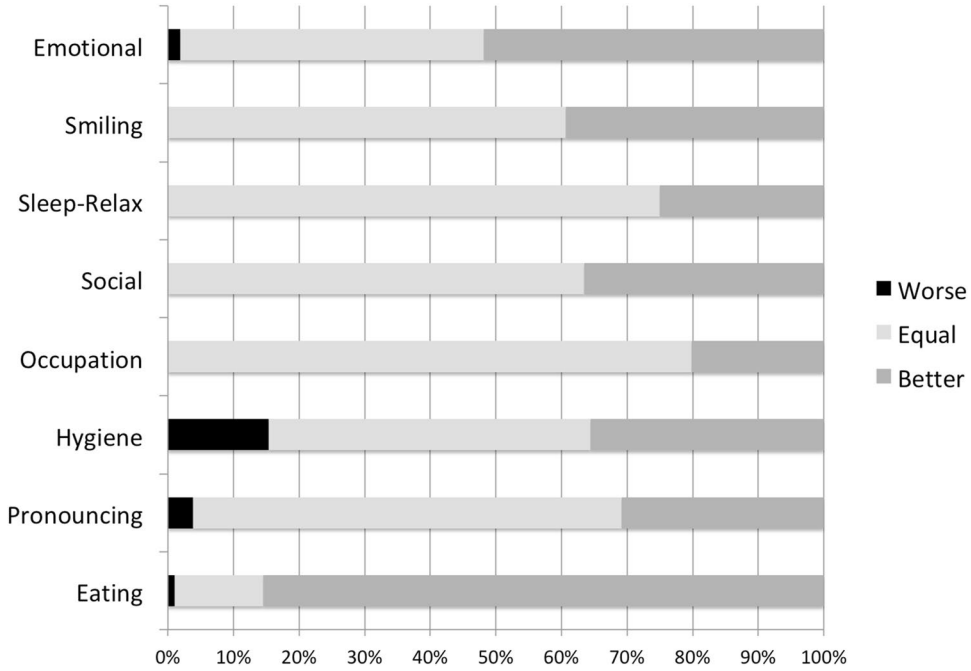

Fig. 1 Change in quality of life after treatment according to the OIDP in the whole sample ($n = 104$)

Discussion

At the beginning of the 21st century, implant placement by guided surgery was introduced and gradually became popular among clinicians. Despite that it has been recently demonstrated that guided placement of dental implants has a similar implant survival rate as the conventional protocols [20], to date, only a few studies have compared the patient-centred outcomes of guided implant placement techniques with the conventional non-guided techniques [13, 14]. In the latter study, Vercruyssen et al. [14] found a significant improvement of the OHQoL between the baseline and the 1-year follow-up, measured by the OHIP-49 instrument, among 59 fully edentulous patients treated with implant-supported fixed restorations, independently of the surgical approach used (either bone or mucosa-supported guided surgery as well as with the conventional approach). The same observation was made in a recent randomized-controlled trial conducted by the same research group regarding the time of loading [13], and it was reported that there was no difference in the patient-centred outcomes 10 days after a flapless-guided surgery. These findings are in agreement with the results of this

Table 4 Change scores and effect sizes of the impact of the implant therapy on the oral health-related quality-of-life assessments (using OIDP)

	Global change (baseline—6 months)		
	CSCL	GSCL	GSIL
Eating*	8.7 (6.8)	12.7 (7.5)	16.0 (7.3)
Effect_size*	1.2 (0.9)	1.8 (0.9)	2.2 (1.0)
Pronouncing*	2.1 (5.4)	3.1 (6.7)	9.9 (10.8)
Effect_size*	0.3 (0.7)	0.5 (0.8)	1.3 (1.2)
Hygiene*	2.2 (7.5)	− 0.6 (8.4)	7.4 (10.9)
Effect_size*	0.6 (0.8)	0.6 (0.9)	1.2 (1.2)
Occupational*	1.5 (4.6)	2.3 (5.9)	6.8 (9.8)
Effect_size*	0.2 (0.7)	0.3 (0.8)	1.0 (1.4)
Social relations*	1.0 (3.7)	5.0 (7.5)	11.5 (10.7)
Effect_size*	0.1 (0.4)	0.6 (0.9)	1.4 (1.3)
Sleep–relax*	1.2 (3.2)	2.9 (6.1)	6.8 (9.2)
Effect_size*	0.2 (0.5)	0.4 (0.9)	1.0 (1.4)
Smiling	4.0 (6.9)	6.3 (8.5)	8.4 (9.8)
Effect_size	0.5 (0.8)	0.8 (1.0)	1.0 (1.2)
Emotional*	3.6 (6.6)	9.1 (8.7)	9.9 (9.1)
Effect_size*	0.5 (0.7)	1.1 (1.0)	1.2 (1.0)
OIDP total score*	1.9 (1.4)	2.7 (1.3)	4.2 (2.1)
Effect_size*	1.1 (0.8)	1.5 (0.7)	2.4 (1.2)
OSS*	2.5 (1.1)	3.5 (1.5)	4.5 (2.4)
Effect_size*	1.6 (0.7)	2.2 (1.0)	2.9 (1.5)

