Immediate Restoration with Ti-Unite Implants: Practice-Based Evidence Compared with Animal Study Outcomes

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Purpose: Clinicians often do not have the benefit of adequate safety or clinical data when evaluating the merit of either newly marketed implant devices or novel clinical procedures. This has been the case for dental implants following the initial documentation of their safety and efficacy and is demonstrated in the evolution of immediate load application. Following demonstration of safety and successful application of an implant in an animal study prior to its market release, this report provides the clinical outcomes for the first 100 Ti-Unite implants provided to 24 patients in a clinical practice over 9 years. ***Materials and Methods:*** An electronic record/clinical database review of consecutive early loaded implants from a multiple surgeon/single prosthodontist practice was conducted for quality assurance. Data extraction of standard exposure and outcome variables was accomplished by a trained individual not affiliated with the clinical practice. ***Results:*** The results revealed one failure before and none following definitive restoration with a variety of prostheses. The mean length of time from immediate to definitive restorations was 5.3 ± 1.1 months for crowns, 3.9 ± 1.3 months for fixed partial dentures, and 7.8 ± 4.1 months for mandibular "hybrid" prostheses. The most common unexpected findings during the initial three postinsertion visits were lost access restoration and cement failure. ***Conclusions:*** Pre-market animal data regarding the safety and success of a new implant used with an early loading protocol was replicated in the clinical results of the first 100 implants used in practice. Additionally, the clinical results are favorable when compared to conventional loading protocols from this same practice and provide helpful comparative metrics (delayed vs immediate loading) to use when discussing implant treatment with patients. *Int J Prosthodont 2011;24:199–203.*

Dental implants have been demonstrated to provide predictable prosthesis support for a broad range of missing tooth conditions.[1–5] Comparative studies suggest implant-supported prostheses to be effective at addressing the perceived functional burden associated with tooth loss,[6] especially those most related to functional stability.[7] Having demonstrated predictable, stable prosthetic performance characteristics with dental implants, additional outcomes have been the focus of significant research and marketing attention.[8,9]

Providers are continually being urged to consider new and improved implant products and techniques that constitute modifications to originally tested clinical protocols. Often, clinicians are provided very little clinical outcome data demonstrating patient benefits to convincingly argue for something new. More specifically, seldom do we, provider "consumers" who use implantable devices in our patients and are faced with making both a business practice and health care decision when considering use of new products or techniques, have the foreknowledge of outcome expectations from human trials when considering implant practice change. Evidence from cell culture studies and animal trials, while providing surrogate measures of tissue-device interaction, safety, and healing expectations, is not often evaluated against subsequent clinical outcomes to understand the validity of early claims and how representative the animal research evidence may be of human outcomes.[10]

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An example of a protocol technique change presented to clinicians over the past 2 decades has involved providing implant-supported replacements during the initial bone wound healing phase, referred to as immediate or early loading.* The initial protocol considered the need to allow wound maturation prior to imposing physical energy to the dynamic wound healing environment to be vitally important,[12] but the delay in treatment was considered objectionable by some patients and clinicians, and earlier restoration of implants began to be performed to address this concern.[13–19]

The research, both animal studies and clinical reports, has described immediate or early restoration results at the tissue[20–22] and patient level.[23–26] A common strategy for many of these studies was investigation of implant surface features, which aimed to guide wound healing responses that might allow earlier mechanical use. Specifically, textured surfaces were claimed to demonstrate improved bone anchorage, as measured structurally and mechanically, suggesting successful earlier functional loading without compromised performance.

A prior animal study investigated the hypothesis that a textured surface implant created through an oxidation process would perform better than a successful standard control machined implant when both were loaded earlier than the conventional protocol.[27] The findings showed early loading of both implant types was well tolerated, since only two failures occurred following loading. The textured surface performed better than the control, lending support to clinical application of early loading protocols by one of the authors.

This report is a follow-up to that animal study[27] and provides clinical outcomes for 24 patients and 100 Ti-Unite (Nobel Biocare) implants exposed to immediate loading with provisional prostheses that were subsequently restored definitively. The outcome summary provides data used to inform patients considering the same intervention in a shared decision-making process[28] using provider-specific data.

Materials and Methods

An electronic record/clinical database review was conducted for clinical use of Ti-Unite implants from their initial placement in 2000 through 2009. The specific clinical application reviewed in this report is that of implants used for supporting tooth replacements either immediately after surgery or within a short time period, dictated by day of surgery anesthesia impact on patient ambulation or the number of visits required to provide acceptable prostheses (ie, all within the first week postoperative).

