

Consensus Statements and Clinical Recommendations for Prevention and Management of Biologic and Technical Implant Complications

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INTRODUCTORY REMARKS

Implant treatment is highly successful, as documented in a wealth of scientific literature. However, patients and clinicians should expect to see complications within their daily practice. The aim of the papers presented by this group was to address the prevention and management of technical and biologic complications in order to make recommendations both for clinical practice and future research. Three topics were chosen within the field of complications of implant treatment, and these addressed prevention and therapy of peri-implant disease and prevention of technical complications.

Three systematic reviews were conducted and formed the basis for discussion of working group 5. The discussions led to the development of statements and recommendations determined by group consensus based on the findings of the systematic reviews. These were then presented and accepted following modifications as necessary at plenary sessions.

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Disclosure

All the group members were asked to reveal any conflicts of interest that could potentially influence the outcomes of the consensus deliberations. No such conflicts were identified.

EFFECTS OF ANTI-INFECTIVE PREVENTIVE MEASURES ON BIOLOGIC IMPLANT COMPLICATIONS AND IMPLANT LOSS

Consensus Statements

The aim of the review by Salvi and Zitzmann was to systematically appraise whether anti-infective protocols are effective in preventing biologic implant complications and implant loss after a mean observation period of at least 10 years following delivery of the prosthesis. Out of 15 included studies, only one comparative study assessed the effects of adherence to supportive periodontal therapy (SPT) on the occurrence of biological complications and implant loss. In view of the lack of randomized trials, observational studies including adherence and lack of adherence to SPT were considered valuable in order to estimate the effects of SPT on implant longevity and the occurrence of biological complications.

- Overall, the outcomes of this systematic review indicated that high long-term survival and success rates of dental implants can be achieved in partially and fully edentulous patients adhering to SPT.
- Long-term implant survival and success rates are lower in patients with a history of periodontal disease adhering to SPT compared with those without a history of periodontal disease.
- The findings of this systematic review indicate that pre-existing peri-implant mucositis in conjunction with lack of adherence to SPT was associated with a higher incidence of peri-implantitis.

Treatment Guidelines

Preventive Measures Before Implant Placement

- Residual periodontal pockets are a risk for peri-implant disease and implant loss. Therefore, completion of active periodontal therapy aiming for elimination of residual pockets with bleeding on probing

should precede implant placement in periodontally compromised patients.

- In cases of residual probing depths (PD) \geq 5 mm with concomitant bleeding on probing, full-mouth plaque scores $>$ 20%, and associated risk factors, retreatment and periodontal reevaluation are recommended before implant placement.
- In subjects diagnosed with aggressive periodontitis, an SPT program with shorter intervals is a prerequisite.
- During implant treatment planning, factors to be considered that may result in biological complications include: insufficient keratinized mucosa and bone volume at the implant recipient site, implant proximity, three-dimensional implant position, and design and cleansability of the prosthesis. Alternative restorative solutions should be considered according to a patient's individual circumstances.

Preventive Measures After Implant Placement

- All oral health care providers, including undergraduate students, should be trained to recognize clinical signs of peri-implant pathology and maintain or reestablish peri-implant health.
- After delivery of the definitive implant-supported prosthesis, clinical and radiographic baseline measurements should be established.
- During SPT, an update of medical and dental history and a clinical inspection of the implant-supported prosthesis including the evaluation of iatrogenic factors (eg, cement remnants, misfit of prostheses, implant proximity with insufficient access for interproximal oral hygiene) should constitute the basis of a proper diagnostic process.
- Regular diagnostic monitoring of the peri-implant tissues includes assessment of presence of plaque, PD, bleeding on gentle probing (approx 0.25 N), and/or sup-puration.
- Changes in PD from a fixed landmark should be assessed regularly and compared to previous examinations.
- In the presence of clinical signs of disease, an appropriate radiograph is indicated in order to detect radiographic bone-level changes compared to previous examinations.
- A diagnosis of *peri-implant health* is given in the absence of clinical signs of inflammation. A recall frequency of at least once per year is recommended unless systemic and/or local conditions require more frequent intervals. In cases of peri-implant health, professional cleaning including reinforcement of self-performed oral hygiene is recommended as a preventive measure.
- A diagnosis of *peri-implant mucositis* is given in the presence of individual clinical signs of soft tissue inflammation (eg, redness, edema, sup-puration) and bleeding on gentle probing. If mucositis is diagnosed, in addition to reinforcement of self-performed oral hygiene, mechanical debridement with or without antiseptics (eg, chlorhexidine) is delivered. The use of systemic

antibiotics for the treatment of peri-implant mucositis is not justified. Therapy of peri-implant mucositis should be considered as a preventive measure for the onset of peri-implantitis.

