

# Consensus Statements and Recommended Clinical Procedures Regarding Implant Survival and Complications

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# **INTRODUCTORY REMARKS**

The working group based its discussion on 2 systematic reviews published in 2002, 2 systematic reviews published in 2004 on related topics, and 3 traditional reviews prepared specifically for this consensus workshop (see reference list).

After extensive discussion, the previously unpublished reviews were amended where indicated, and consensus was reached that the reviews were both comprehensive and complete in covering the available published literature up to August of 2003. Hence, the papers were accepted and formed the basis for the consensus report on implant survival and complications. Subsequent to the consensus meeting, the quoted literature was updated up to December 2003.

For the purpose of clarification and understanding of the evaluated literature, the working group adopted a glossary of terms.

# **GLOSSARY OF TERMS**

- *Survival:* The element (implant or reconstruction) is present at the follow-up examination but its condition is not specified.
- *Success:* The element (implant or reconstruction) is present at the follow-up examination, and complications are absent.
- *Loss*: The element (implant or reconstruction) is no longer present at the time of the follow-up examination.
- *Complications:* Chair time is required after incorporation of the prosthesis.
- *Failure:* Either the element (implant or reconstruction) is lost or a complication is present at

the follow-up examination. Hence, this term will generally be avoided and replaced by the abovementioned terms.

• FPD: Fixed partial denture

Terms related to biologic complications/periimplant disease:

- Mucositis: Localized lesion without bone loss around an osseointegrated implant
- Peri-implantitis: Localized lesion including bone loss around an osseointegrated implant
- Soft tissue complications: Fistula, excessive swelling, hyperplasia, etc

Terms related to technical complications:

- Implant-related: Fracture
- Connection-related: Loosening, fractures
- Suprastructure-related: Framework, veneer, loss of retention (fracture of the cement seal)

# **CONSENSUS STATEMENTS**

#### Single Crowns and Overdentures

A recently published systematic review addressed the incidence of implant loss and complications of oral implants supporting single crowns over at least 5 years.<sup>1</sup> The analysis was based on 8 studies and yielded an early loss of 0.8% before prosthetic placement and an incidence of 2% to 2.5% loss during 5 years of function. The same systematic review reported 2.5% implant loss prior to the placement of overdentures and nearly 6% implant loss during 5 years of function.

#### **Fixed Partial Dentures**

The systematic reviews prepared for this consensus workshop reported exclusively on complica-tion and survival rates of fixed partial dentures (FPDs), either implant-supported or implant/ tooth-supported.

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For implant-supported FPDs<sup>2</sup> the following conclusions were drawn:

- The cumulative survival rate of oral implants supporting FPDs was 95.4% after 5 years of function and 92.8% after 10 years of function. This evidence is derived from 10 prospective and 5 retrospective cohort studies with a mean of 5 years of follow-up and 6 prospective cohort studies with a mean 10-year follow-up.
- With regard to the ITI Dental Implant System, on the basis of 2 prospective cohort studies with 5 years of follow-up and 1 study with 10 years of follow-up, the survival rates were 97.2% and 98.6%, respectively.
- The cumulative survival rate of FPDs supported by oral implants was 95.0% after 5 years of function and 86.7% after 10 years of function. This evidence is derived from 14 studies including 1,289 FPDs after 5 years and 3 studies including 219 FPDs after 10 years.
- With regard to the ITI Dental Implant System, on the basis of 2 prospective cohort studies with 5 years of follow-up (n = 108) and 1 study with 10 years of follow-up (n = 33), the cumulative survival rates for FPDs were 98.3% at 5 years and 93.9% at 10 years, respectively.
- FPDs without any biologic or technical complications were encountered in 61.3% of patients after 5 years. Data on the absence of complications were available from only 4 of the 21 cohort studies. It should be noted that the implant types and components reported in the literature have been modified, and some of them are no longer available.
- Reports of biologic complications were variable in nature. Based on 8 cohort studies, periimplantitis and soft tissue complications occurred in 8.6% of patients after 5 years.
- Reports on technical complications included implant fracture and connection-related and suprastructure-related complications. Based on 7 cohort studies with 5 years of follow-up and 4 studies with 10 years of follow-up, the incidence of implant fracture was 0.4% after 5 years and 1.8% after 10 years. The incidence of connection-related complications (screw loosening or fracture) was 7.3% (5 years). The incidence of suprastructure-related complications (veneer and framework fracture) was 14.0% after 5 years. Of the 7% of the restorations that were cemented, loss of retention of the restoration occurred in 2.9% within 5 years and 16.2% within 10 years.

