

Consensus Statements and Recommended Clinical Procedures Regarding Loading Protocols for Endosseous Dental Implants

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INTRODUCTORY REMARKS

The group was asked to develop evidence-based reviews on topics related to various loading protocols for dental implants. Three reviews were prepared: the first addressed the literature related to different loading protocols for partially edentulous cases, the second examined the literature for loading protocols in completely edentulous cases, and the third addressed clinical procedures for the various loading protocols. Drafts of the manuscripts were prepared and distributed to the members of the group prior to the conference. The overall objective of the literature review was to determine whether a procedure could be recommended as a standard based on the available evidence. The second objective was to identify whether patients perceived a benefit associated with these procedures.

The literature included full-length articles in English on endosseous root-form titanium implants. For edentulous patients, a minimum follow-up of 1 year was required. The volume of literature found was moderate, but the level of evidence was limited at best for the procedures considered. The predominant literature was case reports. The primary goal was to identify survival of the implants and success or failure of the procedure(s), and to relate these to the implant and/or prosthesis. A secondary goal was to identify possible risk factors for the procedures.

At the consensus conference, the authors presented their manuscripts to the group for discussion. There was discussion concerning how the authors approached writing the draft, how the literature was searched and reviewed, what the major

findings were, and finally, what conclusions could be drawn. Following these presentations, group members addressed several aspects of each review, including:

- Did the review adequately address the topic?
- Has any evidence been published since the review that has a significant impact on the topic?
- Do the section members agree with the findings of the review's authors?
- What open questions remain in this area, and what might be investigated in the future regarding this topic?
- What recommendations can be made for patient treatment with regard to loading protocols?

During the discussion, several statements were made regarding immediate or early restoration and/or loading of implants in edentulous and partially edentulous patients. These are listed below, along with issues that were identified throughout the discussions.

Definition of Terms

An important aspect of the discussion of loading protocols for dental implants was to define the terms to be used, since there has been confusion in the past over definitions of terms related to restoration. The group worked to clarify these. Notably, for *immediate restoration* it had not been defined whether the prosthesis is in contact with the opposing dentition; thus it was necessary to clarify the occlusal scheme used at the time of restoration. According to the body of literature, in agreement with the previous (1997) ITI consensus, a minimum of 3 months of healing prior to implant loading had been established as *conventional loading*. However, the group felt that with increasing evidence to support reduced healing times for rough-surfaced titanium implants, the definition of conventional healing periods for these implants might be modified.

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Most of these terms were recently defined in a conference on immediate and early loading that occurred in Spain in May 2002.¹ However, the group modified these definitions for use in this report. The modified definitions are presented here:

- *Immediate restoration*: A restoration inserted within 48 hours of implant placement but not in occlusion with the opposing dentition. The group's decision to use 2 days was not based on strong biologic evidence—rather, it was based on the clinical capacity to perform procedures within a limited time frame following surgery. With regard to the term “immediate” the group felt that future research and clinical experience with peri-implant tissue healing may provide more appropriate definitions.
- *Immediate loading*: A restoration placed in occlusion with the opposing dentition within 48 hours of implant placement.
- *Conventional loading*: The prosthesis is attached in a second procedure after a healing period of 3 to 6 months.
- *Early loading*: A restoration in contact with the opposing dentition and placed at least 48 hours after implant placement but not later than 3 months afterward.
- *Delayed loading*: The prosthesis is attached in a second procedure that takes place some time later than the conventional healing period of 3 to 6 months.

Review of Loading Protocols

Changes in loading protocols are not uncommon in implant dentistry. Early work focused on the predictability of osseointegration, predominantly in edentulous mandibles. Subsequent work focused on implant integration in partially edentulous patients and various clinical indications. More recent studies have been directed at achieving quicker integration and shorter healing periods prior to implant restoration. More rapid integration has been attempted by modifying the titanium implant surface and by stimulating the surrounding tissues with growth-promoting substances such as bone grafts and growth factors. The ultimate loading protocol is immediate: providing the patient with a tooth replacement the day the implant is placed. Loading protocols can best be interpreted on the biologic basis of implant integration.

