

New-Design Dental Implants: A 1-Year Prospective Clinical Study of 344 Consecutively Placed Implants Comparing Immediate Loading Versus Delayed Loading and Flapless Versus Full-Thickness Flap

Eliezer Meizi, DMD¹/Mamraev Meir, DMD, LLB²/Zvi Laster, DMD³

Purpose: This study compared the 1-year success rates of immediately loaded dental implants to delayed loaded implants, regardless of the surgical technique (flapless or conventional full-thickness flap) and regardless of extraction time. It also examined whether the surgical technique had an influence on the success rate of the immediately loaded implants. **Materials and Methods:** A total of 344 dental implants, some with a new expanded winged-thread design, were placed in 155 patients; 53% of the implants were immediately loaded. Of the immediately loaded implants, 68.9% were placed with a flapless surgical technique and 88% were placed in extraction sites. Pocket depth, mobility, bleeding on probing, presence of erythema, pain, or radiolucency around the implants, as well as clinical findings, were recorded. Implants were followed from placement through definitive restoration. Descriptive, univariate, and multivariate analyses using clustered marginal approach of the Cox proportional hazards model were applied. **Results:** Of the 344 implants in the study, 10 (2.9%) failures were recorded, 7 of which were immediately loaded; however, there was no significant difference in failure rates between the immediate and delayed loading groups. Seven of the implants that failed were placed with a flapless (extraction site) technique; however, there was no significant difference in the failure rates between the flapless versus full-thickness flap technique in immediately loaded implants. **Conclusions:** The clinical success of immediately loaded implants after 1 year showed no difference from the success rate of delayed loaded implants. The implantation procedure (flapless versus conventional flap) or extraction time also had no influence on the success rate of the immediately loaded implants. INT J ORAL MAXILLOFAC IMPLANTS 2014;29:e14–e21. doi: 10.11607/jomi.te37

Key words: dental implants, flapless implant placement, immediate loading, implant failure, implant success, open flap

Fixed restoration immediately after implantation has become more commonly used in implant dentistry. Patients seek to reduce discomfort and dysfunction, and often they demand immediate esthetics.^{1,2}

¹Research Assistant, Department of Periodontology, Tel Aviv University School of Dental Medicine, Tel Aviv, Israel.

²Private Practice, Tel Aviv, Israel.

³Head, Department of Oral and Maxillofacial Surgery, Poriya Hospital, Tiberias, Israel.

Correspondence to: Dr Eliezer Meizi, Department of Periodontology, Tel Aviv University School of Dental Medicine, Tel Aviv, Israel. Email: meizi.eliezer@gmail.com

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In the past 25 years, the standard protocol for placing dental implants has been a two-stage approach. During the first stage, the implant is inserted into the bone and it heals without loading for 3 months in the mandible or for 6 months in the maxilla. In the second stage, the implant is exposed and then loaded with a prosthesis.^{3,4} The load-free healing period was suggested to be crucial for implant integration,⁵ with the rationale that osseointegration must take place before the implant is loaded in order to minimize the risk of failure.^{6,7}

Immediate implant loading is defined as occlusal loading of a provisional or definitive prosthesis within 72 hours after implant placement.⁸ In a meta-analysis of 13 prospective clinical studies involving 1,266 implants, Loannidou and Doufexi⁹ reported that implant

failure occurred slightly less often with early loading and slightly more often with immediate loading compared with conventional two-stage implant placement, but these differences were not statistically significant. Although immediate loading of implants shortens treatment duration and also provides patients with an acceptable esthetic appearance, there is concern that immediate loading may increase the risk of implant failure.¹⁰

The aim of this study was to document prospective clinical data on immediate loading of implant-supported prostheses. First, the success rates of immediately loaded dental implants and delayed loaded implants were compared at 1 year post-implant placement. Second, the authors sought to determine whether there was a difference in the success rates of the immediately loaded implants when a flapless versus a conventional full-flap procedure was used.

The hypotheses of this study were that: (1) there is no significance difference in the success rate of immediately loaded implants compared to delayed loaded implants and (2) the surgical procedure—flapless versus conventional flap technique—will not affect the success rate of immediately loaded implants at 1 year post-implant placement.

MATERIALS AND METHODS

Patients were treated with Cortex implants, including regular and the new expanded winged-thread implants (Saturn) (Cortex, Shlomi, Israel), placed by professional dentists with more than 15 years of experience in implant dentistry. The implants were placed from 2009 to 2011. A total of 344 implants were placed in 155 patients during this period, 184 of which were immediately loaded. Of the 184 immediately loaded implants, 155 were placed using a flapless surgical procedure.

