Immediate Versus Delayed Loading of Dental Implants in Edentulous Patients' Maxillae: A 6-Year Prospective Study

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Purpose: This study compared the surgical protocol efficacy of immediate and delayed implant loading in edentulous maxillae opposed by natural or restored mandibular dentitions over an observational period of 6 years or longer. The selected outcome determinants included individual implant survival data, progressive measurements of peri-implant bone resorption, prosthodontic survival and success data, and report of complications. ***Materials and Methods:*** A convenience sample of 49 patients requiring fixed implant-supported maxillary prostheses was split into two groups. The test group (34 patients) was treated according to the Columbus Bridge Protocol, which prescribes the insertion of four to six implants, including distally tilted implants, and load within 24 hours. The control group (15 patients) was treated via a two-stage surgical protocol of 6 to 9 straight implants that were loaded a mean 8.75 months after stage-one implant surgery. Two hundred sixty implants (test: n = 163, control: n = 97) were placed, and all subjects were ultimately treated with screw-retained full-arch prostheses. ***Results:*** Two patients dropped out (one in the test group and one in the control group) by the time of the scheduled sixth annual visit. The other patients were followed up for 75.2 months (range: 72 to 90 months). At the 6-year follow-up, no differences in implant cumulative survival rates were found between groups. Significantly less bone loss was found in the test group (mean: 1.62 mm) compared with the control group (mean: 2.44 mm). All of the original prostheses were maintained throughout the study's observation period and were functioning satisfactorily at each patient's last recall appointment. ***Conclusion:*** Patients who received immediate and delayed implant loading in their edentulous maxillae demonstrated similar survival outcomes. However, less marginal bone loss was recorded around the immediately loaded implants over the study's 6-year follow-up period. *Int J Prosthodont 2014;27:207–214. doi: 10.11607/ijp.3569*

Publications describing the management of patients' edentulous maxillae by immediate loading rehabilitation suggest an efficacious treatment protocol.[1–4] However, long-term and controlled studies are lacking and further research is needed to demonstrate the effectiveness of such procedures.[1]

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The aim of this study was to compare clinical treatment outcomes associated with immediate and delayed implant loading in edentulous patients' maxillae with a medium-term follow-up (6 years).

Materials and Methods

Between September 2005 and January 2006, a convenience sample of 49 patients (25 women, 24 men) with edentulous maxillae, or significantly unfavorable prognoses for their residual maxillary dentitions, was identified for this study.

Patients referred to the Department of Implant and Prosthetic Dentistry of Genoa University were enrolled if they met the following criteria: desire to be treated with fixed prostheses supported by dental implants, good general health condition, and no contraindications for undergoing oral surgery. Exclusion criteria were: an uncontrolled medical condition such as noncompensated diabetes mellitus, immune suppression, intravenous bisphosphonate medication,

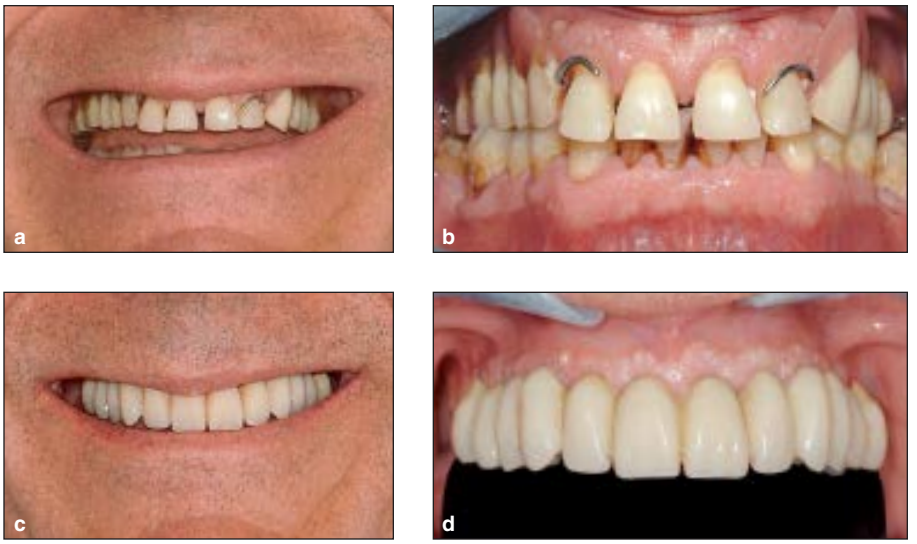

Fig 1 Patient **(a and b)** before and **(c and d)** after rehabilitation following CBP (at 1 year of function).