The process involved in the osseointegration of dental implants is poorly understood. Many professionals do not appreciate the fact that osseointegration is instantaneous. Osseointegration is defined as bone-to-implant contact at the light microscopic

level. As soon as an implant is placed into the jawbone, certain areas of the implant surface are in direct contact with bone, ie, osseointegrated. Cochran and coworkers² have described this as *primary bone contact*. With the ITI Dental Implant System (Institut Straumann), the instrumentation is designed such that the osteotomy preparation has a slightly smaller diameter than the implant, so that the implant has a “press-fit” against the bone tissue. This represents the predominant contact with the bone at early healing times. As healing occurs, however, this bone is remodeled, and areas of new bone contact with the implant surface appear (particularly with more osteoconductive surfaces such as the SLA [sandblasted, large-grit, acid-etched; Institut Straumann]). This remodeled bone and new bone contact, termed *secondary bone contact*, predominates at later healing times when the amount of primary contact is decreased. By understanding these concepts one can appreciate how various loading protocols are possible and can view loading protocols as dependent on 2 distinct processes.

Immediate loading protocols were first described for the completely edentulous mandible. This indication is dependent on existing bone at the implant site. In the completely edentulous anterior mandible, where bone is typically extremely dense, large amounts of primary bone contact occur. Thus, instantaneous osseointegration occurs in large amounts of cortical bone, giving the implant immediate stability. Combined with a rigid connection of the implants, this provides for stability of the entire complex and osseous healing around the implants, ie, clinical implant success. It is not surprising, then, that immediate loading of multiple implants in the edentulous mandible can be a very successful procedure. This represents one scenario for the early/immediate loading of implants and is dependent on the existing quality and quantity of osseous tissue.

Another scenario with implications for early/immediate loading protocols is dependent not only on the existing bone quality and quantity but also on the possibility of rapid formation of bone tissue around the implant. This scenario occurs in indications where the quality and quantity of bone are not ideal, eg, sites with minimal cortical (dense) bone. In these cases, the ability to stimulate bone formation becomes crucial. Thus, early loading protocols become feasible and immediate loading protocols become less likely. The use of implants with modified surfaces that increase bone-to-implant contact and removal torque values has allowed shortened healing times under these conditions. For example, Cochran and coworkers³ have demonstrated that implants with an SLA surface placed in

areas of typically lower-quality bone can be restored after just 6 weeks of healing (early loading).

This analysis suggests that shortened loading protocols should focus on (1) the amount of primary bone contact, (2) the quantity and quality of bone at the implant site, and (3) the rapidity of bone formation around the implant. In addition, 2 general scenarios are possible that relate to mechanisms of implant support that allow for reduced healing times. When existing bone of high quality and quantity is found, immediate loading of the implant may be possible. If the existing bone is not of high quality and quantity, then bone formation must occur in a relatively short time so that early loading of the implants can take place.

Various loading protocols for the restoration of dental implants are described in the literature. Several terms are important to understand when discussing them. In the case of *direct occlusal contact*, the restoration makes contact with the opposing dentition. With *indirect occlusion*, the implant is restored without directly contacting the opposing dentition, ie, it is out of occlusion. With *progressive loading*, the implant is restored in “light” contact initially and is gradually brought into full contact with the opposing dentition. Unfortunately, it is currently unknown whether the type of occlusion has an influence on the success of the timing of loading of the implant.

Another important aspect of loading protocols is the implant site. The site can range from a well-healed edentulous space to an area where a tooth has just been removed—an immediate extraction site. In the latter case, the size of the defect around the implant varies depending on the size of the tooth being extracted. Another section of this consensus conference addressed the placement of implants in extraction sites; however, it is clear that the nature of the implant site can have a significant impact on the outcome of the implant restoration, regardless of the loading protocol. Thus, for the purpose of these reviews, when discussing implant loading protocols it was assumed that the implant is placed in a well-healed edentulous ridge with native bone surrounding the implant.