Reinforced provisional restorations, with or without vertical or lateral contacts with the antagonist teeth, were placed on all of the immediately loaded implants within 36 hours of implant placement. In the majority of cases, the provisional restoration was placed on the same day as implant insertion. Implants that did not achieve primary stability were not included in the research statistics.

Patient Selection

Study candidates were consecutive patients who presented in the dental clinic with at least one missing tooth and who met the study criteria, namely: adequate vertical bone volume (8 mm or more), adequate bone width to retain at least 1 mm of cortical bone on the buccal and lingual/palatal after osteotomy preparation,

skeletal maturity, age between 20 and 70 years, and provision of informed consent. Implants had to achieve a minimum placement torque of 30 Ncm. Subjects with a history of alcoholism, drug abuse, recent myocardial infarction, uncontrolled diabetes, local radiation therapy, or who were on long-term steroid therapy were excluded from participation.

Study Variables

1. Demographic variables: Age at the time of implant placement (year) and gender
2. Health status: Current tobacco use status, presence of controlled diabetes
3. Anatomical variables: Implant location (maxilla, mandible, anterior, posterior), dentition status (partially or completely edentulous), and bone quality (types 1 to 4)
4. Implant-specific variables: Implant diameter and length
5. Prosthetic variable: Provisional restoration for only one tooth or a fixed prosthesis of two or more units
6. Surgical variables: Open or closed sinus elevation, extraction site or nonextraction site, flapless or conventional flap, and autogenous or allogeneic bone grafting
7. Survival analysis: Calculated based on date of implant placement, dates of follow-up visits, and date(s) of implant failure(s)

Medication Protocol

Prophylactic administration of antibiotics in implant therapy is common, as studies have shown an association with lower implant failure rates.^{11–14} Each patient was prescribed amoxicillin (2 g orally 1 hour before surgery, followed by two additional 500-mg doses that day and then 500 mg three times a day for 5 days. Patients with amoxicillin sensitivity were prescribed clindamycin (600 mg 1 hour before surgery, followed by 150 mg four times a day for 5 days). On the day of surgery, patients were prescribed analgesics for pain control.

Surgical and Prosthodontic Procedures

Patients were prepared for aseptic surgery and received local anesthesia. For sites prepared with conventional flap surgery, midcrestal and vertical releasing incisions were made in the gingiva, and full-thickness mucoperiosteal flaps were elevated to expose the underlying alveolar bone. In accordance with the implant manufacturer's protocol, implant osteotomies were prepared according to bone density, and the implants were placed with a self-tapping technique. Only implants that exceeded 30 Ncm of insertion torque were immediately loaded. Periapical radiographs were obtained after implant placement to verify adequate implant positioning.

Table 1 Implant Data

Location/no. of implants	% of patients
Anterior maxilla	
0	56
1	35
2+	9
Posterior maxilla	
0	64
1	22
2+	14
Anterior mandible	
0	90
1	5
2+	6
Posterior mandible	
0	72
1	14
2	8
3+	6
All areas	
1	69
2	12
3	4
4+	15

N = 155 patients, 344 implants.

Provisional restorations were placed 0 to 36 hours after implant and abutment placement. Restorations were designed with or without contacts in lateral movement. The soft tissue was sutured around the prosthesis for implants placed with conventional flap techniques. Ten to 14 days after surgery, after soft tissue healing was complete, the sutures were removed and the occlusion was checked again.

Implants that were not loaded immediately because of inadequate insertion torque were exposed and finalization of the prosthesis proceeded 3 to 6 months after implant placement (mandibular implants exposed 3 months after implantation and maxillary implants after 6 months).

Follow-up

Patients returned 3 to 9 months after implant loading for assessment of implant stability, oral hygiene, and peri-implant marginal bone levels. At these appointments, manual pressure and percussion were applied to rule out the presence of implant mobility, radiographs were obtained to discover any peri-implant radiolucencies, and any changes in peri-implant marginal bone levels were documented. The definitive restorations were provided with final occlusal and lateral contacts 3 to 9 months postoperatively.