This report includes patients provided with implant prostheses by a single prosthodontist in conjunction with two oral and maxillofacial surgeons. The review comprised the first 100 implants in 24 patients managed for various immediate loading missing tooth conditions beginning in 2000. Following institutional requirements, a protocol was approved by the Institutional Review Board at the Mayo Clinic, Rochester, Minnesota, and records were reviewed for data abstraction using a modified template.[29] Data extraction included clinical documentation from the time of implant placement until the last recorded follow-up visit. A pilot trial (5 patients) of data extraction was accomplished to ensure that exposure and outcome variables were abstracted carefully to avoid bias, and records were systematically checked to minimize missing data.

The exposure variables of interest were age, sex, augmentation, implant location, implant geometry, abutment type, prosthesis type, cement- or screw-retained, and condition of the opposing arch. The outcome variables of interest were implant failure, time to definitive prosthesis, prosthesis complications including screw loosening or fracture, cement failure, prosthesis material failure, and overdenture attachment problems.

The analyses chosen included a Kaplan-Meier estimate of implant survival, a Cox proportional hazards model to estimate the influence of the exposure variables on implant survival, and a stratified Cox proportional hazards model to adjust for confounding that might be attributable to age and sex. The analysis was conducted using the SAS System 8e and JMP 4.04 (SAS Institute).

Results

Twenty-four patients with 100 implants supporting a variety of prostheses were identified for outcome summary (Table 1). All patients were specific to one prosthodontic provider and were selected for application of the immediate loading protocol based on both clinical findings and risk/benefit discussions (Table 2).

*While debate regarding the impact of a variable temporal relationship of prosthesis placement and implantation is appropriate,[11] for the purpose of this manuscript, the terms "immediate and early loading" will be used synonymously. Both terms refer to a clinician's provision of implant-tooth replacement connection during the initial postsurgical phase of bone wound healing.

Table 1 Baseline Patient Information and Implant Distribution

Sex	18 F/6 M
Mean age	47.8 years
Implant location	
Maxilla	45
Posterior	20
Anterior	25
Mandible	55
Posterior	14
Anterior	41
Platform	
Narrow	3
Regular	83
Wide	14

F = female; M = male.

Table 2 Prosthesis Characteristics

	No. of implants
Prosthesis type	
Crowns	17
FPDs	11
Hybrids	56
Overdenture	16
Connection mode	
Cemented	19
Screw-retained	65
Attachments	16

FPD = fixed partial denture.

Table 3 Reasons for Postinsertion Visits

Doing well (no intervention)
Implant failure
Screw loosening
Screw fracture
Abutment screw loosening
Abutment screw fracture
Cement failure
Prosthesis material failure
Prosthesis replaced due to complication
Overdenture retention failure
Fractured implant
Other

Table 4 Top Three Reasons for Postinsertion Visits*

	Visit		
	1	2	3
Doing well	20	19	5
Temporary cement failure	2	1	1
Access restoration lost	3	5	14

*All 24 patients provided postoperative data.

Table 5 Immediate Loading Implant Survival Data

Time	At risk (n)	Failed (n)	Interval surviving (%)	Cumulative survival (%)
< 1 y	100	1	99	99
1–2 ys	99	0	100	99
2–3 ys	99	0	100	99
3–4 ys	99	0	100	99
4–5 ys	99	0	100	99
5–9 ys	99	0	100	99

Postinsertion visits for immediately loaded prostheses (visits until definitive prosthesis delivery) were reviewed for all 24 patients (no dropouts) to identify management requirements associated with an immediate loading protocol (Table 3). The immediately loaded prostheses had a range of postoperative visits from 1 to 10; the majority of patients were seen between 2 and 3 times. The top three visit descriptions included: doing well, temporary cement failure, and access restoration lost (Table 4).

The time-to–definitive prosthesis data identifies how long it took after the immediate prosthesis was inserted to deliver the definitive prosthesis. This revealed a range of 3.9 to 7.8 months, with crowns taking 5.3 ± 1.1 months, fixed partial dentures taking 3.9 ± 1.3 months, and hybrids taking 7.8 ± 4.1 months, on average.

Survival analysis revealed 1 failure out of 100 implants (Table 5). Given the limited outcome of failure and small sample size, no exposure variables could be identified as significant risks for failure for this clinical protocol.

Discussion

The findings from this report are helpful in illustrating two purposes of clinical data monitoring. The first is to present practice outcomes related to the use of dental implants that were immediately loaded where the decisions to provide immediate prostheses were based on variable patient desires and clinical features representative of issues common to clinical practice. The major clinical findings included adequate insertion torque (a proxy measure for sufficient resistance to independent implant-bone interface movement, thus allowing predictable interface maturation) and the opportunity to share occlusal load both among implant-supported replacements and natural teeth (if partially edentulous). Second, such a summary of practice outcomes is an important component of clinical practice monitoring and provides specific provider information for shared decision-making discussions with patients. Also noteworthy is that this report provided a unique opportunity for one author to observe whether outcomes seen in an animal study using an experimental implant[27] accurately reflected subsequent human outcomes for that author's prosthodontic practice.