CONSENSUS STATEMENTS

An appreciation of the mechanism governing how an implant interacts with bone tissue provides a basis for understanding how immediate and early loading protocols are possible. Stability of the implant is important for the success of any loading protocol. In fact, the outcome most often assessed

and most often associated with procedure success in the literature was implant stability, and in many citations it was the only outcome assessed. Stability of the implant was found to be influenced by factors including, but not limited to, implant surface and geometry, quality and quantity of bone, splinting of implants, control of occlusal load, and absence of detrimental patient habits.

The literature is often characterized by inclusion and exclusion criteria that limit evaluation to a selected patient population. Thus, the results are often obtained under conditions that are considered favorable. With the understanding that the literature base is small, and the strength of evidence is graded as inadequate to fair, the group reached the following conclusions.

Edentulous Mandible

In edentulous mandibles, the immediate loading of 4 implants with an overdenture in the interforaminal area with rigid bar fixation and cross-arch stabilization is a predictable and well-documented procedure. This indication represents the only indication where the literature includes randomized and controlled studies. According to criteria agreed upon by this consensus group, this procedure is supported by 7 studies involving 376 patients and 1,529 implants.

In contrast, the early loading of implants (splinted or unsplinted) in the edentulous mandible with an overdenture is not well documented. Only 6 publications considered by this consensus group support such a procedure. They involved just 85 patients and 230 implants.

Immediate loading of implants supporting fixed restorations in the edentulous mandible is a predictable and well-documented procedure, provided that a relatively large number of implants are placed. The consensus group considered the procedure to be supported by 15 articles involving 387 patients and 2,088 implants, 1,804 of which were immediately loaded.

The consensus group found only 6 publications supporting the early loading of implants in the edentulous mandible with a fixed restoration. The publications involved 51 patients and 272 implants, 234 of which were loaded early.

Edentulous Maxilla

No articles were found supporting immediate or early loading of implants with an overdenture in the edentulous maxilla. Therefore, this procedure would have to be considered experimental at this time.

In the edentulous maxilla, immediate or early loading of implants utilizing a fixed prosthesis is not

well documented. Regarding immediate loading, 7 publications involving 30 patients and 276 implants were found and discussed by the consensus group. For early loading, 4 articles involving 26 patients and 192 implants were reviewed.

Partially Edentulous Mandible or Maxilla

In the partially dentate maxilla and mandible, the immediate restoration or loading of implants supporting fixed prostheses is not well documented. It should be noted that in many of these cases the restoration is not in contact with the opposing dentition. This observation highlights the care that must be expended to plan and successfully complete such a restoration. Factors that have been highlighted include the absence of parafunctional habits, the use of a roughened implant surface, the use of a threaded implant, and primary stability of the implant.

In contrast, the early restoration or loading of titanium implants with a roughened surface supporting fixed prostheses after 6 to 8 weeks of healing is well documented and predictable in the partially dentate maxilla and mandible. Results seem to indicate that the outcome is similar to results obtained with conventional procedures. However, because of the limited number of implants placed (in comparison to the number of conventionally loaded implants) and the short follow-up period, further studies are necessary before these procedures can be proposed as routine.

Interproximal crestal bone levels and soft tissue changes adjacent to immediately restored or loaded implants were found to be similar to those reported for conventional loading protocols.