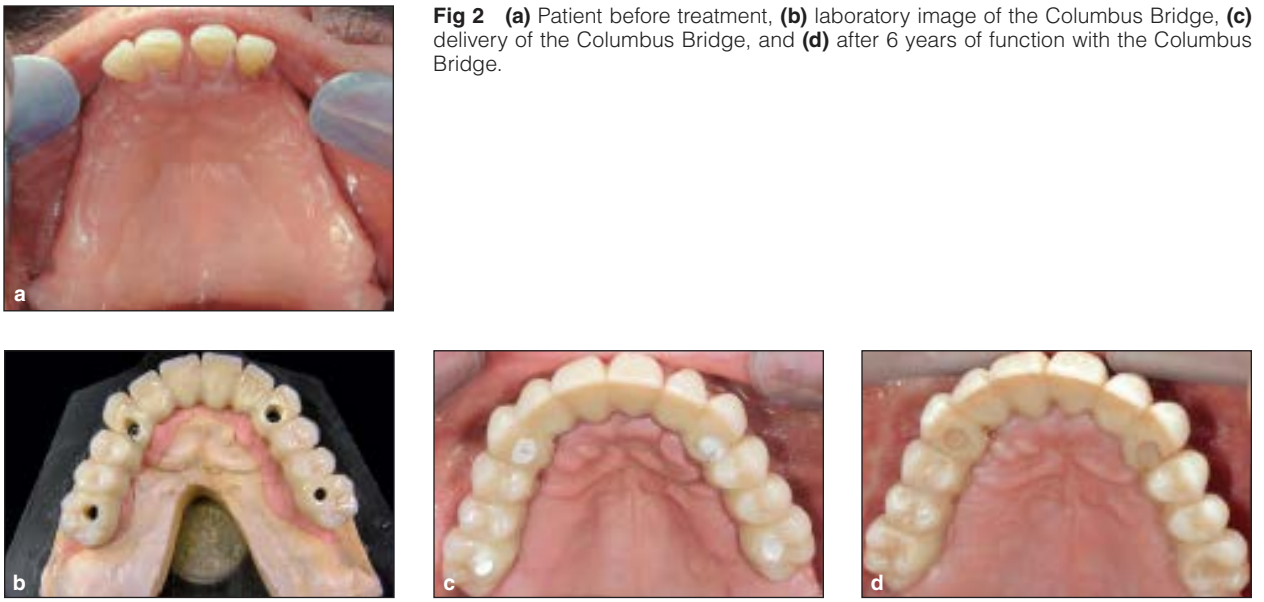

Fig 2 **(a)** Patient before treatment, **(b)** laboratory image of the Columbus Bridge, **(c)** delivery of the Columbus Bridge, and **(d)** after 6 years of function with the Columbus Bridge.

orofacial cancer, chemotherapy or head and neck radiotherapy, or heart attack during the preceding 6 months.

Twenty patients meeting the inclusion criteria did not accept the implant treatment proposed because of economic reasons. All patients who accepted the full-arch implant treatment were enrolled in the study.

The study was designed as a prospective cohort clinical trial. Consecutively treated patients were included and scheduled to be followed for up to 6 years after loading.

Clinical Procedures

The selected patients presented a mean age of 58.2 years (women: 54.8 years, men: 61.5 years) and were treated with fixed screw-retained prostheses supported by implants (n = 260) in the Department of Implant and Prosthetic Dentistry of Genoa University, following either the Columbus Bridge Protocol (CBP),[5,6] with four to six implants loaded within 24 hours (test group: 34 patients) (Figs 1 to 3, Table 1), or the more traditional two-stage surgical procedure,[7] with six to nine implants (mean, 6.5 implants per patient) loaded a mean 8.75 months after surgery (control group: 15 patients) (Figs 4 to 6). The implant number to be placed was decided on the basis of the length of the implants. More than six implants were used in the control group when bone volume did not allow long implants (> 10 mm) to be placed.