For the combined tooth/implant-supported FPDs<sup>3</sup> the following conclusions were drawn:

- The cumulative survival rate of oral implants used in implant/tooth-supported FPDs was 90.1% after 5 years of function and 82.1% after 10 years of function. This evidence is derived from 8 cohort studies with a mean follow-up of 5.7 years and 4 cohort studies with a mean 10year follow-up period.
- With regard to the ITI Dental Implant System, on the basis of 1 prospective cohort study of 5 years of follow-up and 1 study with a 10-year follow-up, the corresponding survival rates were 94.8% and 77.3%, respectively.
- The cumulative survival rate of FPDs supported by oral implants and teeth was 94.1% after 5 years of function and 77.8% after 10 years of function. This evidence is derived from 5 studies including 114 FPDs after 5 years and 3 studies including 60 FPDs after 10 years.
- With regard to the ITI Dental Implant System, on the basis of 1 prospective cohort study of 5 years of follow-up (n = 18) and 1 study of 10 years of follow-up (n = 22), the cumulative survival rates for FPDs were 94.5% and 79.3%, respectively.
- Combined tooth/implant FPDs with no biologic or technical complications were seen in 50% of patients after 10 years. However, data on the absence of complications were only available from 1 of the 13 cohort studies.
- Biologic complications adjacent to implants were reported in 2 studies. Based on these studies, peri-implantitis and soft tissue complications occurred in 11.7% of implants after 5 years.
- Reports on technical complications included implant fracture and connection-related and suprastructure-related complications. Based on 4 cohort studies with 5 years of follow-up and 2 studies with 10 years of follow-up, the incidence of implant fracture was 0.9% after 5 years. The incidence of connection-related complications (screw loosening or fracture) was 4.3% after 5 years and 26.4% after 10 years. The incidence of suprastructure-related complications (veneer and framework fracture) was 9.8% after 5 years. Of the 9% of restorations that were cemented, loss of retention of the restoration occurred in 6.2% (2 studies) within 5 years and 24.9% (1 study) within 10 years.
- The incidence of abutment tooth loss was 3.2% after 5 years and 10.6% after 10 years. Implants were lost in 3.4% and 15.4%, respectively. These observations are based on six 5-year cohort studies and two 10-year cohort studies, respectively. Information about the association between biologic complications around teeth (caries, tooth

fractures, endodontic complications, and periodontitis) and the loss of the abutment teeth could not be determined from these studies.

• The reported incidence of complications encountered, especially over the 10-year observation period, should be interpreted cautiously because of the limited number of studies (n = 2) available and the small sample sizes (n = 20 and 22).

# **CLINICAL IMPLICATIONS**

Implant-supported and implant/tooth-supported FPDs present with high implant and restoration survival rates. However, biologic and technical complications occurred in about half the cases after 5 years of function.

The combined implant/tooth-supported FPDs showed slightly elevated rates of technical complications after 5 years of function. In addition to the expected complications encountered with oral implants or components, abutment teeth may develop additional biologic complications (endodontic, caries, fracture) leading to abutment loss. Therefore, implant-supported FPDs appear to be preferable to combined tooth/implant-supported FPDs.

Because of the limited availability of long-term documentation (10 years) for combined implant/ tooth-supported FPDs, no clinical estimates can be made with regard to longevity or complication rates.

#### **Diagnostic Parameters**

For the review of diagnostic parameters<sup>4</sup> the following conclusions and clinical recommendations are presented.

Systematic and continuous monitoring of periimplant tissues is recommended for the early diagnosis of peri-implant disease. The parameters that may be used to assess the presence and severity of disease include assessment of plaque accumulation, scrutiny of mucosal conditions, peri-implant probing depth (PD), width of peri-implant keratinized mucosa, analysis of peri-implant sulcus fluid, monitoring for suppuration, and evaluation of aspects of the bone-implant interface such as implant mobility, radiographic interpretation and—maybe—resonance frequency analysis.

