Consensus Report

Biomechanics/risk management (Working Group 2)

Mariano Sanz
Ignace Naert

Members of Working Group:
Klaus Gotfredsen
Flemming Isidor
Franck Renouard
Phoebus Madianos
Carlos Madrid
Pascal Marquart
Victor Palarie
Alberto Sicilia
Jose Zurdo
Rafael Juan Blanes

Authors' affiliations:
Mariano Sanz, Department of Prosthetic Dentistry, Universidad Complutense de Madrid, Madrid, Spain
Ignace Naert, Department of Periodontology, Katholieke Universiteit Leuven, Leuven, Belgium

Correspondence to:
Ignace Naert
Katholieke Universiteit Leuven
Leuven
Belgium
Tel.: + 32 16 33 24 38
Fax: + 32 16 33 23 09
e-mail: ignace.naert@med.kuleuven.ac.be

Conflict of interest and source of funding statement:
The authors have declared no conflicts of interest. Workgroup 2 participants declared that they had no conflict of interests.

Key words: anticoagulants, bisphosphonates, cantilevers, crown–implant ratio, guided implant surgery, implant-supported restorations

Abstract

Introduction: The remit of this workgroup was to update the existing knowledge base in biomechanical factors, navigation systems and medications that may affect the outcome of implant therapy.

Material and methods: The literature was systematically searched and critically reviewed. Five manuscripts were produced in five specific topics identified as areas where innovative approaches have been developed in biomechanical factors, navigation systems and medications that may affect the outcome of implant therapy.

Results: The results and conclusions of the review process are presented in the following papers, together with the group consensus statements, clinical implications and directions for future research:

- To what extent do cantilevers affect survival and complications of implant supported restorations in partially dentate patients?
- To what extent does the crown–implant ratio affect survival and complications of implant supported restorations?
- A systematic review on the accuracy and the clinical outcome of computer-guided template based implant dentistry.
- What is the impact of systemic bisphosphonates on patients undergoing oral implant therapy?
- What is the impact of anticoagulants on patients undergoing oral implant therapy?

The remit of this workgroup was to update the existing knowledge base in biomechanical factors, navigation systems and medications that may affect the outcome of implant therapy. For this purpose the literature was systematically searched and critically reviewed. Five manuscripts were produced in five specific topics identified as areas that may have an impact in the outcome of implant therapy and which were deemed to be strategically important for patient care and clinical practice:

1. To what extent do cantilevers affect survival and complications of implant supported restorations in partially dentate patients (J. Zurdo, C. Romao, J. Wennström).
2. To what extent does the crown–implant ratio affect survival and complications of implant supported restorations? (R. Blanes)
3. A systematic review on the accuracy and the clinical outcome of computer-guided template based implant dentistry.

To cite this article:
Sanz M, Naert I. Biomechanics/risk management (Working Group 2).
Clin. Oral Impl. Res. **20** (Suppl. 4), 2009; 107–111.
doi: 10.1111/j.1600-0501.2009.01780.x

(D. Schneider, P. Marquardt, M. Zwahlen and R. E. Jung)

4. What is the impact of systemic bisphosphonates on patients undergoing oral implant therapy? (C. Madrid and M. Sanz)
5. What is the impact of anticoagulants on patients undergoing oral implant therapy? (C. Madrid and M. Sanz)

To what extent do cantilevers affect survival and complications of implant supported restorations in partially dentate patients?

Zurdo, J., Romao, C. Wennström, J.

Aim

- To analyze systematically the potential effects of cantilevers, consisting of one unit, on the survival rate of implant-supported fixed partial dental prostheses (FPDPs.) and the incidence of technical and biological complications, as reported in longitudinal cohort studies with at least 5 years of follow-up.

Major conclusions from the paper

- Data on implant-supported FPDPs. with cantilevers are limited and therefore the reported results on survival and complication rates should be interpreted with caution.
- The use of cantilevers is not associated with a significant amount of peri-implant marginal bone loss, neither at the implant site close to the cantilever nor at the neighboring implants.
- The incorporation of cantilevers to implant supported restorations is associated with a higher incidence of technical complications.

