Chapter 10

Conclusions
Conclusions (English)

Treatment sequencing, patient selection and implant-prosthetic design are of paramount importance for achieving long-lasting results. These parameters should be analyzed separately for edentulous maxilla and mandible with fixed implant prosthesis.

Treatment Sequence – Loading Protocols.

The highest level of scientific and clinical validation was found for conventional loading with mandibular and maxillary fixed dental prostheses. Insufficient scientific or clinical documentation/validation was found for immediate loading of immediately placed implants combined with fixed dental prostheses in either jaw. All other loading protocols for edentulous arches showed different degrees of clinical documentation without proper scientific validation.

*Conventional loading in the edentulous maxilla:* this protocol describes the use of dental implants placed in an edentulous maxilla to support fixed prostheses after a healing period of 2 months. Prosthetic designs for maxillary fixed rehabilitation include: (a) fixed splinted rehabilitation supported by 4 to 6 anterior implants (placed in between maxillary sinuses) and bilateral distal cantilevers; (b) fixed splinted rehabilitation supported by 6 to 8 anterior–posterior implants without bilateral cantilevers; and (c) complete fixed segmented rehabilitation supported by 8 anterior–posterior implants. (Table 2)

Scientific evidence on fixed-implant rehabilitations in the edentulous maxilla reports an implant survival rate ranging from 95.5% to 97.9%. This clinical situation with a conventional loading approach is scientifically and clinically validated according to the validation methodology proposed at the 4th ITI Consensus Conference.

Conventional loading protocols for maxillary fixed implant rehabilitations are indicated in cases with poor primary stability, in implants placed in association with bone augmentation, in short implants, or in implant/prosthetic protocols with minimal number of implants. Here the number of implants and their distribution along the arch would only play a role in the long-term implant survival rate. This is not the case for reducing healing periods where this particular
parameter plays an important role in early failures. Current scientific evidence for fixed implant rehabilitation in the edentulous maxilla indicates that a minimum of six implants with the anterior posterior distribution present more favorable survival rate at 10 years when compared with prosthetic designs with 4 or 5 implants with the anterior distribution only.

Since a conventional loading protocol allows for at least a 2-month healing phase, one particular concern during this period is the provisional prosthesis. Options include relining of the existing denture or fabrication of a new complete removable prosthesis. It is critical at this stage to avoid the direct contact between the denture base and the freshly placed implants. To lessen the force spread from the prosthesis to the recently placed implants it is advisable to use soft relining material.

*Early loading in the edentulous maxilla:* Early implant loading with fixed rehabilitations describes a protocol in which implants have been in occlusal contact no earlier than one week and no later than 2 months. (Table 2)

Early loading protocols can be applied with predictable results using rough-surfaced implants for the rehabilitation of the completely edentulous maxilla with fixed prostheses. Clinical studies have shown no important differences between early and conventional loading of implants with fixed prostheses in the edentulous maxilla with a follow-up time of 1 to 5 years. Resulting implant survival rates range from 93% to 99%. However, early loading protocol also requires a removable transition period similar to the conventional one, but shorter. Because of this, an early loading approach for maxillary fixed prosthesis offers slightly different results than conventional loading. Recent improvements in the implant surface could be beneficial for this loading protocol, although more scientific and clinical evidence is still being developed.

Early loading protocol for maxillary fixed implant rehabilitations is indicated in cases where bone volume is adequate to allocate at least six standard size implants in native bone. It should ideally be avoided in cases with insufficient primary stability, in implants placed in association with simultaneous bone augmentation, in short implants, or in implant/prosthetic protocols with minimal number of implants.
**Immediate loading in the edentulous maxilla:** This loading protocol describes maxillary implants that have been placed in occlusal function via fixed prostheses no later than one week after placement.

Various implant/prosthetic protocols have been proposed for immediate implant loading in the edentulous maxilla. (a) 8 maxillary implants immediately loaded via a full-arch fixed interim prosthesis that was later replaced by a segmented final rehabilitation. This approach is compatible with the achievement of osseointegration as shown with other prosthetic designs. (b) 6 to 7 implants for immediate loading of a maxillary fixed provisional prosthesis subsequently replaced by a full arch one piece final prosthesis as a final prosthetic design. (c) A protocol of 4 immediately loaded implants. Here the scientific evidence is scarce and often some rescue implants left unloaded have been recommended. This is an indicator that such a small number of implants would not be appropriate for immediate loading.

Scientific background for immediate loading with fixed interim prostheses in the edentulous maxilla presents an implant survival rate ranging from 95.4% to 100%. One notable finding was that most of the failed implants were located in the posterior maxilla. According to the 4th ITI Consensus Meeting, this loading protocol is clinically well documented with six or more implants.

