

Consensus Statements and Clinical Recommendations for Implant Loading Protocols

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INTRODUCTORY REMARKS

This report summarizes the statements and clinical recommendations for implant loading protocols as per consensus agreement among the participants at the 5th ITI Consensus Conference.

Group 4 was composed of participants from 13 different countries and of various specialties in dental medicine. Prior to the conference, scientific evidence on conventional, early, and immediate implant loading

protocols was evaluated by four systematic reviews according to well-differentiated clinical situations: single implant crowns, extended edentulous spaces in partially edentulous patients, edentulous jaws with fixed prostheses, and edentulous jaws with overdenture prostheses. The primary outcome was implant survival. In addition, number of implants, prosthetic design, marginal bone loss, stability of peri-implant soft tissue, prosthetic failures, treatment modifiers, esthetics, and patient satisfaction were considered as secondary outcomes.

Reports from previous consensus conferences^{1,2} stated that conventional and early implant loading are well-established protocols and should be considered routine. In particular, several clinical studies³⁻⁵ demonstrated the high predictability of early loading protocols when compared to conventional healing times, showing no differences in regard to implant survival rates. In this context, the design of the systematic reviews presented at the 5th ITI Consensus Conference aimed to assess whether immediate loading showed similar clinical outcomes to early and conventional loading.

At the conference, the authors presented their methodology, results, and conclusions for the four systematic reviews to all participants in the loading protocols group. These manuscripts provided substance for a comprehensive and methodical discussion leading to the unbiased formulation of consensus statements, clinical recommendations, and directions for future research on implant loading protocols. The group's determinations were then presented to the plenum, where additional input was collected for the preparation of this final report.

Definition of Terms

The definitions of loading protocols presented by Weber et al² were used for the calibration of the systematic reviews and endorsed without modifications by the group as follows:

- *Conventional loading* of dental implants is defined as being greater than 2 months subsequent to implant placement.

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- *Early loading* of dental implants is defined as being between 1 week and 2 months subsequent to implant placement.
- *Immediate loading* of dental implants is defined as being earlier than 1 week subsequent to implant placement.

Disclosure

All the group members were asked to reveal any conflicts of interest potentially influencing the outcomes of the consensus work. No such conflicts were identified.

LOADING PROTOCOLS FOR SINGLE IMPLANTS IN PARTIALLY EDENTULOUS PATIENTS

Focus Question

Does immediate loading of single-implant crowns render different results from early and conventional loading with respect to implant survival rate, marginal bone loss, stability of peri-implant soft tissue, esthetics, and patient satisfaction?

Consensus Statements

1. In general, there is a high level of comparative evidence supporting the use of both immediate and conventional loading of single-implant crowns in terms of implant survival and marginal bone level stability.
2. A minimal insertion torque in the range of 20 to 45 Ncm, a minimal implant stability quotient (ISQ) in the range of 60 to 65, and the need for simultaneous bone augmentation were the most common inclusion/exclusion criteria.
3. There are limited data comparing immediate and conventional loading in terms of stability of the papilla height and of the facial mucosal margin.
4. Esthetics and patient satisfaction were measured only in a few trials that compared immediate and conventional loading, rendering insufficient data to draw conclusions.

Treatment Guidelines

The recommendations for immediate and early loading of single-implant crowns are limited to situations fulfilling the following prerequisites:

- Primary implant stability (insertion torque ≥ 20 to 45 Ncm and/or implant stability quotient (ISQ) ≥ 60 to 65)
- Absence of systemic or local contraindications (eg, parafunctional activities, large bone defects, need for sinus floor elevation)
- When the clinical benefits exceed the risks

1. For the anterior and premolar regions, immediate and early loading of single-implant crowns are predictable procedures in terms of implant survival and stability of the marginal bone. However, data regarding soft tissue aspects are not conclusive enough to recommend immediate or early loading of single-implant crowns in esthetically demanding sites as a routine procedure. Immediate loading in such sites should be approached with caution and by experienced clinicians.
2. For the mandibular molar region, immediate and early loading of single-implant crowns is a predictable procedure and can generally be recommended in cases where clinical benefits are identified.
3. The low amount of data on immediate and early loading of single-implant crowns in the maxillary molar region does not allow general recommendation of these loading procedures. In these sites, conventional loading should be the procedure of choice.