While the authors admit that this report does not provide comparative clinical data between different implants used for immediate loading purposes, it does allow comparison of observed outcomes to those of conventional loading from the same practice, an equivalence comparison.[30] These results, to date, support the finding of practice-specific equivalence of delayed loading for carefully selected application.

Monitoring of clinical outcomes related to immediate loading serves practical needs in clinical practice. As a means of quality assurance monitoring, clinical outcomes of specific interventions help identify adverse events (eg, implant failure) as well as service-specific information (eg, postinsertion visit specifics, time to definitive prosthesis) that may be informative to patients. Adverse outcomes are critical to eliminate, and their early identification in a systematic manner can alert clinicians to harmful practice trends. Delineating and the subsequent reduction of unexpected postinsertion visits, for example, is an important focus for both a more efficient practice as well as patient satisfaction. In this study, screw access obturation processes have changed as a result of the review.

All outcomes can be useful for providing practice-specific answers to patient questions related to treatment options delivered by a provider. While evidence-based research findings are sometimes necessary to guide practice decisions targeting knowledge gaps, data specific to a practice provider are most useful for shared decision-making interactions. Having the ability to provide data specific to the provider team with whom a patient is consulting is more meaningful to the patient-provider interaction.[31] Frequently asked questions surrounding important risks and benefits help define a core set of outcomes to follow in practice-based monitoring.

In comparing the clinical outcomes of this study to those seen in a previous animal study,[27] it is evident that occlusal loading was not detrimental to implant survival. While the animal application did not benefit from a soft diet and therefore all implants were under an uncontrolled functional load, in practice, the decision was made to carefully guard against interface stress by careful patient selection and splinting of multiple implants when possible. Additionally, all patients were placed on a soft diet for a 6-week period. Both the animal study and this report demonstrated that when failure did occur, it was early on in the wound healing phase.

Conclusions

The clinical results from this practice setting, where 24 patients were managed with 100 implants delivered using immediate loading, are both consistent with the preceding animal results and favorable when compared to conventional loading protocols from the same practice. The data represent outcomes specific to the provider group that were used for practice modification (access obturation) and are part of the shared decision-making discussions with patients considering the merits of alternative protocols for management of their tooth loss using dental implants.

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References

1. Adell R, Lekholm U, Rockler B, Brånemark PI. A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. Int J Oral Surg 1981;10:387–416.
2. Albrektss on T, Dahl E, Enbom L, et al. Osseointegrated oral implants. A Swedish multicenter study of 8139 consecutively inserted Nobelpharma implants. J Periodontol 1988;59:287–296.
3. Engquist B, Bergendal T, Kallus T, Linden U. A retrospective multicenter evaluation of osseointegrated implants supporting overdentures. Int J Oral Maxillofac Implants 1988;3:129–134.
4. Ericsson I, Lekholm U, Brånemark PI, Lindhe J, Glantz PO, Nyman S. A clinical evaluation of fixed-bridge restorations supported by the combination of teeth and osseointegrated titanium implants. J Clin Periodontol 1986;13:307–312.