- A diagnosis of *peri-implantitis* is given in the presence of mucositis in conjunction with progressive crestal bone loss. When peri-implantitis is diagnosed, early implementation of appropriate therapy is recommended to prevent further progression of the disease.

Recommendations for Future Research

Future clinical research on preventive measures should include:

- Establishment of baseline data reflecting healthy peri-implant conditions at time of delivery of the definitive prosthesis should constitute the basis for conducting a study on the effects of SPT on the occurrence of biological complications and implant loss.
- Randomized controlled trials (RCTs) comparing SPT protocols with different frequencies should be conducted in patient populations characterized by different risk factors (eg, periodontal health vs history of treated periodontitis, smokers vs nonsmokers, healthy vs systemically compromised patients). These studies may be directed to investigate surrogate measures and risk indicators of peri-implantitis (eg, diagnosis of mucositis, increase in PD, and bone loss on radiographs).
- Studies evaluating the effects of SPT programs in patients with dental implants should assess the occurrence of peri-implant diseases and implant loss as well as the need for interventions. Patient-reported outcomes and health economic aspects of different SPT protocols should be investigated.
- Although RCTs and prospective studies are desirable, well-conducted and reported observational studies are likely to be required in view of the long-term follow-up necessary to detect peri-implantitis.
- All trials should be prospectively registered on an open-access database to minimize publication bias.

THERAPY OF PERI-IMPLANTITIS

Consensus Statements

The focus question for the review by Heitz-Mayfield and Mombelli was: In patients with osseointegrated implants diagnosed with peri-implantitis, how successful is treatment aimed at resolution of the disease?

Currently, there is no standard of care for treating peri-implantitis. Various clinical protocols for treating peri-implantitis have been proposed, including mechanical debridement, the use of antiseptics and local and systemic antibiotics, as well as surgical and regenerative procedures. In view of the lack of comparable randomized controlled trials (RCTs) this review has taken a broader approach to

capture as many relevant studies as possible, including randomized and observational studies, but with consideration to the strengths and limitations of the included research.

The ideal goal of the treatment of peri-implantitis would be the resolution of disease, ie, no suppuration or bleeding on probing, no further bone loss, and the reestablishment and maintenance of healthy peri-implant tissues. A composite outcome to reflect this would include absence of peri-implant PD \geq 5 mm with concomitant bleeding on probing and no suppuration, in addition to no further bone loss. If these criteria are met, it can be assumed that no further intervention other than nonsurgical maintenance care would be required, and the treatment outcome would therefore be regarded as successful. Unfortunately these data were rarely reported in the literature and therefore a compromise composite criterion for successful treatment outcome was employed, ie, implant survival with mean PD < 5 mm and no further bone loss. Although there is no consensus in the literature on whether a 5-mm peri-implant PD alone represents health or disease, this threshold was adopted for the purposes of the review.

This review was based on 33 studies reported in 43 papers including case-series of at least 5 patients treated with the same protocol and comparative studies. No studies were found comparing surgical and nonsurgical protocols. Based on this literature, the following conclusions were drawn:

1. The case definition of peri-implantitis remains unclear and varies substantially between studies.
2. There is a great variety of treatment protocols for both nonsurgical and surgical treatment.
 - a. Nonsurgical therapy included: debridement with hand and powered instruments, air-powder abrasive devices, laser treatment, and local and systemic antimicrobial agents.
 - b. Surgical therapy included: elevation of a mucoperiosteal flap and removal of granulation tissue to gain access to the implant and defect surfaces, decontamination of the implant surface (various techniques) with or without implant surface modification. Some studies also evaluated resective therapy or a variety of regenerative procedures. The majority of the studies employed systemic antimicrobial administration.
3. The following elements are common to most protocols for peri-implantitis therapy:
 - a. Pretreatment phase including establishment of good oral hygiene
 - b. Anti-infective treatment including implant surface cleaning achieved by nonsurgical/surgical access
 - c. Supportive maintenance care
4. The available evidence does not allow recommendation of specific treatment options for peri-implantitis. However, improvement of clinical parameters was reported for the majority of patients, although complete resolution according to a composite success criterion was not usually achieved for all patients. Favorable short-term outcomes were reported in many studies; however, lack of disease resolution as well as progression or recurrence of disease and implant loss, despite treatment, were also reported.
5. Interpretation of the results of studies is complicated by unclear or high risk of bias, heterogeneity of study design, and difficulty of generalizing outcomes to practice settings due to frequent exclusion of patients who smoke, those with poorly controlled diabetes, and other conditions that may affect clinical outcomes.
6. There are no data investigating patient-reported outcomes and economic analysis of therapy.
7. Peri-implantitis therapy was associated with soft-tissue recession, which was most evident following surgical treatment. Postsurgery complications including membrane exposure and infection were also reported.