Inter-group comparisons made by ANOVA tests within each period of observation

Change scores for OIDP domains are calculated by subtracting a respondent's score at follow-up from the score at baseline; thus, a positive value indicates an improvement during such interval. Changes in OSS were inversely calculated to maintain the interpretation that a positive value means there was an improvement

*Significant differences between groups within the same period of observation after ANOVA Tests

Table 5 Forward step-wise logistic regression model having an impact, according to the post-treatment OIDP total score, after including all the potentially related sociodemographic, behavioural, clinical, and subjective variables

Impact on OHQoL after treatment (OID, $p>0$)[A]	Hypothesis contrast		OR CI 95%		
Parameters	*B*	*p* value	OR	Lower	Upper
(Intersection)	− 1.5	0.018	0.22		
Gender	− 1.0	0.027	0.38	0.16	0.89
Inflammation after implant surgery	1.8	0.007	6.15	1.66	22.83

[A]Chi = 14.8; $p<0.01$; Nagelkerke $R^2=0.18$

non-randomized-controlled trial, which demonstrate that OHQoL and patient satisfaction after implant therapy are significantly higher than at baseline, independently of the surgical or loading strategies applied in each treatment protocol (Table 3), but, at the final follow-up time, no inter-group differences were found in terms of OHQoL 5–6 months after surgery. The effect sizes of the OIDP scores are greater than those reported for the OHIP-20 (Oral Health Impact Profile-20) after implant therapy [21], suggesting that the OIDP seems to be more sensitive for assessing change than this other widely used instrument. In a previous paper [22], we demonstrated that the Spanish version of the OHIP-49 had a good level of sensitivity to change, exceeding the threshold value of 0.8 for Functional Limitation, Pain/Discomfort, and Psychological Discomfort, as well as the OHIP total score. Similarly, the effect sizes of the OHIP-49 total score, when used to assess change after implant therapy according to Vercruyssen et al. [14], ranged from 1.3 to 1.6 in flapless-guided surgery and 1.7 for the conventional procedure (results calculated from data shown in the paper). However, in spite of being demonstrated the sensitivity of such large indicator, as the OIDP is a short instrument but also sensitive to change, we encourage researchers to choose it instead of the OHIP-49 or OHIP-20 for clinical trials with several observations during the follow-up or in large samples.

In this study, a clear improvement in the OHQoL scores was observed in all the treatment groups after implant therapy, as previously reported [11–14, 22]. The effect of the immediate loaded prostheses (GSIL group), which instantly restores aesthetics and chewing function, generates a major change in the impact of most of the OIDP domains (Table 4). However, the final impact of the OIDP was comparable to the other treatment strategies (Table 3). The rationale for explaining such observation may rely on the fact that the GSIL group had a significantly higher impact at baseline and greater prosthetic needs than other two groups. Thus, despite the greater change, the final level of well-being is comparable to the other treatment groups. In addition, all groups have a lower impact than that reported for the reference population [17], in which some minor problems were reported even when the subjects were satisfied or very satisfied with their mouths (OIDP total: 4.8 ± 9.5 and 2.1 ± 5.3 points, respectively). Other authors have not found significant differences in the OHQoL between immediate and delayed loading protocols during short-term follow-up (10 days) [13]. However, according to our experience [22], in which we compare the baseline and the post-treatment OHQoL scores (3–5 months after the insertion of the definitive prostheses), we observed a better final OHQoL according to the OHIP-49 among patients of the GSIL group than those with the conventional loading (which would aggregate both the CGCL and GSCL groups). The explanation for this dissimilarity may rely on the small sample size of the Vercruyssen study [13] ($n=15$; 7 patients with immediate loading and 8 patients left without a prosthesis) and the assessment of the OHQoL during the

acute post-treatment period (10 days after surgery). Thus, the statistical power required to detect significant differences between both loading-type approaches during the immediate post-operative period are limited. Moreover, when comparing our current findings to those of the previous work [22], it should be taken into account that, in the latter study, we used the OHIP-49, a frequency-based instrument, which might have overestimated the impact of several frequent but not severe events. In this study, we have used a severity-based approach (with the OIDP) that only computes impact if it has an effect on daily performance, which seems to be preferable in assessing patient-centred outcomes.

