

How Does Immediately Loaded Implant-Supported Fixed Rehabilitation Influence the Oral Health-Related Quality of Life?

Federico Berton^{1,*}, Claudio Stacchi¹, Teresa Lombardi², Antonio Rapani¹, Roberto Rizzo¹ and Roberto Di Lenarda

¹Department of Medical, Surgical and Health Sciences, University of Trieste, Italy and ²Cassano allo Ionio, Italy

Abstract: *Aim:* To test the null hypothesis that implant-supported fixed immediately loaded rehabilitation of partial or total edentulism has no impact on oral health-related quality of life against the alternative hypothesis of an impact.

Materials and Method: Partially and totally edentulous patients were recruited following exclusion and inclusion criteria. After an accurate pre-surgical planning, dental implants were inserted and immediately loaded with partial or full-arch rehabilitations. Patients were asked to fill out a questionnaire (OHIP-14) before surgery, 3 months and 3 years after prosthetic loading. The significance of the difference in OHIP score at different time points was evaluated.

Results: Twenty-one patients were treated with immediately loaded partial or total implant-supported fixed prostheses: eighteen patients completed the three-year follow up period, during which three patients dropped out. Five implants out of 82 (3-year survival rate 93.9%) were lost in four patients with one prosthetic failure (3-year survival rate 94.5%). Mean value of OHIP-14 score was significantly higher at baseline than at the end of the follow-up period. Furthermore, baseline scores were different when comparing full-arch and partial rehabilitations, even if not significantly.

Conclusion: The results of this prospective cohort study suggested that oral health-related quality of life was significantly improved by immediately loaded implant-supported fixed prosthesis. A gradual improvement in OHIP-14 scores was observed both for partial and full-arch rehabilitations, from the three-month follow up to the final evaluation after three years. However, intergroup differences were significant only when comparing baseline with the final observations.

Keywords: Oral health-related quality of life, patient satisfaction, dental implant, immediate loading.

1. INTRODUCTION

Since the introduction of the modern concept of osseointegration [1], implants have been used to solve a wide range of therapeutic challenges, from complete edentulism to single tooth replacement. Both loading protocols and clinical approaches have been modified and updated over time, evolving from conventional loading protocols (three and six months for mandible and maxilla, respectively) [2-3] to immediate loading (within 72 hours) [4], in the attempt to satisfy the increasing aesthetic and functional demands of the patients. Immediate loading of dental implants is nowadays considered as an effective and predictable protocol, allowing to reduce treatment time and to increase patient satisfaction without jeopardizing the successful outcome of the therapy [5]. Occlusal loading of dental implants at the same time of their insertion, if correctly planned and checked during the healing period, seems not to affect the osseointegration process [6-10]: some studies even showed an improvement of the bone-implant interface in terms of bone-to-implant

contact and implant stability [7-9]. Recent systematic reviews compared conventional and immediate loading and/or restoration [11-13], concluding that there are no statistically significant differences between the two techniques both in terms of implant survival and marginal bone loss.

The focus of the implantologists recently broadened from the mere evaluation of anatomic and surgical issues to the consideration of patient demands. Patient needs have an increasing influence in treatment planning, as reported in several papers centered on patient satisfaction and oral health related quality of life [14-17]. An adequate identification of patient-related outcomes within the global treatment parameters requires the use of specific and validated tools such as OHIP (Oral Health Impact Profile) [18,19], whose Italian version has been recently updated [20] and assessed [21]. Although many studies showed that implant therapy has a positive effect on OHIP, recent systematic reviews pointed out that most of these results were obtained by using questionable methods, and recommended to implement scientific evidence by well-designed clinical trials [22]. Finally, according to the strength of recommendation taxonomy (SORT),

*Address correspondence to this author at the Dental Sciences School, Piazza dell'Ospitale 1, 34129 Trieste, Italy; Tel: 0039 040 3992254; Fax: 0039 040 3992022; E-mail: fberton@units.it

patient-oriented evidence improves the study quality and increases the strength of its recommendations [23].

The present study tested the null hypothesis that immediately loaded fixed implant-supported rehabilitation does not affect the perceived quality of life, evaluated by using OHIP, against the alternative hypothesis of a difference.

2. MATERIALS AND METHOD

2.1. Study Design

This prospective study was conducted in the Implantology Department of the University Hospital of Trieste (Italy), in accordance with the Good Clinical Practice Guidelines (GCPs) and with the recommendations of the Declaration of Helsinki as revised in Seoul (2008) for investigations with human subjects. The study protocol had been approved by the relevant Ethical Committee (Azienda Ospedaliero Universitaria "Ospedali Riuniti", Trieste, Italy).