Treatment Guidelines

1. As peri-implantitis is an infection associated with the presence of a submucosal bacterial biofilm around implants, the primary goal of therapy must be the resolution of the infection, which is achieved by the disruption of the biofilm, the removal of calculus and/or overhanging restoration margins, and the prevention of recurrence of the disease.
2. It is important to try to establish if iatrogenic or other factors have contributed to the infection, for example, ill-fitting or noncleansable overcontoured prostheses, malpositioned implants, or foreign bodies such as impression material or excess luting cement. Noniatrogenic factors may include impacted dental floss.
3. The following sequence of treatment of peri-implantitis is normally recommended.
 - a. Pretreatment phase including:
 - i. Thorough assessment and diagnosis
 - ii. Reduction of risk factors for peri-implantitis; in particular poor oral hygiene, prostheses that prevent adequate access for plaque control, tobacco use, presence of periodontal diseases, and systemic diseases that may predispose to peri-implant disease
 - iii. If required, prosthesis removal and adjustment/replacement
 - b. Nonsurgical debridement focused on maximal removal of biofilm, with or without antimicrobials
 - c. Early reassessment of peri-implant health; normally within 1 to 2 months
 - d. Surgical access if resolution of peri-implantitis has not been achieved. This should include:
 - i. Full-thickness mucoperiosteal flaps and removal of granulation tissue to allow thorough cleaning of the implant surface.
 - ii. Thorough surface decontamination of the implant and restorative components. The following

techniques have been proposed: locally applied chemicals, gauze soaked with saline or antiseptics, hand-powered instruments, air-powder abrasives, Er-YAG lasers, photodynamic therapy, and implant surface modification. There is no evidence for the superiority of any one approach.

- iii. Surgical therapy might also include regenerative or resective approaches
 1. Regenerative approaches include filling of the intraosseous peri-implant defect with a bone substitute/graft/bioactive substance with or without a resorbable barrier membrane. Defect morphology for regeneration would normally require a contained defect. Submerged healing might reduce the risk of membrane exposure. Reestablishment of osseointegration following treatment has not been demonstrated in humans.
 2. Resective approaches include osseous recontouring with apical positioning of the flap.
- iv. Immediate postoperative anti-infective protocol should include daily chlorhexidine rinsing during the healing period until mechanical oral hygiene can be resumed. In the absence of evidence comparing surgical treatment with or without antibiotics, peri- or postoperative systemic antibiotics are recommended in view of the aggressive nature of disease. Professional support of healing and plaque control will be needed during this phase.
- e. Clinical monitoring should be performed on a regular basis and supplemented by appropriate radiographic evaluation as required. Supportive maintenance therapy including reinforcement of effective oral hygiene and professional biofilm removal should be provided on a frequency determined by oral health and the risk profile, likely to be between every 3 to 6 months.
4. Surgical access is likely to be needed for the majority of deep lesions due to the difficulty of accessing the threads and surfaces of the implant.
5. The patient should be advised that:
 - a. Recession of the peri-implant mucosa should be expected following peri-implantitis treatment, in particular after surgical therapy.
 - b. Progression or recurrence of disease might require additional therapy or implant removal.
6. The clinician should consider implant removal as a treatment option. Factors influencing this decision may include the severity of the peri-implantitis lesion, the position of the implant, the surrounding tissues, or when the treatment outcomes are likely to be unsatisfactory.
7. Referral to specialist care for nonresponding peri-implantitis should be considered.

8. Regular assessment of peri-implant health is recommended during SPT to identify disease at an early stage.
9. Training of dental team professionals should include diagnosis and management of peri-implant disease.

Recommendations for Future Research

1. Future research should try to simplify experimental interventions with few component aspects. If possible, the most effective single procedures derived from the literature should be used.
2. Studies are needed to compare surgical and non-surgical therapy of peri-implantitis.
3. The role of systemic antibiotics in treating peri-implantitis needs to be investigated in RCTs.
4. Reporting of peri-implantitis research outcomes:
 - a. Clinical evaluation should report the number of patients with resolution of peri-implantitis defined as: implant survival with no PD greater than 5 mm with concomitant bleeding on probing or suppuration, and no further bone loss.
 - b. Patient-reported outcomes (oral health-related quality of life, esthetics, preferences, etc) should be routinely included in research on peri-implantitis therapy.
 - c. Health economic evaluation of treatment options is needed to help inform choice of therapy.
 - d. Adverse events and complications following treatment should be fully reported.
5. The relatively small differences in outcomes between experimental groups that are common in the existing literature underline the need for RCTs to be confident of the potential to conclude clinically important differences.
6. Critical methodological issues for future research include
 - a. Maximizing protection from bias
 - b. Power calculation for all important outcomes
 - c. Study design to allow and account for drop-outs with full reporting of losses to follow-up
7. All trials should be prospectively registered on an open-access database to minimize publication bias.