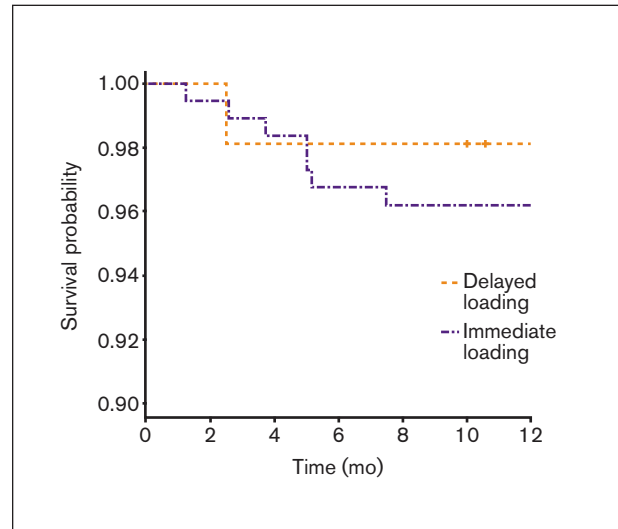


Fig 1 Kaplan-Meier survival curves. The 1-year survival rate of immediately loaded implants (purple line) is 96.2% and that of delayed loading (after 3 to 6 months, depending on the jaw) implants (gold line) is 97.1%.

Statistical Analyses

Microsoft Excel was used to create a database of patient information. R statistical software (R, Coreteam) was used for analyses of the data. Descriptive statistics were computed for all study variables. Nonparametric Kaplan-Meier survival analyses were used to predict the overall 1-year survival rate with associated 95% confidence intervals. The criteria for success included presence of an occlusal functioning asymptomatic implant restoration with stable peri-implant bone levels observed on periapical radiographs as well as healthy peri-implant gingival tissue. The log-rank test was used to indicate the differences in survival across loading methods. The chi-square test was applied to determine whether there was an association between implant failure, loading method (immediate loading versus late loading), and extraction or nonextraction site placement. This test was used to indicate whether there was a significant difference in the proportion of implant success identified in the current sample versus known values obtained in previous studies. The Fisher exact test was applied to determine whether there was a difference in the failure rate associated with implants that were placed without flaps, usually in extraction sites, and those that were placed with flaps.



Fig 2 Case 1. Winged implant (Saturn) with abutment and impression coping.



Fig 3 Saturn implant and abutment. The extended wing is self-tapped.

RESULTS

The mean age of the patients in this study was 47.5 ± 9.3 years; 61% were female. The majority of the patients (92%) were healthy; 7% had controlled diabetes mellitus, and 8% had smoked more than 10 cigarettes per day for more than 1 year.

A total of 344 implants were placed in 155 patients between 2009 and 2011. One hundred eighty-four implants were loaded immediately and 160 implants were loaded after a healing period of 3 to 6 months (3 months for mandibular implants and 6 months for maxillary implants). Two hundred thirty-seven implants were placed with a flapless procedure and 107 implants were placed with conventional flaps. Of the 184 immediately loaded implants, 155 were placed with the flapless protocol and 161 were inserted at the time of extraction. Most of the implants were placed in the maxilla (211 implants), most frequently in the posterior arch (113 implants) (Table 1). Two hundred fifteen implants (62.5%) were inserted immediately after extraction and 129 implants were placed into osseous sites healed at least 3 months after extraction and up to 10 years after extraction.

During the follow-up period, 10 implants failed (2.9%); 7 had been loaded immediately and 3 had been loaded later. The overall 1-year survival rate (95% confidence interval [CI]) was 97.1% (95.3%, 98.9%). The median time to failure was 45 days. The overall 1-year survival rates were 96.2% (95% CI: 93.5%, 99.0%) for immediate loading and 98.2% (95% CI: 96.05%, 100.00%) for delayed loading.

However, the log-rank test indicated that the differences in survival with respect to loading method were not significant ($\chi^2 = 1.1$; $P = .29$) (Fig 1).

One hundred fifty-five implants were placed without a flap and loaded immediately. Seven failures were recorded for flapless/immediately loaded implants, compared to zero failures for full flap/immediately loaded implants. However, there was no significant difference in the failure rate between the two methods ($P > .05$).

Two hundred fifteen of the implants (62.5%) were placed immediately after extraction; of these, 161 (88%) were immediately loaded. Seven implant failures were recorded for immediately placed (post-extraction) implants that were also immediately loaded. The results indicated that there was no significant difference in the proportions of failure between immediately loaded implants that had been placed immediately postextraction compared with implants that had been placed into healed sites ($P > .05$).