A history of smoking or parafunctional habits did not disqualify any patient, although smokers were

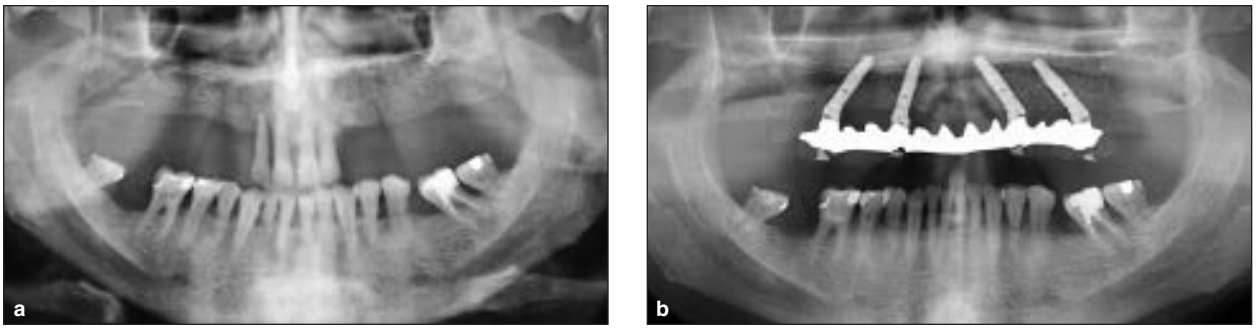

Fig 3 Panoramic radiographs of patient **(a)** before treatment and **(b)** after 6 years of function with the Columbus Bridge.

Table 1 Columbus Bridge Protocol: Main Characteristics of the Surgical and Prosthodontic Protocols for Full-Arch Treatment of Edentulous Maxillae with Immediate Loading

Surgical protocol	Prosthodontic protocol
External hex rough-surface implants	Screw-retained fixed prosthesis
Implant length ≥ 10 mm, ∅ 4 mm	Plaster impression with pick-up technique
Underprepared osteotomy	Rigid splinting with metal framework
Implant insertion torque ≥ 40 Ncm	Passive fit with the luting technique
Angled implants in pristine bone	Acrylic resin occlusal surfaces
Angled conical abutments	No distal cantilevers
No bone-regeneration techniques	Immediate functional loading 24 h postsurgery

advised to give up smoking. A smoking-cessation protocol was not provided. However, none of the included patients was a heavy smoker (> 20 cigarettes/day). All patients signed an informed consent form and agreed to return for the required recall appointments.

The surgical and prosthodontic protocols required sufficient bone volume to accommodate a minimum of four implants (with a 4-mm diameter and ≥ 10-mm length) in the selected host bone sites. Patients who required bone grafting prior to implant placement were excluded. Opposing dentitions consisted of natural teeth or were restored with fixed or removable prostheses. Patients with opposing mandibular complete dentures were excluded because they were not able to load the study prostheses with forces comparable with the other patients.

The unfavorable prognoses for the maxillary dentitions of patients in this study were attributed to periodontal disease (n = 28), endodontic failures (n = 10), and caries (n = 11).

When appropriate, patients were offered conservative teeth retention therapy. However, dissatisfaction with previous conservative therapies and economic considerations induced patients to refuse this kind of treatment.

Patients were divided into two unmatched groups based on their existing maxillary condition (preexisting maxillary edentulism or candidates for a similar predicament) and on their preference. The patients in the test group were selected for treatment with the immediate loading protocol because of both their expectations and demand for immediate, fixed implant prostheses; they sought to avoid the use of a transitional complete denture. On the other hand, the patients in the control group were willing to accept wearing a complete denture for a short time interval, and this cohort was composed of older patients relative to the test group (median age: 59.3 vs 57.1 years).[5]

The test group included 34 patients (19 women, 15 men; mean age: women = 53.7 years, men = 60.5 years) with poor prognoses for their residual maxillary dentitions. These subjects underwent postextraction implant placement with immediate loading according to the CBP. Provisional fixed screw-retained prostheses were placed within 24 hours of implant placement. The definitive prostheses were delivered after a mean healing period of 4.5 months.