Immediate loading protocol for maxillary fixed implant rehabilitations is indicated in cases where bone volume is adequate to allocate at least six standard size implants in native or previously grafted jaw bone. In addition, an adequate inter-arch relationship is desirable. Like with early loading, this protocol should ideally be avoided in cases with insufficient primary stability, in implants placed in association with simultaneous bone augmentation, in short implants, or in implant/prosthetic protocols with minimal number of implants.

Long-term results for conventional and immediate loading are reported as similar in terms of implant survival rate, level of scientific evidence, sample population, and outcome homogeneity. In this context, immediate loading avoids the necessity of an often complex adaptation of the provisional complete denture after surgery and possibly exposing the implants to non-controlled premature loading.

Several immediate provisional techniques have been proposed: (a) Complete denture conversion for either intra-surgical impressions or direct relining, (b) pre-fabricated provisional
template to be adapted either in the mouth by direct relining or in the laboratory on a working model obtained from an intra-surgical impression and (c) pick-up technique avoiding intrasurgical impression, direct relining, or master cast fabrication.

Clinical observations have demonstrated that the placement of an immediate provisional has some bearing the peri-implant tissue morphology according to the emergence profile created at the cervical aspect of such provisional. The contour of the peri-implant soft tissue after treatment resulted as wider and was located in a more apical position than the original mucosal level. Thus, the tip of the papilla-like mucosa (interproximal sites) would be located at the shortest distance to the original mucosal level before treatment. Clinically, the scalloped mucosal configuration with immediate loading provisional prosthesis was rather consistent along the rehabilitated arch. Significant dimensional changes of the peri-implant mucosa were observed with an immediate loading approach.

**Conventional loading in the edentulous Mandible:** This loading protocol describes the use of dental implants placed in an edentulous mandible to support a fixed dental prosthesis after a healing period of 2 months. Implant prosthetic designs included 4 to 6 implants with a one-piece full-arch fixed prosthesis and 6 implants with a segmented fixed prosthesis. The long-term clinical results of mandibular implant-supported fixed rehabilitations are predictable in terms of prosthetic function and implant stability. Conventional loading of mandibular fixed-implant prostheses is generally scientifically and clinically validated with implant survival rates ranging from 97.2% to 98.7% in a 10 year follow-up.

Implant number and distribution is directly influenced by the anatomical situation and implant prosthetic designs present an anterior only or an anterior- posterior distribution. In the anterior distribution the length of the distal cantilevers is determined by the number of implants supporting such rehabilitation.

Similar to conventional loading protocols in other clinical indications, special attention should be given to the post-operative adjustment of the mandibular denture.
**Early loading in the edentulous Mandible:** This loading protocol describes mandibular fixed-implant rehabilitations that have been in functional loading between one week and 2 months after implant placement. Early loading of implants in the edentulous mandible with fixed-implant rehabilitations is clinically documented with a survival rate ranging from 98.6% to 100% in a 1 to 3 year follow-up. Here, a small number of studies report that early loading of implants supporting cross-arch fixed prostheses in the edentulous mandible can be a predictable procedure. Clinical trials with one-year follow-up of early loading with rough- and machined-surface implants report that the implant survival rate was significantly higher for rough-surface implants. Treatment outcomes for early loading in the edentulous mandible with fixed prostheses are comparable with conventional protocols.

Early loading protocol for fixed implant rehabilitations in the edentulous mandible is indicated in cases where bone volume is adequate to allocate at least six standard size implants. It should ideally be deferred in cases with insufficient primary stability, in implants placed in association with simultaneous bone augmentation, in implants reduced in length, and minimal number of implants used to support the fixed prosthesis.

**Immediate loading in the edentulous Mandible:** Immediate loading with fixed mandibular implant-supported prosthesis describes a protocol in which a fixed provisional is attached to the implants and placed in occlusal function within one week after implant placement. Osseointegration with immediate implant loading via fixed provisional restorations can be successfully achieved in the edentulous mandible.

However, implant–prosthetic protocols with 5-6 implants are better documented than those with 4 implants. (Table 4) This protocol with fewer implants raises the concern of jeopardizing the stability of a fixed prosthesis in the adverse event of one implant failure.

Immediate loading of rough-surface implants with a fixed provisional restoration is clinically well documented, presenting 1 to 3 year survival rates ranging from 99.4% to 100%.
Similar to immediate loading in other clinical situations, standard implant size, primary stability and implant placement into an adequate bone volume are prerequisites for this loading protocol.