LOADING PROTOCOLS FOR PARTIALLY EDENTULOUS PATIENTS IN EXTENDED EDENTULOUS SITES

Focus Question

In partially edentulous patients with extended edentulous sites, what is the effect of immediate implant loading with implant-supported fixed dental prostheses compared to early or conventional loading on implant survival?

Consensus Statements

1. Based on limited scientific evidence and under strict selection criteria, immediate implant loading in partially edentulous patients with healed posterior extended edentulous sites presents similar implant survival rates compared to early or conventional loading.
2. Insufficient evidence exists to support immediate implant loading in anterior maxillary or mandibular extended edentulous sites.
3. Insertion torque, ISQ values, implant length, the need for bone augmentation procedures, the timing of implant placement, smoking, and the presence of parafunctional habits were common criteria in selecting a loading protocol.

Treatment Guidelines

1. In the absence of modifying factors, early loading of solid-screw-type implants with a microtextured surface after 4 to 8 weeks in extended edentulous sites of partially edentulous patients is a predictable treatment approach.

2. Immediate loading of posterior implants in healed extended edentulous sites seems to be predictable. However, in such cases immediate implant loading is of limited clinical benefit.
3. Immediate loading of anterior implants in extended edentulous sites of partially edentulous patients should be approached with caution and by experienced clinicians, since insufficient evidence exists to support such treatment.
4. When immediate implant loading is intended, the following criteria should be considered: primary implant stability, need for substantial bone augmentation, implant design and dimension, occlusal factors, patient habits, systemic health, and clinician experience.
3. The number, size, and distribution of implants for a full-arch fixed prosthesis needs to be based on the implant-prosthetic plan, arch form, and bone volume, regardless of the loading protocol.
4. Primary implant stability is critical for predictable osseointegration regardless of the loading protocol. It is suggested that prior to immediate loading in the edentulous arch, the primary stability of each implant must be confirmed.
5. The need for simultaneous procedures such as bone augmentation or sinus floor elevation is considered a relative contraindication for immediate loading.

LOADING PROTOCOLS FOR FIXED PROSTHESES IN EDENTULOUS JAWS

Focus Question

In edentulous patients, what is the effect of immediate implant loading with fixed prostheses compared to early and conventional loading on implant and prosthesis survival?

Consensus Statements

1. The existing literature provides high evidence that immediate loading of microtextured dental implants with one-piece fixed interim prostheses in both the edentulous mandible and maxilla is as predictable as early and conventional loading.
2. Inclusion criteria, such as insertion torque ≥ 30 Ncm, ISQ ≥ 60 , and minimal implant length ≥ 10 mm, have been used in the majority of the included studies.
3. The number of implants used to support a fixed prosthesis varied from 2 to 10 in the mandible and 4 to 12 in the maxilla.

Treatment Guidelines

1. The treatment of edentulism with fixed implant-supported prostheses is complex according to the ITI SAC criteria. Therefore, careful case selection and treatment planning, as well as adequate knowledge, skill, and experience of the clinician(s) performing the procedures are key. Immediate, early, or conventional loading with one-piece fixed interim prostheses have demonstrated high implant and prosthesis survival rates and can be recommended for the mandible and maxilla.
2. Patient-centered benefits of immediate loading include the immediate fixed restoration of function, the reduction of postoperative discomfort caused by a removable interim prosthesis, as well as the reduction of overall treatment time.

LOADING PROTOCOLS FOR IMPLANT-SUPPORTED OVERDENTURES IN EDENTULOUS JAWS

Focus Question

In edentulous jaws with implant-supported overdentures, what is the effect of immediate implant loading versus early or conventional loading on implant survival at 1 year?