*Plaque Assessment.* Like tooth surfaces, implant surfaces are subjected to biofilm formation. Hence, patients should be instructed and motivated to regularly perform an adequate level of plaque control around both teeth and implants. To assess the level of oral hygiene during maintenance care, plaque deposits may be visualized with staining solutions and, if indicated, the patient re-instructed in the correct use of cleansing devices.

*Mucosal Conditions*. As a result of biofilm formation, an inflammatory host response develops in the peri-implant soft tissue compartment. Although a modification of the Gingival Index has been used to assess peri-implant mucosal health or marginal inflammation (ie, peri-implant mucositis), the bleeding on probing (BOP) parameter may be preferred for longitudinal clinical documentation.

Absence of BOP may represent stable periimplant soft tissue status, similar to the way that absence of BOP indicates periodontal health. Therefore, periodic recording of this parameter in conjunction with light probing force (ie, 0.2 to 0.25 N) can be recommended to monitor peri-implant soft tissue conditions.

Peri-implant PD. As a result of inflammation, the peri-implant sulcus may develop into a pocket. Therefore, peri-implant probing should be performed with a light force (ie, 0.2 to 0.25 N) to avoid tissue trauma. It should be viewed as an important and reliable diagnostic parameter in the longitudinal monitoring of peri-implant soft tissue conditions. No adverse effects on the integrity of the peri-implant soft tissue seal should occur from repeated probing.

PDs for conventionally placed implants generally range between 2 and 4 mm under healthy conditions. In sites of esthetic priority, where the implant shoulder has intentionally been placed submucosally, or where mucosal tissues are thick, deeper baseline PDs may be present. Increases in PD above these baseline values should be viewed as a sign of peri-implant disease.

Width of Peri-implant Keratinized Mucosa. No definite recommendation can be made on the need for keratinized mucosa around implants in humans. Nevertheless, preservation of the peri-implant keratinized mucosa is advocated. In the absence of keratinized mucosa around implants, the indications for soft tissue grafting are unclear.

Peri-implant Sulcus Fluid Analysis. Although biochemical markers reflecting the host-parasite interaction in the peri-implant sulcus may be useful for the study of the pathogenesis of peri-implant disease, no specific marker has been identified for routine diagnostic use.

Suppuration. Suppuration has been associated with peri-implantitis in case reports. However, sensitivity and specificity of suppuration as a marker for the detection of initial peri-implantitis or its progression are lacking.

#### **Evaluation of the Bone-Implant Interface**

*Implant Mobility.* Implant mobility is indicative of the absence of osseointegration. However, it is not a sensitive parameter for the detection of periimplant disease. Therefore, routine assessment of implant mobility is not essential. When it is used, it should always be performed in conjunction with evaluation of the clinical and radiographic parameters. Because of its poor diagnostic accuracy, the Periotest cannot be recommended.

Radiographic Interpretation. It is appropriate to establish baseline bone levels at the time of prosthesis placement. However, justification for repeated exposure to radiation during maintenance care should not be based on predetermined protocols. The indication for radiographic examination should be made following individual clinical assessment. The imaging method should be selected to minimize radiation exposure and may be influenced by the number of implants to be imaged and their distribution in the jaws.

Resonance Frequency Analysis. This recently developed diagnostic instrument is intended to assess implant stability. However, studies validating its diagnostic utility are still lacking.