SURVIVAL RATES OF IMPLANT-SUPPORTED FIXED PROSTHESES OVER THE LAST DECADES

Consensus Statements

The systematic review by Pjetursson et al was conducted to compare the survival and complication rates of implant-supported prostheses published up to the year 2000 with those reported in studies published after the year 2000. An association between period of publication and fixed implant-supported prosthesis outcomes were found with higher survival rates and overall lower rates of mechanical

and technical complications reported in more recent clinical studies. However, the incidence of reported technical complications is still high. The difference in survival rates was most evident for screw-retained prostheses, where the reported survival rate of 77.6% in the older publications was increased to 96.8% in the more recent ones.

Treatment Guidelines

Risk of Fracture—Implants

1. Implant fracture is a rare complication. To avoid implant fracture it is recommended that clinicians consider the use of appropriately designed and manufactured implants with properly investigated and documented low fracture rates. Similarly, the clinician should use implants manufactured from materials that have been thoroughly investigated.
2. The risk of implant fracture can be considered extremely low when:
 - a. The appropriate distribution, number, and diameter of implants are used
 - b. Implants are placed using a restoratively driven protocol
 - c. Implants are combined with an adequately fitting prosthesis

Risk of Fracture and/or Loosening—Prosthetic Screws

Fracture of manufacturer screws made to specified tolerances can be influenced by three factors: mishandling, misfit, and occlusal forces.

1. Mishandling: To reduce the risk of fracture of prosthetic screws, it is recommended that a clinician follow the manufacturer's instructions for use.
2. Misfit: An inadequately fitting framework may be a predisposing factor to prosthetic screw fracture or loosening. It is recommended to prioritize evaluation of the accuracy of the interface between the machined head of the screw and its seating surface over the entire area of contact to reduce the risk of loosening and fracture.
3. Occlusal forces, usually in the presence of other predisposing factors, misfit, and mishandling, may lead to prosthetic screw fracture or loosening.

Risk of Fracture and/or Loosening—Abutments

1. It is recommended that the clinician carefully evaluate the differential etiology of screw loosening, as the literature does not differentiate between abutment or prosthetic screw loosening sufficiently to conclude which type of screw is more likely to loosen.
2. Metal abutment fracture is a rare complication. Greater caution is advised with ceramic abutments. It is recommended that the specific material-based requirements of ceramics should be respected when choosing, designing, and handling these abutments.

Risk of Fracture of Framework and/or Veneering Materials

1. Currently framework fracture is a rare complication. The choice of material, appropriate design, and method of

fabrication are all factors in reducing the risk of framework fracture.

2. To reduce the risk of fracturing the veneering materials, the framework must provide adequate support for the veneering ceramic or resin in order to avoid excessive thickness of the veneering material.
3. When choosing the material and determining framework design, it is recommended that the final contour of the definitive prosthesis be visualized prior to framework fabrication.
4. Scheduled regular maintenance appointments should include a careful occlusal review. It is recommended that clinicians undertake any required adjustments to the prosthesis, inclusive of meticulous polishing of worn ceramic surfaces, to reduce the risk of fracturing of the veneer material.

Quality Assurance

It is recommended that clinicians, technicians, and manufacturers employ a tracking system for implants and restorative components. Clinicians should be aware that not all implant systems have the same level of documentation. The clinician should be aware of the origin of the components used.

Recommendations for Future Research

In order to deliver relevant information for the understanding and the improvement of technical outcomes, future clinical studies should include the following information:

- The definition of technical complications should be specified as either mechanical, ie, failure of components resulting from standardized production procedures (industrial), or technical, ie, failure of custom components (laboratory-fabricated or modified).
- Mechanical and technical complications should further be divided into (1) major: such as implant fracture, framework fracture, abutment fracture, loss of prosthesis, etc; (2) intermediate: such as abutment fracture, abutment screw loosening, veneer or framework fractures, phonetic complications, etc; or (3) minor: such as abutment and screw loosening, loss of retention, debonding, loss of screw hole sealing, chipping of veneering material (to be polished), and occlusal adjustments.
- Patient-based and prosthesis-based rates of mechanical and technical complications as well as time/cost required for the management should be reported. Moreover, detailed information on the components, materials, procedures, and techniques utilized should be given.
- Well-designed RCTs with adequate statistical power should be initiated to address specific issues in restorative dentistry, such as abutment materials and types (ceramics vs metals), customized vs stock components, restorative outcomes of different implant types, and screw-retained vs cemented prostheses.
- All trials should be prospectively registered on an open-access database to minimize publication bias.