The control group was composed of 15 patients (6 women, 9 men; mean age: women = 56.0 years, men = 62.6 years) with maxillary teeth with poor prognoses who were made edentulous at least 3 months prior to implant surgery and were treated with transitional complete dentures.

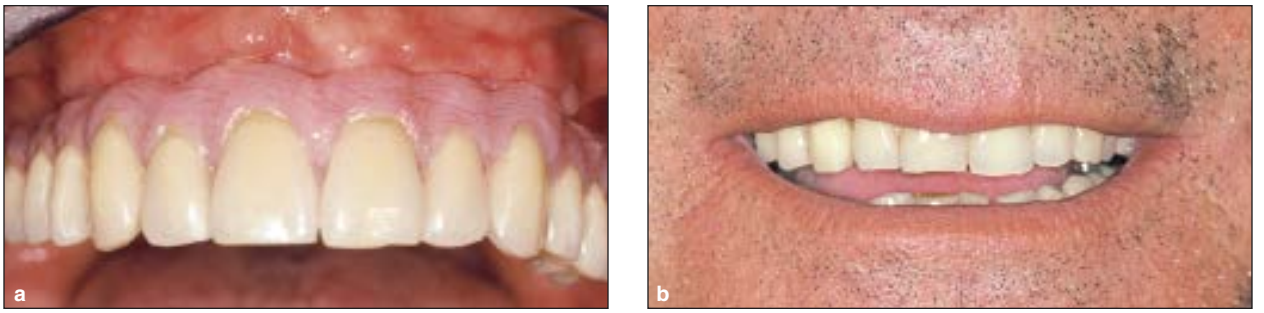

Fig 4 Control group patient **(a)** at the delivery of the fixed prosthesis and **(b)** at 1 year of function.

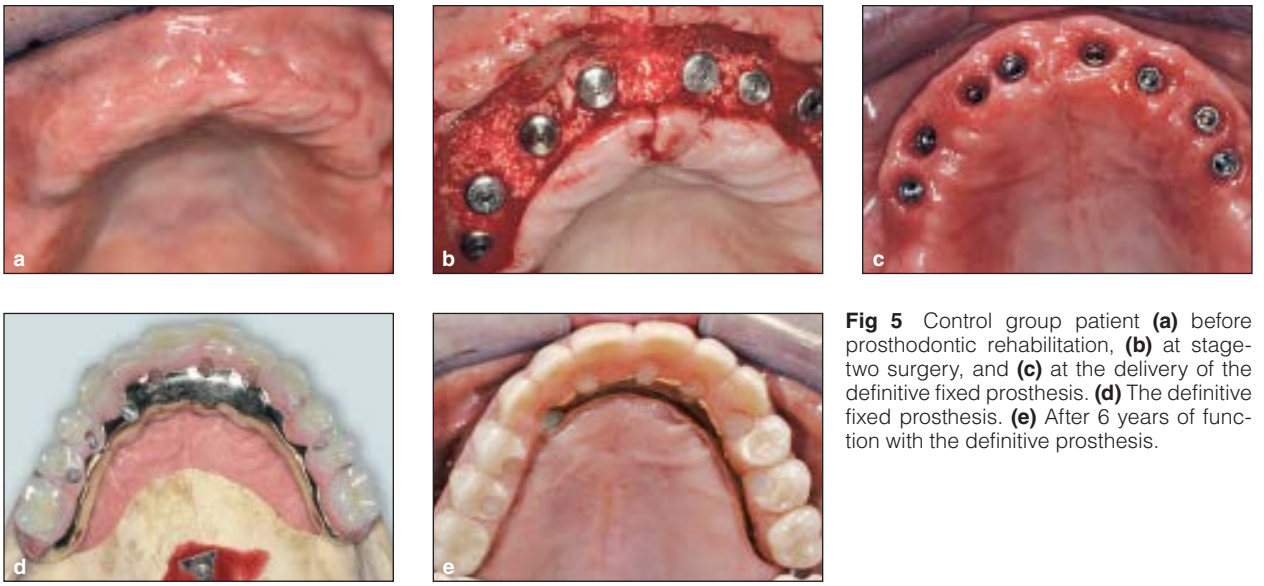

Fig 5 Control group patient **(a)** before prosthodontic rehabilitation, **(b)** at stage-two surgery, and **(c)** at the delivery of the definitive fixed prosthesis. **(d)** The definitive fixed prosthesis. **(e)** After 6 years of function with the definitive prosthesis.