### **Treatment of Peri-implant Diseases**

For the review of antimicrobial treatment of periimplant diseases<sup>5</sup> and surgical treatment of periimplantitis,<sup>6</sup> the following conclusions are presented:

- Evidence for antimicrobial treatment of periimplant diseases is limited. There is a need to determine whether antimicrobials are effective in the treatment of peri-implant diseases.
- A variety of antimicrobial treatment regimens, in combination with nonsurgical or surgical debridement and with and without regenerative therapy, have been reported. Use of antimicrobials varied between studies with respect to type of drug, dosage, delivery system, time of initial administration, and duration. Patient compliance and adverse effects related to the antimicrobials were mostly not mentioned. While the majority of the case reports and studies available showed positive outcomes following antimicrobial treatment, no nonmedicated controls were included; therefore the relative effect of the antimicrobial agent(s) cannot be evaluated.
- Surgical procedures have been assessed in case report series and animal experiments. Clinically healthy peri-implant tissues have been reported following treatment. However, the amount of bone regeneration and re-osseointegration varied

substantially. Recently performed animal experiments including implants with a titanium plasma-sprayed or sandblasted/acid-etched surface indicate that considerable bone regeneration and re-osseointegration can be obtained with and without membrane-covered bone grafts. However, these results should be confirmed in prospective cohort studies before specific recommendations on surgical treatment procedures in humans are made.

• Numerous methods to decontaminate implant surfaces have been used as a part of the surgical procedure. Comparisons of decontamination methods did not reveal any statistically significant differences in treatment outcomes.

#### RECOMMENDATIONS

- Following successful implant therapy, patients should be offered an individualized supportive care program.
- Systematic and continuous monitoring of periimplant tissue conditions is recommended for the diagnosis of peri-implant health and disease. The parameters that are recommended to assess the presence and severity of disease include: presence of plaque and calculus, peri-implant PD, presence of BOP, presence of suppuration, and, if indicated, radiographic evaluation.
- Based on periodic diagnosis, and in agreement with the previous ITI consensus report,<sup>7</sup> the Cumulative Interceptive Supportive Therapy (CIST) protocol (Fig 1) is recommended. This protocol includes 4 treatment modalities: A = mechanical debridement; B = antiseptic treatment; C = antibiotic treatment; and D = regenerative or resective surgery. Although this protocol has not been assessed in its entirety, 2 prospective cohort studies have evaluated the treatment modalities A + B + C. The benefits of adding surgical therapy (D) to the CIST protocol are documented in case series, single case reports, and a series of animal experiments.

The CIST protocol is also in agreement with the systematic review<sup>8</sup> presented at the 4th European Workshop on Periodontology in Ittingen, Switzerland, which suggested a combination of various anti-infective therapies (mechanical, antiseptic, and antibiotic) to prior surgical intervention.



**Fig 1** Cumulative Interceptive Supportive Therapy (CIST) protocol. Note that PDs may exceed the normal range stated here, so that PDs used to determine the protocol may have to be adjusted for these differences. In part A of the CIST protocol, typically initiated when plaque and BOP are present but PDs are 3 mm or less, patients are re-instructed in oral hygiene and motivated to initiate and continue maintenance; mechanical debridement is performed using nonmetallic curettes; and polishing takes place using a rubber cup and nonbarsive polishing paste. Part B, when PDs of 4 to 5 mm are found, consists of antiseptic treatment. Here, chemical plaque control is performed using chlorhexidine digluconate, typically as mouthrinses with 0.1% to 0.2% chlorhexidine for 30 seconds using approximately 10 mL, application of local chlorhexidine gle (0.2%), and/or local irrigation with chlorhexidine (0.2%), 2 times a day for 3 to 4 weeks. Protocol C, systemic or local antibiotic treatment, is initiated when PDs are greater than 5 mm. In addition, radiography should be used to supplement clinical findings. Typical systemic treatment is with ornidazole (1,000 mg  $\times$  1) or metronidazole (250 mg  $\times$  3) for 10 days, or a combination of amoxicillin (375 mg  $\times$  3) and metronidazole (250 mg  $\times$  3) for 10 days. Local treatment might include local application of antibiotics using a controlled-release device for 10 days, eg, tetracycline fibers and minocycline microspheres. Once treatment modalities A, B, and C have been completed, a surgical approach (D) may be considered. Surgical therapy for peri-implantitis should be performed in conjunction with systemic antibiotics and implant surface decontamination. If regenerative treatment is chosen, a barrier membrane technique alone or in combination with autogenous grafts and/or bone substitutes (deproteinized bovine bone mineral) may be considered. Resective surgery may be considered when the peri-implant defect is not suitable for regenerative techniques.

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