Prior to enrollment, all patients were asked to sign an informed consent form to document that they understood the aims of the study (including procedures, follow-up evaluations, and any potential risk involved). Patients were allowed to ask questions pertaining to this study, and were thoroughly informed of alternative treatments.

2.2. Study Population

Any healthy patient (\leq ASA 2), age >18 years, presenting full-arch edentulism or at least three adjacent missing teeth, with sufficient bone volume to allow dental implants placement and able to sign an informed consent was eligible to enter this study. Exclusion criteria were the following: acute myocardial infarction within the past 2 months; uncontrolled coagulation disorders; uncontrolled diabetes (HBA1c $> 7.5\%$); radiotherapy to the head/neck district within the past 24 months; immunocompromised patient (HIV infection or chemotherapy within the past 5 years); present or past treatment with intravenous bisphosphonates; psychological or psychiatric problems; alcohol or drugs abuse; heavy smokers (>10 cigarettes/day); presence of bruxism or clenching; presence of uncontrolled or untreated periodontal disease, implant stability quotient (ISQ) <65 at the time of implant positioning, according to the results reported by Benic and co-workers [24].

2.3. Clinical Protocol

All patients underwent clinical and radiographic examinations, using intraoral and panoramic radiographs. Impressions were taken to perform a diagnostic wax-up and to manufacture a radiological resin template. In case of full-arch edentulism, the radiological template was manufactured as a replica of the provisional removable prosthesis. Cone beam computed tomography scans were acquired with the same device (NewTom, QR, Verona, Italy) and FOV (15 x 12). DICOM datasets were then processed with an imaging software (Dental Vox, Era Scientific Service, San Giovanni in Marignano, Italy) to evaluate bone volume and plan implants insertion. Electronic files with the implant planning were matched with the resin casts, allowing a numerical control milling machine to insert implant analogs into the cast in the planned position (Idea, Plan 1 Health, Amaro, Italy). Therefore, a surgical template was manufactured by screwing cylindrical titanium sleeves to the analogs, and embedding them in a steel reinforced resin (ACRON MC, GC, Tokyo, Japan).

All the patients received professional deplaqueing three days prior to surgery and were instructed to rinse with a 0.2% chlorhexidine mouthwash for 1 minute twice a day until the intervention. Patients were asked to fill in a survey (OHIP-14, Oral Health Impact Profile, Italian edition).

The outpatient procedure was held under local anaesthesia, with flapless approach when possible, according to the residual keratinized mucosa. The surgical template had dental support or, in edentulous arches, was stabilized by three screws (one paramedian, two in left and right posterior areas). Guided preparation of the implant sites was performed under copious irrigation of cold saline solution and implants (IHC, Plan 1 Health, Amaro, Italy) were inserted according to the pre-surgical planning. An intra-operative impression was taken to manufacture screwed provisional prosthesis, which was delivered within 72 hours and accurately checked for adaptation and occlusion.

Antibiotics (amoxicillin/clavulanate 875mg + 125mg, twice a day for six days), NSAIDs (ibuprofen 400mg, when needed) and antiseptic rinses (chlorhexidine 0,12% 1 min twice a day) were prescribed. Sutures, when present, were removed after 10 days and patients were re-evaluated after one month, three months, six months, one year, two years and three years.

Clinical and radiological evaluations were performed at each time point and patients were asked to fill in the OHIP-14 questionnaire three months and three years after the intervention. OHIP investigates seven topics: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap; every area includes two items, for a total of 14 records. Evaluation scores consist in a 4-points scale: never (= 0), hardly ever (= 1), occasionally (= 2), fairly often (= 3), very often (= 4). Lower OHIP scores indicate better oral health-related quality of life.

Patient satisfaction on the functional and aesthetic outcomes of the rehabilitation was expressed on a 4-points scale (insufficient-sufficient-good-excellent) at three-month follow up and at three years.

2.4. Outcome Measures

This study tested the null hypothesis that there were no differences in OHIP scores and patient satisfaction among the different time points.

Primary outcome measures:

- OHIP-14 score at baseline, three months and three years after intervention
- patient satisfaction measured on a 4-points scale

Secondary outcome measures:

- implant failure: implant mobility or implant removal suggested by progressive marginal bone loss
- prosthesis failure: prosthesis which had to be removed because the remaining implants were insufficient to support it
- any biological or mechanical complications or adverse events were recorded and reported.