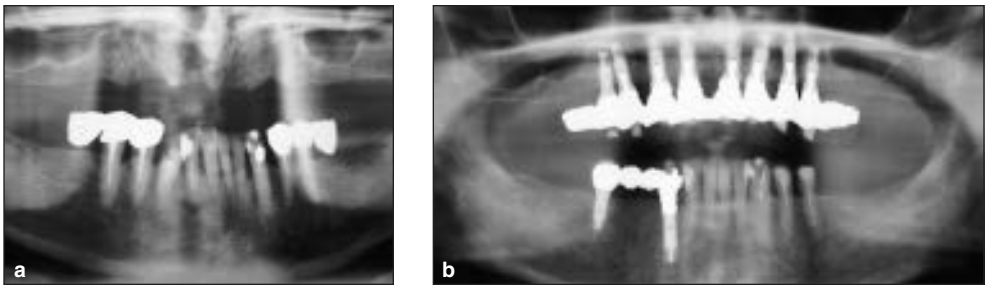

Fig 6 Panoramic radiographs of control group patient **(a)** before treatment and **(b)** after 6 years of function with a delayed loading fixed prosthesis.

These patients underwent the standard two-stage protocol with delayed loading.[7] Definitive fixed screw-retained prostheses were placed after a mean healing period of 8.75 months. Details about the surgical and prosthodontic protocol applied are reported in previous papers.[5,6]

Patients were selected and treated by expert clinicians (three of the authors: PP, TT, MB), and the only differences in surgical/prosthodontic protocols and maintenance programs between the control and test groups were time sequence for teeth extraction and implant loading and number and inclination of implants.

Assessment

Parameters evaluated were: implant and prosthodontic cumulative survival rate, prosthodontic complications, and cumulative success rate and peri-implant bone resorption by means of periapical radiographs with individualized film holders.[5]

Cumulative implant survival outcomes were based on clinical testing only; therefore, only implant losses were considered failures.

Maintenance considerations for each prosthesis were recorded as per the traditional protocols[8] and included the nature and number of events per patient, such as fractured hardware and acrylic resin superstructure, prosthesis remakes, and screw loosening. Prosthodontic success was defined as an unmodified original prosthodontic treatment plan.

Success criteria were derived from Zarb et al.[9] Implant therapy was considered successful when it resolved prosthodontic problems meeting the clinically evolved standards of function, comfort, and esthetics. It had also to allow for routine maintenance and permit planned or unplanned revisions of the existing design.

The criteria for implant success applied to individual endosseous implants and included the following: at the time of testing, the implants have been under functional loading; all implants under investigation must be accounted for; individual unattached implants were immobile when tested clinically; radiographs to measure bone loss were standard periapical films with specified reference points and angulations as described below; the resultant implant support did not preclude the placement of a planned functional and esthetic prosthesis that was satisfactory to both patient and clinician; there was no pain, discomfort, altered sensation, or infection attributable to the implants; and the mean vertical bone loss was less than 0.2 mm annually after the first year of function.

Implant mobility was clinically assessed by torquing the abutment screws to 20 Ncm with a calibrated torque wrench (Contra Angle Torque Driver, Biomet 3i).

To guarantee reproducibility of the radiographs over time, they were made using a long-cone paralleling technique with an individualized film holder (Rinn bite film holder for periapical radiographs, Dentsply) and a customized centric occlusion registration with a polyvinyl siloxane impression material putty (Express STD, 3M ESPE).[5]

The implant-abutment interface was used as the reference point for the bone-level measurements. Interproximal bone levels were assessed from these reference points to the most coronal bone levels at the mesial and distal surfaces of each implant, using a diaphanoscope (Tecno-Gaz) and magnifying lens.

Statistical Analysis

Mean values and SDs were reported for bone resorption at baseline and at 3 and 6 years from surgery. The generalized estimating equation (GEE) model was used to take into account the possible correlation between measurements of implants from the same patient. Statistical analysis was completed using SPSS version 15.0 software (IBM) with alpha set to .05.