Consensus Statements

1. Current clinical research supports high survival with the use of threaded, microtextured implants with a minimum diameter of 3 mm for the support of overdenture prostheses when used with immediate, early, or conventional loading protocols. Limited evidence exists for immediate loading of implants supporting overdentures in the maxilla.
2. Descriptive material from the review in this group for immediate loading by Schimmel et al lists inclusion criteria of: insertion torque (≥ 30 Ncm), ISQ value (≥ 60), two or more implants in the mandible, or four or more implants in the maxilla.
3. Splinting of implants and the type of attachment system had no effect on 1-year survival rate compared to freestanding implants.

Treatment Guidelines

1. The intended loading protocol should be selected considering implant-prosthetic parameters as well as functional, psychosocial, and financial aspects and patient preference.
2. Early loading represents a satisfactory treatment modality in the management of the edentulous jaw, when using implants to support/retain an overdenture prosthesis, and can be recommended as routine in the absence of modifying factors.
3. Immediate loading protocols in implant-supported/retained overdentures appear predictable. The available research arbitrarily uses an insertion torque of 30 Ncm or greater and/or an ISQ value of 60 or greater. The evidence for immediate implant

loading in the maxilla is less compelling. However, there is no reliable pretreatment predictor that has determined conclusively that the clinician can perform an immediate loading procedure.

4. Given the lack of research, the use of a single implant in an immediately loaded fashion may not be indicated for support/retention of overdenture prostheses.

GENERAL STATEMENTS

General Clinical Recommendations for Loading Protocols

Conventional implant loading is predictable in all clinical situations and is particularly recommended in the presence of treatment modifiers such as poor primary implant stability, substantial bone augmentation, implants of reduced dimensions, and compromised host conditions.

General Recommendations for Future Research

Future research should ideally evaluate the following aspects of loading protocols in oral implantology:

1. Timing of implant placement following tooth extraction and the time of implant loading as associated variables
2. Validity of selection criteria as predictors for treatment outcomes, including clinically validated thresholds for resonance frequency analysis and/or insertion torque
3. Clinical research for implant loading protocols, ideally including an Intention-to-Treat (ITT) analysis.
4. Surrogates that can be applied presurgically to determine the possibility of immediate implant loading

5. Outcome of immediate loading protocols in situations with a clear clinical benefit, such as anterior implants and implants placed into fresh extraction sockets (type 1 placement)
6. Patient-centered outcomes (eg, psychosocial, functional) and clinical benefits associated with immediate implant placement and loading
7. Esthetic outcome of an intervention using reproducible methods, standardized baseline measurements, and validated indices
8. Cost-effectiveness of different implant loading concepts to support/retain overdentures
9. Effect on implant survival when implants are loaded between 1 and 4 weeks after implant placement

REFERENCES

1. Cochran DL, Morton D, Weber HP. Consensus statements and recommended clinical procedures regarding loading protocols for endosseous dental implants. *Int J Oral Maxillofac Implants*. 2004;19(suppl):109–113.
2. Weber HP, Morton D, Gallucci GO, Rocuzzo M, Cordaro L, Grutter L. Consensus statements and recommended clinical procedures regarding loading protocols. *Int J Oral Maxillofac Implants* 2009;24(suppl):180–183.
3. Cochran DL, Jackson JM, Bernard JP, et al. A 5-year prospective multicenter study of early-loaded titanium implants with a sandblasted and acid-etched surface. *Int J Oral Maxillofac Implants* 2011;26:1324–1332.
4. Bornstein MM, Wittneben JG, Brägger U, Buser D. Early loading at 21 days of non-submerged titanium implants with a chemically modified sandblasted and acid-etched surface: 3-year results of a prospective study in the posterior mandible. *J Periodontol* 2010;81:809–818.
5. Morton D, Bornstein MM, Wittneben JG, et al. Early loading after 21 days of healing of nonsubmerged titanium implants with a chemically modified sandblasted and acid-etched surface: Two-year results of a prospective two-center study. *Implant Dent Relat Res* 2010;12:9–17.