When the implant/prosthetic design includes implants placed in the anterior mandible, distal cantilevers should ideally be avoided in the immediate provisional and hence functional and esthetic parameters should be carefully assessed. Immediate provisional techniques are similar to those presented for the edentulous maxilla with immediate loading, including complete denture conversion and pick-up technique.

Immediate loading by means of screw-retained one-piece (cross-arch) provisional restorations of implants placed in edentulous jaws does not appear to jeopardize achievement of osseointegration. Neither the metal-free provisional design nor removal of the provisional prosthesis during the healing phase adversely affected osseointegration.

Implant Prosthetic Design - Mandible

In the mandible, the resorption pattern after tooth extraction often involves bone remodeling that takes place at the two coronal thirds, while the basal third of the mandible remains stable. Another important anatomical element in the mandible is the dental nerve running along the posterior segments until its emergence at the premolar areas. Based on these anatomical considerations, there is a clear distinction between the anterior and posterior segments of the edentulous mandible.

The mandibular interforaminal zone represents an ideal area for implant placement. Here the bone volume is normally adequate for allocating up to 6 implants. In addition, the bone density of the area is favorable for achieving implant primary stability. Among all these anatomical perks, the interforaminal area often allows for an anterior implant distribution exclusively. While this situation is suitable for implants intended to support/retain a mandibular overdenture, mandibular fixed rehabilitations often call for distal cantilevers.

When implants can be allocated in an anterior and posterior distribution, one particular clinical consideration is the flexural deformation of the mandible at movement. In this context, when
Implants are distributed in the anterior and posterior area of the mandible, a segmented prosthetic design can be used for the final rehabilitation.

Clinical considerations presented above, along with implant prosthetic parameters are taken into consideration when selecting the appropriate loading protocol.

Mandibular fixed implant-supported rehabilitation with distal cantilever resulted in a reliable treatment modality over the 5-year observation period. Although biological parameters of MPI, SBI, keratinized tissue and peri-implant mucosal levels showed statistically significant differences over time, the mean values for each patient remained within the normal limits of oral health. Complications were categorized as biological or technical. The majority of complications were technical complications (54/79) and of these most involved fracture of the acrylic teeth and base (20/54). While the survival rate was 100% for implants and 95.5% for prostheses, the application of strict criteria for treatment success resulted in an overall treatment success rate of 86.7%.

In order to improve the accuracy of fitting in fixed implant-supported rehabilitations in the edentulous jaws, a splinted impression technique generated more accurate master casts than the non-splinted technique for one-piece IFCDPs. These clinical implications demonstrate improved accuracy of splinted impression techniques compared to the non-splinted technique. For the external connection implant system used in this study, a 3-D misfit ranging from 59 to 72 µm may be considered the maximum discrepancy resulting in an acceptable clinical fit with one-piece IFCDPs.

Implant Prosthetic Design – Maxilla

In the case of maxillary rehabilitations, the implant/prosthetic design should ideally result from careful patient selection and diagnostic planning. This allows for evaluation of an appropriate artificial teeth allocation and emergence profile, as well as occlusion, phonetics, lips and facial support, and esthetic parameters - all of which will determine the treatment feasibility and the patient’s approval of the proposed treatment plan.
Parameters for loading protocols are of particular importance regarding the maxillary bone volume and density, the relationship of maxillary sinuses with the alveolar process and the resorption pattern after tooth extraction. Here, the achievement of primary stability may be influenced by the placement of shorter or smaller diameter implants due to reduced bone volume, or standard size implant placed in bone of low density. In this context, selection of a specific loading protocol is often based on the achieved primary stability after implant placement.

For maxillary Implants with rough surfaces showed a statistically higher survival rate than machined implants. Implants placed in augmented bone had a statistically lower survival rate, except for rough-surface implants, for which no statistical difference between augmented and non-augmented bone survival rates was found. Machined implants showed a stable survival rate only when placed in native bone. When machined implants were placed in augmented bone, the survival rate decreased significantly at each study endpoint. The prosthetic design, veneering material, and the number of prostheses per arch had no influence on the prosthodontic survival rate. Implant number and distribution along the edentulous maxilla seemed to influence the prosthodontic survival rate.

Patient medical condition, local risk factors, and complications

Treatment regulators involve clinical considerations at all diagnostic, planning, surgical, and prosthodontic and maintenance levels, suggesting a specific indication for a given loading protocol.

Patient medical condition: Reports regarding tendency for subjects with diabetes to have higher failure rates are conflicting. Clinical studies show no or minimal statistical difference for increased risk of implant failure. Once the indication for implant placement in an edentulous patient with diabetes is confirmed, a conventional or early loading approach should ideally be
selected. This allows for monitoring post-operative healing during the determined healing phase.