Results

A total of 260 implants (test: n = 163, control: n = 97) were placed in the maxillae of 49 patients (test: n = 34, control: n = 15). At the 6-year follow-up, 2 patients had dropped out. One patient with 4 implants in the test group died, and 1 patient in the control group with 7 implants relocated.

The other 47 patients were followed up for a mean observation period of 75.2 months (range, 72 to 90 months) after surgery.

As described in a previous paper reporting the 36-month follow-up for these patients,[5] 10 implants (6.1%) failed in the test group during the first 3 months after implant placement. Two patients lost 2 implants each, and 6 patients lost 1 implant each. Six of the 10 implants lost were distal implants. Of the 10 implants that failed in the test group, 6 new implants were placed into the distal areas to increase molar support in the prostheses and were immediately loaded. These implants were not considered in the survival calculations or for peri-implant bone-level evaluations.

In the control group, 4 implants (4.1%) failed during the first 12 months after implant placement. One implant failed before it was uncovered, and 3 implants were lost 2 months postloading, approximately 8 months after implant placement. No patients had more than 1 implant failure, and no additional implants were placed after implant failure.

No implants were lost between the 36-month and 75.2-month follow-ups, resulting in a cumulative survival rate of 93.9% (95% confidence interval [CI]: 90% to 97.8%) for the test group and 95.9% (95% CI: 92% to 99.8%) for the control group at the 6-year follow-up (Fig 7). The difference in cumulative survival rates between the test and control groups was not statistically significant ($P = .42$).

All the original fixed prostheses were functioning and did not need to be replaced, resulting in a prosthodontic cumulative survival rate of 100% for both the test and the control groups. Ten fractures of the veneering material were recorded. Minor fractures (four in the test group and three in the control group) were easily adjusted by the clinician without sending the

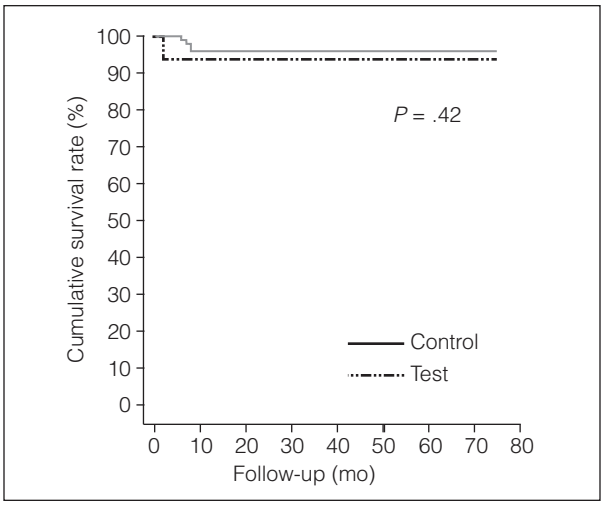

Fig 7 Life table analysis for implants in the test and control groups.

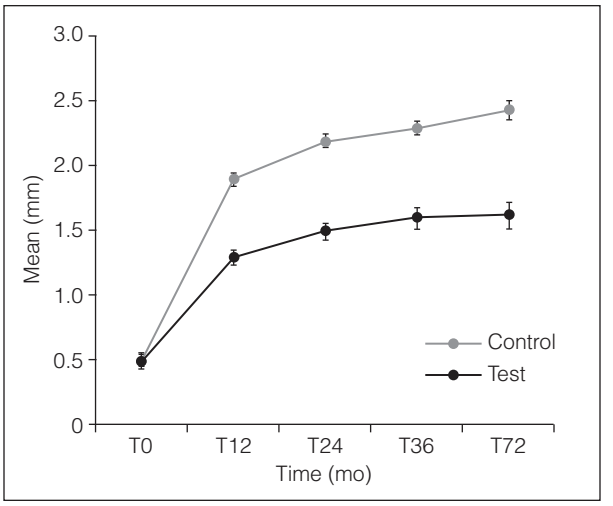

Fig 8 Bone-level comparisons between baseline (T0) and 6-year follow-up appointments (T72) for the test and the control groups.

Table 2 Mean bone loss (mm) comparison during the 6-year follow-up.