Group's consensus

- There is a paucity of literature available from comparative studies on the use of cantilevers in FPDPs ($n = 3$ longitudinal studies).
- Both types of restorations provided high implant survival rates (91.9% with cantilevers vs. 95.8%).
- The use of cantilevers is not associated with significant amount of peri-implant marginal bone loss, neither at the implant site close to the cantilever nor at the neighboring implants.
- The use of cantilevers is associated with a higher incidence of technical complications (21.6% with cantilevers vs. 10.3%).

Clinical implications

An implant-supported FPDP with a short extension (one unit) is an acceptable restorative therapy, and might be considered as an alternative to procedures that require more advanced surgery (e.g. sinus graft, etc.) or for esthetic reasons.

Implications for research

There is a need of:

- More controlled clinical trials in partially dentate patients.
- Randomized controlled clinical trials comparing this treatment modality with advanced surgical techniques aimed to increase bone availability and including the evaluation of cost-effectiveness.
- Studies evaluating the influence of location and dimension of the cantilever pontic.

To what extent does the crown–implant ratio affect survival and complications of implant supported restorations?

Blanes, R. J.

Aim

- To analyze systematically the potential effects of C/I ratio on the survival rate of implant-supported FPDPs and/or single restorations and on the incidence of technical and biological complications.

Major conclusions from the paper

Despite scarcity of data and diversity among studies with respect to data collection and study design, the following conclusions can be drawn:

- C/I ratios of implant-supported restorations do not influence the peri-implant crestal bone loss.
- There is no data available to assess the relationship between the C/I ratio and implant survival rates or the occurrence of technical or biological complications in implant-supported restorations.

Group's consensus:

- There is scarcity of evidence from comparative studies on the use of C/I ratios > 1 in FPDPs. and single-tooth restorations ($n = 2$ longitudinal cohort studies).
- The use of implant-supported restorations with C/I ratios up to two do not influence crestal bone loss

Clinical implications

- An FPDP or single-tooth restorations with C/I ratios up to two is an acceptable prosthetic treatment option, and might be considered as an alternative to procedures that require more advanced surgery aimed to decrease the C/I ratio (e.g. vertical augmentation, sinus graft, etc.).

Implications for research

- There is a need for prospective controlled trials evaluating the impact of C/I ratio on survival rates, peri-implant crestal bone loss and the occurrence of technical complications.
- In clinical situations with a reduced ridge height, there is a need for RCTs to compare restorations with high C/I ratio with advanced surgery to decrease the C/I ratio, including its cost-effectiveness.
- The biomechanical effect of C/I ratio should be investigated in single-tooth implant-supported restorations.
- Future research should evaluate the influence of C/I ratio with regard to implant design and surface configurations, prosthetic treatment modalities and arch locations (e.g., anterior, posterior).

A systematic review on the accuracy and the clinical outcome of computer-guided template based implant dentistry

David Schneider, Pascal Marquardt, Marcel Zwahlen, Ronald E. Jung

Aim

The aim of this systematic review was to analyze the dental literature regarding accuracy and clinical application in computer-guided template based implant dentistry.

Major conclusions from the paper

Based on the data analysis of this systematic review it is concluded that various systems for computer-guided, template-based implant treatment are available. Different types of software, template production and template stabilization as well as variations of the surgical and prosthetic protocol are reported. However, limited data and relatively short observation periods are available in the literature reporting accuracy and clinical performance.

Accuracy

The analysis of the acquired data revealed that the mean horizontal deviation of the described computer-guided systems lies within approximately 1 mm at the entry point and around 1.6 mm at the apex, 0.5 mm in height and 5–6° in axis. Deviations of up to several millimeters were reported. Outliers seem to be a major problem. After comparison of the data on deviation the hypothesis that a template supported by bone, teeth or implants provides superior accuracy than a mucosa-supported template, could not be confirmed .The same applies for the deviation dependent on template production; stereolithographic versus lab-made. The amount of mean deviation with free-hand drilling in single-tooth gaps is similar to the results of the present review on computer-guided accuracy including partially and fully edentulous patients.

Clinical performance

Peri-operative surgical complications occurred in 9.1% of the patients. Early prosthetic complications occurred in 18.8% of the patients. All complications were encountered in connection with immediate restoration and prefabricated prostheses. Discrepancies between the planned and actual implant position leading to a misfit of the restoration (7.2%) as well as extensive occlusal adjustments (4.3%) are described.

Late prosthetic complications occurred in 12% of the patients and may be associated with the prosthesis material or improper seating. The tolerance and effect of specially designed abutments to compensate for a certain amount of deviation between implant and prosthesis position seems to be limited.