Bisphosphonate therapy and implant surgery including the duration and the dosage of the medication, as well as the type of the bisphosphonate are reported to play an important role in a potential bisphosphonate-related osteonecrosis of the jaws. Although there is not enough data to estimate the risk for oral bisphosphonates in implant therapy, decision making involving patient’s physician would help determine the adequate treatment selection. In case of indication for implant placement, a conventional loading protocol would be indicated.

Smoking is a risk factor for implant survival and success. Data suggests that smoking is a risk factor for implants placed in augmented sinuses. In addition, several studies demonstrate that smoking is a risk factor for radiographic marginal bone loss with a dose-effect related to cigarette smoking. Before selecting a conventional loading approach in smoker patients the indication for implant placement has to be confirmed in relation to the smoking frequency and willingness of the patient to reduce smoking during treatment.

Reduced manual dexterity is presented as a risk factor for edentulous patients when it comes to oral hygiene maintenance and removal of overdentures. In this case, the ideal implant-prosthetic design should be carefully selected to ensure that these patients can effectively perform oral care. Here, a conventional loading protocol with regular check-ups seems to be the indicated approach.

**Treatment regulators:** Bone volume and density, surgical technique, implant size and primary stability are important treatment regulators in the decision making for loading protocols in edentulous patients. For protocols with reduced healing time such as early or immediate loading, an ideal implant length of 10 mm intraosseous anchorage in native or healed bone is recommended. In cases of implant placement with simultaneous bone augmentation to regenerate any bone deficiency, conventional loading is indicated. The extent of the healing period is normally determined by the magnitude of the bone regeneration technique in association with the achieved implant primary stability. In some cases it is necessary to extend
the healing time beyond the 2-month minimum recommended for a conventional loading protocol.

Implant surface properties play an important role in reducing the loading time. In particular, rough surface implant demonstrated both improved bone to implant contact (BIC) and resistance to motion. Rough surface implants are largely used for all loading protocols nowadays. Later improvements, including a chemically modified rough surface, show data reporting on increased BIC and higher implant torque values at 3 weeks after placement. This particular finding, when implants comply with all other treatment regulators, broadens the indication for early loading in several clinical situations.

The number of implants and their distribution along the arch is another important regulator and it should primarily be related to the desired final implant-prosthetic protocol. A larger number of implants with an anterior-posterior distribution (cross-arch stabilization) for fixed prosthesis are the most suitable for early or immediate loading when other treatment regulators are optimal. For implant prosthetic designs with fewer implants, for implants with only an anterior distribution, or for freestanding implants a conventional loading approach seems to be an appropriated loading protocol.

Patient expectations regarding the treatment planning are considered another regulator influencing the selection of a specific loading protocol. Thus, edentulous patients with a successful history of a complete denture, seeking to improve their comfort by means of dental implants may tolerate well a conventional healing time without the associated difficulties of other loading protocols. Conversely, edentulous patients with difficulties carrying a complete denture might favor a shorter protocol.

All above described treatment regulators are normally conjunctly assessed in order to select the adequate loading protocol.

**Risk for Complications:**

As in any other clinical situation, biological and technical complications can occur in the treatment of edentulous jaws with implant-prosthetic rehabilitations. In terms of complications associated with the selected protocol, one of primary concern is the interference with the
normal implant osseointegration process during the healing phase. For conventional and early loading protocols in edentulous patients, the avoidance of loading the implant with uncontrolled forces from prosthesis is essential. Here, a soft relining is normally used to prevent this condition. When the implants are planned to be loaded in a conventional way, some protocols suggest a one-week period before wearing the prosthesis.

For immediate loading with a fixed provisional, the loading transfer to the implants should ensure implant micro-motion to a minimum in order to avoid early implant failures. In the case of fixed provisional, a rigid splinting of all immediately loaded implants is paramount for avoiding implant overloading. Fractures of the immediate transitional fixed prosthesis are also responsible for implant overloading and subsequent interference with osseointegration. In all cases of fixed temporary prosthesis, a screwed retention approach is recommended. This design eliminates the complication of cement excesses being displaced into the wound zone.

During the healing phase under immediate implant loading, a monthly follow-up schedule is advisable to monitor implant stability and assess oral hygiene.

Biological and technical complications with fixed implant supported rehabilitations occur continuously over time due to the fatigue and stress on the materials that are selected. These events may lead to implant/prosthetic failures, but are significant in relation to the number of repair and maintenance sessions, time, and cost to both the clinician and patient. In selecting loading protocols for the treatment of edentulous patients, several parameters should be considered, including the systemic and local risk factors. Some of the implant-prosthetic diagnostic parameters discussed in earlier chapters play an important role as treatment regulators.