2.5. Statistical Analysis

For descriptive statistics, data were expressed as mean \pm standard deviation and 95% confidence interval (CI). Kolmogorov-Smirnov and Levene tests were applied to assess data normality. Difference in age between genders was evaluated by means of an independent sample t-test. OHIP variations over time were evaluated by using Friedman test, while the pairwise comparisons among different time points were performed by using Bonferroni-corrected Wilcoxon test.

Furthermore, a correlation analysis was performed by means of the Spearman's rank correlation coefficient between OHIP variations, age and number of implants. A p-value <0.05 was set for the rejection of the null hypothesis. All statistical procedures were performed with SPSS 19 (SPSS, Chicago, USA).

3. RESULTS

From April 2011 to January 2013, 32 patients were recruited and screened for entering this study protocol. Among them, 21 consecutive patients (14 M, 7F; mean age 54.9 ± 12.4) were enrolled and treated by a single operator expert in implant therapy (RDL). All the implants were loaded immediately (mean ISQ 72.4 ± 5.6). Ninety-four implants were inserted in twenty-one patients: eighteen patients completed the 3-year follow-up period, and three drop-outs occurred (one patient deceased, two moved abroad). Demographics and interventions are summarized in Table 1.

At three-year follow up five implants out of 82 were lost (93,9% implant survival rate). One patient lost two implants (out of three) 4 months after loading, causing also a prosthetic failure. Three distal implants were lost in three patients (with full-arch rehabilitation) within the first year of loading: none of these cases caused a prosthetic failure. Overall prosthetic survival rate at three-year follow up was 94.5%.

No significant difference in age between genders was present. OHIP value decreased significantly over time ranging from 23.4 ± 14.4 (95% CI, 6.7-30.1) to 9.4 ± 6.6 (95% CI, 6.3-12.5) at baseline and 3 years, respectively ($p=0.000$). At the pairwise comparisons, OHIP at 3 months and 3 years were significantly lower compared to baseline. On the contrary, no significant difference was seen in OHIP scores recorded at 3 months and 3 years. Finally, correlations of OHIP with age and number of implants did not result statistically significant ($p>0.05$). Complete OHIP scores are reported in Table 2. Functional and aesthetic outcomes of both full-arch and partial prostheses were generally evaluated by patients from good to excellent, at three-month and three-year follow up; two patients considered as "sufficient" the rehabilitation outcomes. Complete results are listed in Table 3.

4. DISCUSSION

The main objective of this study was to evaluate changes in oral health-related quality of life after implant-supported partial and full-arch fixed rehabilitations. The results of this prospective clinical study

Table 1: Study Population and type of Intervention

Gender	Age	Edentulism	Site	N° of Implants	Follow-up (years)
M	51	Partial	PMAN	3	3
M	52	Total	MAN	6	3
F	39	Partial	PMAN	3	3
M	39	Partial	PMAX	4	3
M	53	Partial	PMAND	3	3
F	58	Total	MAX	6	3
F	56	Total	MAN	6	3
F	37	Partial	PMAN	3	3
F	43	Partial	AMAX	3	3
M	49	Total	MAX	6	3
M	71	Partial	AMAX	3	3
M	45	Total	MAN	3	3
M	75	Total	MAN	6	3
M	72	Total	MAX	6	3
M	61	Total	MAX	6	3
M	74	Partial	PMAN	3	3
M	54	Total	MAX	6	3
M	58	Total	MAX	6	3
F	39	Partial	PMAN	3	drop-out
M	76	Partial	PMAN	3	drop-out
F	45	Total	MAX	6	drop-out

MAN, mandible, MAX, maxilla, PMAN, posterior mandible, PMAX, posterior maxilla, AMAX, anterior maxilla.

showed a significant improvement of perceived quality of life in patients who received implant-supported prostheses, irrespective of the type of edentulism. This positive effect of dental implant treatment on the quality of life confirms data reported by several systematic reviews [25-27]. Mean OHIP scores decreased in the entire pool of patients both between baseline and three-month follow up and between baseline and 3-year visit. In both partially and totally edentulous patients there was no statistically significant difference between 3-months and 3-year scores, even if 9 patients (50%) demonstrated improved OHIP values in this interval. This finding could be explained with a high level of acceptance of the immediate rehabilitation, with a continuous benefit over time or by the presence of confounding factors which could hamper the comparison, such as patient-related variables, as suggested by Zani *et al.* [28]. On these premises, some researchers proposed that the assessment of treatment success should be determined individually for each patient, oppositely to the current methods of clinical evaluation [29].