In any case, we have observed that when a fixed prosthesis is inserted in patients mostly accustomed to removable dentures, or without any experience with dentures at all, some minor problems (mainly food packing or difficulties with oral hygiene) arise (Table 3). This fact should encourage researchers, when designing different types of prostheses, to make cleaning easier to address the most common post-operative impact on daily performance (Table 3). An interesting finding observed in this study is that, among those patients treated with guided surgery, the difficulties in oral hygiene tended to be higher when loading is delayed than when implants were loaded immediately. This fact may reveal that soft tissues are able to fill the prosthesis-gingiva space more effectively when prosthetic rehabilitation is connected to the implants immediately. By contrast, soft tissues may suffer, to some extent, from flattening when no fixed prosthesis is immediately delivered. These results are in agreement with the recent literature [23, 24], but the explanation of the biological mechanisms involved in the maintenance of soft tissue when the prosthesis is immediately connected to the implant remains unclear.

The combination of two instruments (OIDP and OSS) for assessing the impact on OHQoL and satisfaction, respectively, which are considered to be complementary measures of patient-centred treatment outcomes, is often assessed during clinical trials [25–28] and havse been shown to be highly related to the improving well-being [29].

Another interesting finding of the present study is that the presence of facial inflammation 7 days after implant surgery (a very common consequence, as shown in Table 2) was a significant predictor of the post-operative impact on OHQoL. We, therefore, analysed those patients who did not suffer from facial inflammation ($n = 23$), and found that the prevalence of post-operative impact (OIDP total > 1) ranged from 0% in the GSIL group to 20% among the patients of the CGCL group. In addition, in those patients who presented facial inflammation, the prevalence of post-operative impact ranged from 37.5% of the GSIL group to 63% of the GSCL group. Hence, it seems that the absence of this common clinical sign/symptom could be used as an indicator of a good patient-centred treatment outcome. The inflammatory response plays a fundamental role in oral surgery, being an essential process for repairing traumatized or infected tissues, although the persistence of inflammation may result in suboptimal tissue healing [30]. Clinicians are aware that the degree of inflammation is usually proportional to the surgical trauma and the virulence of tissue infection. Future studies should analyse the prognosis capacity of this clinical marker of post-operative well-being. Several authors have stated that one of the major advantages of guided implant surgery (mucosa-supported) is reduced pain and inflammation [20, 31], which occurs during the immediate post-operative period [10] and mainly the day of surgery and the following day [32]. In our study, no significant differences were observed regarding the presence of facial inflammation 7 days after surgery between groups. However, there was a higher incidence of this potential marker within the GSIL group, probably due to the manipulation of the tissues for matching the pre-fabricated prosthesis to the actual position of the immediately inserted implants.

Another widely known prognostic factor was gender. Females perceived greater impact in OHQoL than males, in agreement with the majority of other authors [17, 21, 22, 25–28, 31].

All the findings reported here should be taken with caution, since there are some inherent limitations that hamper the accuracy of the interpretation of our results and the corresponding conclusions. First, the patient recruitment procedure (from a private dental office in a consecutive manner) and the treatment allocation method (based on patient preference and clinical diagnosis) generated three non-comparable groups regarding age, sample size, clinical conditions, and baseline oral well-being that could bias the assessment of the effect of the treatment. Using our method, we have reduced the risk of potential bias of the final OHQoL scores reported by subjects who did not receive their treatment of choice, as reported elsewhere [28]. In this study, we have applied different treatment approaches on groups of patients who reflect everyday clinical reality, and therefore, the results of this trial should be of interest to clinicians. Ideally, future clinical trials should recruit patients, with no treatment preference and with similar baseline scores and conditions, who would be randomly assigned to each treatment protocol.

In summary, a clear improvement in oral well-being was detected after implant therapy. This benefit was markedly greater for those treated with the guided surgery and immediately loading protocol, although all groups finally reached a similar level of well-being. Females and those suffering from facial inflammation 7 days after surgery were at risk of having a poorer OHQoL 6 months after treatment.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study. There were no financial, economic, or professional interests that influenced the design, execution, or presentation of this work.

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