After a follow-up of 12–60 months an implant survival rate of 91–100% was reported in a total of six studies with 79 patients and 587 implants. Keeping in mind that in four out of six studies implants were inserted in fully edentulous patients and immediately loaded the implant failure rates are similar to conventional procedures.

Group's consensus

In order to evaluate the accuracy and clinical performance of available implant guided systems; there is a need of information at different levels:

- Accuracy of the radiographic technique.
- Accuracy of the 3-D positioning of the implant in relation of the bone in the software planning.
- Accuracy of the 3-D position in relation to the clinical pre-operatory design especially related to the esthetic judgment of the soft tissues and the pre-manufactured final/temporary FDP.
- Clinical efficacy in comparison to conventional surgical and restorative procedures is warranted.

Clinical implications

It seems that the reliability of the computer-guided systems is insufficient to justify a 'blind' implantation. Thus, the diagnostic and surgical procedures require constant verification after each step. Especially in flapless procedures, when visual control is limited, the risk of malpositioning the implant is imminent.

The technical requirements of guided implant surgery, together with their inherent limited accuracy warrants advanced training and surgical experience before they can be used safely.

Implications for research

There is need for:

- RCTs to evaluate the efficacy and cost-effectiveness of guided implant surgery when compared with the conventional surgical procedures.
- RCTs to evaluate the accuracy, radiation load, handling characteristics and cost cost-effectiveness of the different commercially available systems.
- RCTs to assess the efficacy of guided implant surgical protocols (flapless/immediate loading, etc.).
- Owing to the relatively short observation period, further investigations are necessary to confirm the long-term implant survival.
- Guided surgical protocols that should be critically evaluated in regards to esthetic outcomes and prosthetically related complications.
- New approaches that should be incorporated including 3-D pre-operatory diagnosis of the soft tissues and for new mechanisms to stabilize the template especially in edentulous patients.

What is the impact of systemic bisphosphonates on patients undergoing oral implant therapy?

Madrid, C., Sanz, M.

Aim

- This systematic review aims to assess if patients under IV (intravenous) or oral BPs can receive implant oral therapy and what could be the risk of developing *B*isphosphonate-*R*elated *O*steo-*N*ecrosis of the *J*aws (BRONJ).

Major conclusions from the paper

- There is a paucity of scientific information regarding the possible risks of oral implant therapy in the development of BRONJ in patients taking oral BPs. However, data extrapolated from population-based studies indicate that minor oral surgeries (dental extractions) could increase the risk of developing BRONJ (ranging from 0.01% to 0.04% spontaneously to 0.09–0.34 after tooth extractions).
- The literature search on oral implant therapy in patients under systemic BPs therapy resulted in one prospective and three retrospective studies (217 patients). It can be concluded

from the analysis of these studies that the placement of an oral implant can be considered a safe procedure in patients taking oral BPs (<3 years) in regards to the occurrence of BRONJ, because no single case has been reported.

- The intake of oral BPs did not influence the short-term (1–4 years) implant survival rates [95–100% (BPs) vs. 96.5–99% (control)].
- The literature search on internationally accepted guidelines and recommendations related to the risk of BRONJ found 59 papers, from which six were retrieved for the current review.
- BRONJ is reported a prevalence between 5% and 12% for IV BPs and between 0.01% and 0.04% for oral BPs.

Group's consensus

- There is hardly any evidence on the risk of developing BRONJ when placing oral implants in patients under oral (10 mg/day.) BP therapy. Therefore, in patients on oral BPs (10 mg/day) during <3 years, minor oral surgery is considered a low risk for developing BRONJ.
- In patients on IV BPs, minor oral surgery (dental extraction, periodontal surgery) is considered a risk factor for developing BRONJ (5–12%).
- There are several well-documented case reports on the occurrence of BRONJ in patients on IV BPs affecting jawbone surrounding osseointegrated oral implants.
- There is a consented recommendation that in IV BPs. patients, elective surgery (such as implant therapy) is contraindicated.
- In patients on oral BPs. the risk of developing BRONJ increase with time drug exposure, concomitant medication (corticosteroids) and in presence of chronic infections (periodontal diseases, poor oral hygiene . . .).