Other issues that were discussed included the following:

- A conventional loading period of 3 to 6 months is likely to be modified for implants with roughened surfaces. The 3- to 6-month period was originally defined for implants with machined surfaces, and it is well documented that the machined surface is not as successful as the roughened surface in certain indications.
- A question that needs to be addressed is whether the patient benefits from an immediate or early loading protocol. There is an associated risk with immediate and/or early loading, and this risk must be evaluated in terms of patient benefit. Postoperative care must be evaluated in such calculations.
- A related question is whether conventional loading is justified in certain cases. For example, does delaying the restoration of an implant place the patient at a disadvantage?
- The types of occlusal schemes need to be specified in various loading protocols. Occlusal schemes for immediate and early loaded implants that result in successful outcomes need to be determined.

CLINICAL RECOMMENDATIONS

The following types of treatment are recommended, provided that all other aspects of diagnosis and treatment planning have been performed and considered acceptable by the clinician. Immediate restoration and loading procedures are considered to be advanced or complex. As such, it is assumed that the clinician has the required level of skill and experience. The recommendations are based on the literature and the collective experience of the consensus working group.

Immediate Restoration or Loading

Edentulous Mandible. Four implants are suitable for use in 2 protocols: an overdenture retained and/or supported by a bar that rigidly connects the implants, or a fixed restoration on a framework (acrylic resin and/or metal) that rigidly connects the implants. More than 4 implants are suited for a rigid provisional restoration connecting all of the implants, or for a fixed restoration on a framework (acrylic resin and/or metal) that rigidly connects the implants.

Edentulous Maxilla. No routine procedure is recommended.

Partially Dentate Maxilla and Mandible. No routine procedure is recommended.

Early Restoration or Loading

Edentulous Mandible. Two implants may be placed to retain an overdenture, supported by a bar connecting the implants or by free-standing implants, when the implants are characterized by a rough titanium surface and allowed to heal for at least 6 weeks. In a 4-implant scenario, either of 2 options is recommended: an overdenture retained and supported by a bar connecting the implants or by unconnected implants, or a fixed restoration on a framework that rigidly connects the implants. The implants should be characterized by a rough titanium surface and allowed to heal for at least 6 weeks. More than 4 implants may be used for a fixed restoration on a framework that rigidly connects the implants; again, the implants are characterized by a rough titanium surface and allowed to heal for at least 6 weeks.

Edentulous Maxilla. Four different early loading scenarios are possible.

1. Four implants retaining an overdenture, supported by a bar connecting the implants or by unconnected implants, with implants characterized by a rough titanium surface and allowed to heal for at least 6 weeks. The site must be characterized by type 1, 2, or 3 bone.⁴
2. Four implants supporting a fixed restoration on a framework that rigidly connects the implants. As with the above scheme, the implants are characterized by a rough titanium surface and allowed to heal for at least 6 weeks, and the site is characterized by type 1, 2, or 3 bone.
3. More than 4 implants retaining an overdenture, supported by a bar connecting the implants or by unconnected implants, with implants characterized by a rough titanium surface and allowed to heal for at least 6 weeks, in a site characterized by type 1, 2, or 3 bone.
4. More than 4 implants supporting a fixed restoration on a framework that rigidly connects the implants. Again, the implants are characterized by a rough titanium surface and allowed to heal for at least 6 weeks, and the site is characterized by type 1, 2, or 3 bone.

Partially Dentate Maxilla and Mandible. A fixed prosthesis is recommended in these cases.

Implant number and distribution are dependent on patient circumstances, including bone quality and quantity, number of missing teeth, condition of opposing dentition, type of occlusion, and bruxism. Implants must be characterized by a rough titanium surface and are allowed to heal for at least 6 weeks and in type 1, 2, or 3 bone.

CONCLUSION

Consideration should be given to the quality of available evidence for these procedures. It is recognized that many of the clinical recommendations suggested by the consensus group are not yet associated with strong evidence. Readers should note that the experience of the group was used in formulating the recommendations.

Additional outcomes to be evaluated in future studies include:

- Physiologic impact (chewing, phonetics, maintenance of supporting tissues)
- Psychologic impact (patient satisfaction, esthetics, quality of life)
- Cost and effort (initial and recurring)

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