	Mean bone loss (SD)				
	Test group		Control group		
Time	Mesial	Distal	Mesial	Distal	P*
Baseline	0.6 (0.7)	0.4 (0.6)	0.49 (0.66)	0.47 (0.68)	
3 y	1.6 (0.8)	1.5 (0.9)	2.35 (1.12)	2.27 (1.04)	< .001
6 y	1.62 (1.12)	1.63 (1.34)	2.43 (1.44)	2.48 (1.44)	

**P* value for the difference between test and control group on trend over follow-up.

prostheses back to the laboratory. Major fractures (two in the test group and one in the control group) were adjusted on the same day by sending the screw-retained prostheses back to the laboratory. No complete fractures (fracture of the metal framework) were encountered. This led to a prosthodontic cumulative success rate of 82.4% for the test group and 73.3% for the control group at the 6-year follow-up.

Another technical complication was the loosening of prosthetic screws (three in the test group and five in the control group). This inconvenience was detected during the annual follow-up visit and promptly solved.

Mean bone level at baseline was approximately 0.5 mm from the implant-abutment connection in both the test and control groups. After 12 months, it was 1.33 ± 0.85 mm in the test group and 1.94 ± 0.79 mm in the control group, while at 36 months it was 1.56 ± 0.85 mm in the test group and 2.31 ± 1.08 mm in the control group. At 72 months, it was 1.62 ± 1.23 mm in the test group (1.62 ± 1.12 mm on the mesial side and 1.63 ± 1.34 mm on the distal side) and 2.44 ± 1.44 mm in the control group (2.43 ± 1.44 mm on the mesial side and 2.48 ± 1.44 mm on the distal side) (Fig 8). Globally, the trend over time was statistically significant ($P < .001$), as previously reported.

Based on the considerations for successful outcomes with implant-supported prostheses proposed by Zarb et al[9] and reported in the Materials and Methods section, implant therapy both in the test and control groups was considered successful in all patients who did not report any implant loss.

A significant difference on trend over time was observed when comparing the test and control groups ($P = .001$), with a nonsignificant difference when comparing measurements at 36 months and at 72 months ($P = 0.63$). No significant differences in bone resorption were present between the mesial and distal aspects of implants ($P = .73$), and the interaction between groups and mesial or distal sides was not statistically significant ($P = .84$). This implies that the impact of treatment group on bone resorption did not depend on mesial or distal sides. Results for bone resorption are reported in Table 2.

Discussion

Based on the present study, the immediate loading protocol demonstrated good outcomes at the medium-term follow-up (75.2 months). No statistically significant differences were found in implant and

prosthodontic cumulative survival rates with respect to the traditional two-stage delayed loading protocol. Bone-level analysis revealed moderate peri-implant bone resorption during the first 12 months and a steady-state condition during all other intervals. This is consistent with a normal bone-remodeling phase subsequent to surgical trauma.

In the present investigation, the control group exhibited a greater survival rate but also a greater bone resorption when compared with long-term studies using similar approaches.[7,8] This might be due to differences in clinical procedures, such as a greater implant number per arch in the present study. However, a similar pattern in implant failure has been found. In fact, the long-term study by Attard and Zarb[8] found a greater number of implant failures in stage-two surgery and after loading. Only one late implant failure occurred after 17 years of loading because of fracture of the implant. Similarly, no implant failures occurred after the 1 year follow-up in the present study.

In the test group, the induced ankylotic response of osseointegration enabled the authors to compensate for the reduction in the number of prescribed implants through angulated placement of longer implants (see Table 1). In fact, it has been reported that an 11.5-mm-long implant presents a 10% greater surface area compared with a 10-mm-long implant, a 13-mm-long implant presents 20% more surface area compared with a 10-mm-long implant, and a 15-mm-long implant presents 33.3% more surface area compared with a 10-mm-long implant. Longer implants increase the extension of induced areas of osseointegration. This approach also has the added merit of bypassing postextraction sites and low-density bone anatomical sites and avoiding too short a dental arch. This might be of interest in cases of enhanced esthetic concerns in the maxilla (eg, patients with a broad smile).