Regardless of surgical technique (flapless versus full flap), the success of immediate loading of implants in the present study was statistically significantly not different from the success of implants in other published studies ($P < .05$).

Two cases are presented to illustrate the study findings. In the first case (Figs 2 to 9), side-by-side winged-thread implants were placed and immediately loaded due to high insertion torque provided by the expanded thread design. A full-arch case (Figs 10 to 15) shows the use of multiple implant designs used in an immediately loaded splinted scheme. All implants osseointegrated and proceeded to final restoration uneventfully.

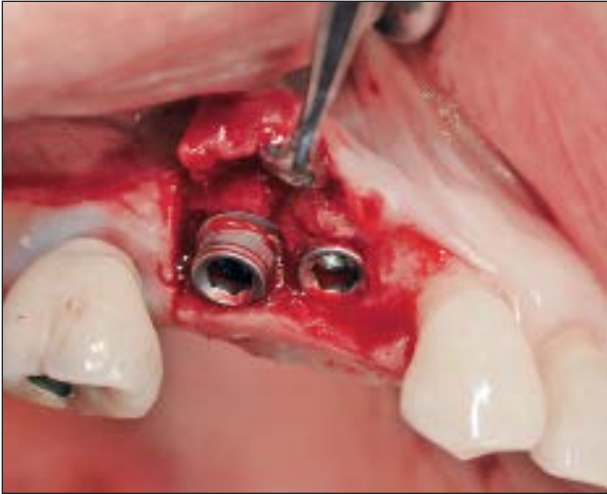


Fig 4 Second winged implant is inserted.



Fig 5 Abutments are seated.



Fig 6 Provisional prosthesis is made on two preformed plastic caps.



Fig 7 The flap is sutured.



Fig 8 Periapical radiograph.



Fig 9 Provisional prosthesis 4 months postoperative.



Fig 10 Case 2. Flapless preparation.



Fig 11 Temporary abutments.



Fig 12 Provisional prosthesis.



Fig 13 Postoperative radiograph.



Fig 14 Provisional prosthesis cemented.



Fig 15 Final restoration.

DISCUSSION

The standard protocol for placing dental implants has been a two-stage approach, a protocol with very good long-term results.^{3,4} However, patients have found the lengthy healing period uncomfortable, unesthetic, and excessive,¹⁵ and have demanded shortened healing periods and immediate loading of implants.⁵ The aims of this study were: (1) to determine the 1-year survival of immediately loaded implants using three different types of Cortex implants and (2) to conclude whether the survival rate of immediately loaded implants differed according to surgical procedures used (flap-less versus conventional flap).

In the present study, the overall 1-year survival rates with associated 95% confidence intervals were 96.2% (93.5%, 99.0%) for immediate loading and 98.2% (96.05%, 100.00%) for delayed loading. The log-rank test indicated that these differences in survival with respect to the timing of loading were not significant ($\chi^2 = 1.1$; $P = .29$) (see Fig 1). The survival rates seen here are better than the mean survival rates reported in other studies, which have observed 1-year survival rates of 90.3% to 95% for immediately loaded implants.^{16–19}

The second goal of this study was to determine whether the surgical technique influenced the survival rate of immediately loaded implants. Immediately

loaded implants, whether placed with or without a conventional flap, achieved similar survival rates as previous studies ($P < .05$).

This study, along with other studies of immediately loaded implants,¹⁶⁻¹⁹ provides further evidence that this procedure is safe and predictable. Moreover, the results of the three techniques—flapless/open flap, immediate postextraction placement or placement in healed sites, and immediate or delayed loading—should help clinicians to choose the appropriate surgical techniques for a given patient, with the understanding that the surgical protocol will not influence the success rate of immediately loaded implants.

The fact that 95 of the 164 immediately loaded after extraction implants were expanded winged-thread implants (Saturn) leads us to believe that the new design of these implants may have helped to achieve the better success rates for the implants that were immediately loaded after extraction.

CONCLUSION

Implants were loaded immediately in selected subjects when good primary stability and appropriate occlusal load was achieved. The overall 1-year survival rate for immediately loaded implants was 96.2%. Although the sample size was too small to statistically compare flapless to full-flap implant placement in the present cohort, it was significant that there was not an increased failure rate for immediate loading compared to delayed loading. The overall conclusion is that immediate loading of implants can be safely performed.

DISCLOSURE

Dr Laster has a financial interest in Cortex Implants, Inc.

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