Table 2: OHIP Scores Variations (n=18)

Time Point	Mean \pm SD	Min-Max
Baseline	23.4 \pm 14.4	2.0-50.0
3 months	11.7 \pm 6.2*	1.0-23.0
3 years	9.4 \pm 6.6*	0-19.0
Diff.	0.000	

Diff., significance of the difference over time (Friedman test). Min, minimum score, Max, maximum score. Results at the pairwise comparisons (Wilcoxon test): *, significantly different as compared to the baseline score.

Several methods for assessing patient response to changes in terms of quality of life have been reported [30-32]. Although none of them is universally accepted, in this study it was considered as main indicator the difference among scores at different time points (i.e., subtracting post-intervention from pre-intervention scores), which is one of the most widely used approaches. The Italian version of OHIP-14 questionnaire, whose internal consistency had been previously demonstrated [33], was the tool selected in the present study to evaluate changes in oral health-related quality

Table 3: OHIP Scores and Patient Satisfaction

Edentulism	N° of Implants	OHIP Baseline	OHIP 3 Mo	OHIP 3 Y	AesSat 3 Mo	AesSat 3 Y	FunSat 3 Mo	FunSat 3 Y
Partial	3	15	7	8	2	2	2	2
Total	6	22	4	9	1	2	1	2
Partial	3	6	15	16	1	1	1	1
Partial	4	21	7	0	2	2	2	3
Partial	3	13	7	0	1	1	1	1
Total	6	39	19	4	2	1	2	1
Total	6	39	18	4	2	1	2	1
Partial	3	7	11	0	1	1	1	1
Partial	3	44	14	10	1	1	1	1
Total	6	6	2	2	1	1	1	1
Partial	3	36	23	19	1	1	3	1
Total	3	50	14	18	1	1	2	2
Total	6	16	17	16	2	1	2	1
Total	6	17	16	16	2	2	2	2
Total	6	28	10	13	2	2	2	2
Partial	3	2	1	1	1	1	1	1
Total	6	33	16	14	2	2	2	2
Total	6	28	10	9	2	2	2	2

AesSat, patient satisfaction about aesthetics, **FunSat**, patient satisfaction about function, **Mo**, months, **Y**, years. OHIP score ranges from 0 to 56 (the higher the score, the lower the oral health-related quality of life); Aesthetics and function scale: 1= excellent; 2 = good; 3= sufficient; 4= insufficient

of life. This psychometric test consists of 14 items with multiple choices and its accuracy in assessing the impact of oral health on quality of life was demonstrated [34,35]. OHIP-14 success also derives from its smaller size compared to the original OHIP-49, with an improved manageability, which facilitates the administration of the test to patients both in terms of time and understanding. The questionnaire analyzes various aspects of patient's perception of oral health such as comfort, function, aesthetics, physical pain, psychological disability and social disability. The loss of one or more teeth is differently perceived by the patient as impairment, disability or handicap [36]. In the same way, an unstable prosthesis or a poor aesthetics could have a different psychosocial impact in different subjects. The overall grade of satisfaction depends on both technical and patient-related variables [28]: in fact, while some authors suggested a weak relationship between perceived quality of life and loss of teeth [37], others demonstrated that this correlation is highly significant [38].

The use of digital systems in the pre-surgical planning as well in the surgical session resulted in a correct and predictable guided implant positioning, following

the concept of "prosthetically-guided" implant insertion, currently proposed and encouraged in several publications [39,40]. The optimization of implant placement allowed an easier manufacturing of the prosthesis, by planning the three-dimensional location of the emergence profiles and the position of the screw access channels: these details could lead to a more functional and aesthetic rehabilitation, possibly improving both final result and patient satisfaction [41]. Furthermore, the additional advantages of computer-guided implant surgery were represented by the lower morbidity (flapless procedures could be safely performed when there was an adequate width of keratinized tissue) and a shorter surgical time, with evident benefits both for the patient and the clinician [42].

5. CONCLUSION

Within the limits of the present study, the application of immediately loaded fixed implant-supported prosthesis showed an improvement in patient's perceived oral health-related quality of life. The medium-term follow up showed a satisfactory survival rate for the immediately loaded implants, both in partial and in total edentulism, confirming the reliability of this technique in

accordance with the results reported in literature. Nowadays patient satisfaction and quality of life should be considered among the primary goals when planning any medical treatment: therefore also oral rehabilitation should be tailored on the different needs of each single patient, considering the great psychological impact of dental implant therapy.

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