Slightly greater bone resorption was found in the control group, with a statistically significant difference compared to the test group. This finding might be dependent on differing number of implants or on the differences in loading. While the proximity of adjacent implants in the control group could have had a bearing on marginal bone loss,[10] a minimum interimplant distance of 3 mm was always maintained, as suggested in the literature.[11]

It is the authors' opinion that extraneous lateral loads and stresses on the nonloaded, covered implants could be responsible for increased bone loss in the control group in the first 12 months after implant placement. In fact, the provisional removable denture is responsible for a "mucosal load" on the unsplinted implants. In contrast, in the test group, fixed provisional prostheses were fabricated with metal substructures and inserted within 24 hours of implant placement. Metal substructures increase prosthesis rigidity in splinting implants and appear to provide superior stress distribution in supporting tissues.[12,13]

Moreover, the apices of the longer implants in the test group were more likely to be placed in healed native bone as opposed to the implants placed in mouths in the control group (implants were inserted at least 3 months postextraction).

It is recognized that individual implant success should not be assessed separately from a successful prosthodontic result.[8,14] If maintenance of an implant-supported prosthesis is viewed as the objective of treatment, the cumulative survival rate in this study was 100% for both the test and the control groups. Several technical complications occurred (veneering material fractures) but were repaired the same day.

Some shortcomings of the present study must be emphasized. First of all, the patients selected were part of a convenience sample and not the result of a power analysis to determine an optimal sample size. Moreover, the test and control groups were not randomly selected; they were unmatched, treated differently, and seen by the same team of experts. All of these concerns demand that the reported results be interpreted with caution. Test group patients received four to six implants in fresh extraction or healed edentulous sites, while control group patients received six to nine implants in recently healed edentulous sites. Tapered implants were placed in extraction sites while cylindric implants were placed in healed sites. Other differences between the groups related to the prosthodontic treatment phase. The test group was treated according to the CBP for immediate rehabilitation of edentulous maxillae,[5] while the control group was treated according to the two-stage protocol as proposed by Brånemark et al.[7,15,16] Therefore, it must be considered that overall differences between the two groups could affect the interpretation of the results.

Within these limits, the present study, with a 6-year follow-up, demonstrated that the immediate loading of implants placed in edentulous maxillae, out of the traditional vertical alignment protocol, was successful in both promoting osseointegration during the initial healing phase and maintaining osseointegration in the long term with similar or better outcomes when compared with the traditional two-stage delayed loading protocol.

Conclusions

A 6-year follow-up of the application of the CBP for immediate rehabilitation of edentulous maxillae led to similar treatment outcomes with the traditional two-stage protocol in terms of implant and prosthodontic

cumulative survival and success rates. Moreover, greater peri-implant bone loss was noted in patients treated with the delayed loading protocol.

Acknowledgments

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Literature Abstract

Clinical recommendations regarding use of cone beam computed tomography in orthodontics. Position statement by the American Academy of Oral and Maxillofacial Radiology

This positional paper summarized the benefits and risks of maxillofacial cone beam computed tomography (CBCT) use in orthodontic diagnosis, treatment, and outcomes and provides clinical guidance to dental practitioners. CBCT in orthodontics has the advantage of generating numerous linear and curved planar projections derived from a single CBCT scan and the possibility of image reconstruction. Guidelines for the suggested use of CBCT in orthodontic practice consider four factors. *(1)* The appropriate image according to clinical condition, ie, the clinical condition must justify the exposure of the patient to radiation, and no existence of a better choice of imaging method with a lower or nil radiation exposure. The CBCT protocol must restrict the field of view (FOV) and minimize exposure (mA and kVp). Additional two-dimensional radiographs are to be avoided if a CBCT is justified. *(2)* Assess the radiation dose risk. Relative radiation level should be considered over the course of orthodontic treatment. Patients must be informed of the risk and benefits of CBCT, considering that CBCT is an ionizing radiation. *(3)* Minimize patient radiation exposure through proper setting of CBCT parameters, reduction of FOV to match region of interest, use of patient protective shields, and ensuring that CBCT equipment is properly calibrated, maintained, and inspected. *(4)* Maintain professional competency in performing and interpreting CBCT studies, including the attendance of continuing education courses, compliance with regulatory requirements, and having patients/guardians informed of the limitations of CBCT in visualizing soft tissues, artifacts, and noise.

American Academy of Oral and Maxillofacial Radiology. *Oral Surg Oral Med Oral Pathol Oral Radiol* 2013;116:238–257. **References:** 216.
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