5. van Steenberghe D, Brånemark PI, Quirynen M, De Mars G, Naert I. The rehabilitation of oral defects by osseointegrated implants. J Clin Periodontol 1991;18:488–493.
6. Kapur KK. Veterans Administration Cooperative Dental Implant Study—Comparisons between fixed partial dentures supported by blade-vent implants and removable partial dentures. Part III: Comparisons of masticatory scores between two treatment modalities. J Prosthet Dent 1991;65:272–283.
7. Zarb GA, Schmitt A. The edentulous predicament. I: A prospective study of the effectiveness of implant-supported fixed prostheses. J Am Dent Assoc 1996;127:59–65.
8. Bhatavadekar N. Assessing the evidence supporting the claims of select dental implant surfaces: A systematic review. Int Dent J 2008;58:363–370.
9. Tepper G, Haas R, Mailath G, et al. Representative marketing-oriented study on implants in the Austrian population. I. Level of information, sources of information and need for patient information. Clin Oral Implants Res 2003;14:621–633.
10. Cooper LF. A role for surface topography in creating and maintaining bone at titanium endosseous implants. J Prosthet Dent 2000;84:522–534.
11. Jokstad A, Carr AB. What is the effect on outcomes of time-to-loading of a fixed or removable prosthesis placed on implant(s)? Int J Oral Maxillofac Implants 2007;22(suppl):19–48.
12. Brånemark PI, Hansson BO, Adell R, et al. Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period. Scand J Plast Reconstr Surg Suppl 1977;16:1–132.
13. Babbush CA, Kent JN, Misiek DJ. Titanium plasma-sprayed (TPS) screw implants for the reconstruction of the edentulous mandible. J Oral Maxillofac Surg 1986;44:274–282.
14. Chiapasco M, Gatti C, Rossi E, Haefliger W, Markwalder TH. Implant-retained mandibular overdentures with immediate loading. A retrospective multicenter study on 226 consecutive cases. Clin Oral Implants Res 1997;8:48–57.
15. Spiekermann H, Jansen VK, Richter EJ. A 10-year follow-up study of IMZ and TPS implants in the edentulous mandible using bar-retained overdentures. Int J Oral Maxillofac Implants 1995;10:231–243.
16. Salama H, Rose LF, Salama M, Betts NJ. Immediate loading of bilaterally splinted titanium root-form implants in fixed prosthodontics—A technique reexamined: Two case reports. Int J Periodontics Restorative Dent 1995;15:344–361.
17. Schnitman PA, Wöhrle PS, Rubenstein JE, DaSilva JD, Wang NH. Ten-year results for Brånemark implants immediately loaded with fixed prostheses at implant placement. Int J Oral Maxillofac Implants 1997;12:495–503.
18. Tarnow DP, Emtiaz S, Classi A. Immediate loading of threaded implants at stage 1 surgery in edentulous arches: Ten consecutive case reports with 1- to 5-year data. Int J Oral Maxillofac Implants 1997;12:319–324.
19. Balshi TJ, Wolfinger GJ. Immediate loading of Brånemark implants in edentulous mandibles: A preliminary report. Implant Dent 1997;6:83–88.
20. Testori T, Szmukler-Moncler S, Francetti L, Del Fabbro M, Trisi P, Weinstein RL. Healing of Osseotite implants under submerged and immediate loading conditions in a single patient: A case report and interface analysis after 2 months. Int J Periodontics Restorative Dent 2002;22:345–353.
21. Cochran DL, Schenk RK, Lussi A, Higginbottom FL, Buser D. Bone response to unloaded and loaded titanium implants with a sandblasted and acid-etched surface: A histometric study in the canine mandible. J Biomed Mater Res 1998;40:1–11.
22. Piattelli A, Corigliano M, Scarano A, Quaranta M. Bone reactions to early occlusal loading of two-stage titanium plasma-sprayed implants: A pilot study in monkeys. Int J Periodontics Restorative Dent 1997;17:162–169.
23. Ericsson I, Randow K, Nilner K, Peterson A. Early functional loading of Brånemark dental implants: 5-year clinical follow-up study. Clin Implant Dent Relat Res 2000;2:70–77.
24. Cooper LF, Rahman A, Moriarty J, Chaffee N, Sacco D. Immediate mandibular rehabilitation with endosseous implants: Simultaneous extraction, implant placement, and loading. Int J Oral Maxillofac Implants 2002;17:517–525.
25. Andersen E, Haanaes HR, Knutsen BM. Immediate loading of single-tooth ITI implants in the anterior maxilla: A prospective 5-year pilot study. Clin Oral Implants Res 2002;13:281–287.
26. Chiapasco M, Abati S, Romeo E, Vogel G. Implant-retained mandibular overdentures with Brånemark System MKII implants: A prospective comparative study between delayed and immediate loading. Int J Oral Maxillofac Implants 2001;16:537–546.
27. Knobloch L, Larsen PA, Rashid B, Carr AB. Six-month performance of implants with oxidized and machined surfaces restored at 2, 4, and 6 weeks postimplantation in adult beagle dogs. Int J Oral Maxillofac Implants 2004;19:350–356.
28. Wills CE, Holmes-Rovner M. Patient comprehension of information for shared treatment decision making: State of the art and future directions. Patient Educ Couns 2003;50:285–290.
29. Carr AB, Choi YG, Eckert SE, Desjardins RP. Retrospective cohort study of the clinical performance of 1-stage dental implants. Int J Oral Maxillofac Implants 2003;18:399–405.
30. Wiens BL. Choosing an equivalence limit for noninferiority or equivalence studies. Control Clin Trials 2002;23:2–14 [erratum 2002;23:774].
31. Weiner BK. Matching patient-specific expectations with physician-specific outcomes: Towards transparency in treatment decision-making and consent. Med Hypotheses 2007;68:1287–1291.