Clinical implications

- Implant placement in patients on IV BPs should be contraindicated.
- In case of BRONJ affecting jawbone surrounding implants, if the patient's systemic conditions assessed by IV-BPs prescriptor permit, long-term discontinuation may be beneficial in stabilizing established sites of BRONJ, reducing the risk for new areas BRONJ areas and the clinical symptomatology. In this situation, the administration of long-term wide-spectrum antibiotics together with topical antiseptics is recommended.
- Patients taking oral BPs for <3 years are considered at low risk for BRONJ. Nevertheless, patients should be provided detailed information about BRONJ and informed consent should be documented before implant placement.
- Although some international guidelines assign a higher risk of developing BRONJ in patients on oral BPs for >5 years, there is no evidence derived from population studies.
- Similarly, although some international guidelines (ADA) assign a higher risk of developing BRONJ in patients having extensive implant placement or advanced implant surgeries, such as bone regeneration, sinus lift, etc., there is no evidence derived from clinical research.
- In case of implant therapy in patients on oral BP, a drug holiday of 3–6 months before implant placement and until completing the healing is optional and unlikely to have adverse effects on the patient's bone metabolic disease. The efficacy of this regime has not been demonstrated by clinical research.

Implications for research

There is a need for:

- Experimental studies to elucidate the causative relationship between BPs and bone necrosis.
- Prospective cohort studies on patients on oral BPs subjected to implant therapy.
- Prospective cohort studies on patients on oral BPs having extensive implant placement or advanced surgical procedures.
- Clinical research on the management on BRONJ lesions.
- Population-based studies aimed to understand the risk of BPs medication on the development of BRONJ lesions, mainly the impact of oral interventions.

What influence do anticoagulants have on oral implant therapy?

Madrid, C., Sanz, M.

Aim

- To evaluate the risk of postoperative bleeding in patients under oral anticoagulant therapy (OAT) undergoing oral surgical procedures, such as implant therapy.
- To provide a management protocol to patients under OAT undergoing implant therapy.

Major conclusions from the paper

- Results from RCTs demonstrate that OAT patients [international normalized ratio (INR) 2–4] that do not discontinue the AC medication do not have a significantly higher risk of postoperative bleeding than non-OAT patients.
- Results from RCTs demonstrate that OAT patients (INR 2–4) that do not discontinue the AC medication do not have a higher risk of postoperative bleeding than OAT patients that discontinued the medication.
- Results from RCTs in patients with OAT (INR 2–4) without discontinuation demonstrate that the topical application of hemostatic agents is effective in preventing postoperative bleeding.
- RCTs comparing different hemostatic agents (tranexamic acid mouthrinses, gelatin sponges and fibrin glue) have shown similar results in preventing postoperative bleeding.

Group's consensus

- Anticoagulant therapy (vitamin K antagonists, e.g. warfarin, cumarin) is the most prescribed therapy in the secondary prevention of thrombo-embolic events.
- INR is the accepted monitoring tool to evaluate the patient's anticoagulation. Depending on the patient's thrombo-embolic risk, the INR target will vary

from 2–3 (low to moderate risk) to 2.5–3.5 (high risk).
- Implant therapy in OAT patients is not contraindicated provided the INR values are stable and lower than 3.5.
- Oral anticoagulant therapy patients (INR 2–3.5) that do not discontinue the AC medication do not have a higher risk of postoperative bleeding than OAT patients that discontinue the medication.
- In OAT patients (INR 2–3.5) without AC discontinuation, the topical application of hemostatic agents is effective in preventing postoperative bleeding.
- In OAT patients (INR 2–3.5) undergoing major implant therapy (extensive surgical flaps, bone harvesting, sinus lift, etc.) discontinuation of OAT should be discussed with the patient's physician and patient informed consent documented.
- In OAT (INR $\geq$ 3.5) the patient should be referred to his/her physician for dose adjustment before any invasive oral procedure.

Clinical recommendations

The potential strategy before an OAT patient requesting implant therapy should be:

- Consult with the patient's physician and request advice.
- Identify the patient's thrombo-embolic risk and monitor INR status.
- Evaluate medical history, medications and record previous bleeding events.
- In case of concomitant anti-aggregant therapy (aspirin, clopidogrel, ticlopidin), it is recommended its temporary discontinuation (1–2 weeks around the surgical intervention), but it must be discussed with the patient's physician and a documented informed consent obtained.
- Under stable INR conditions (2–3.5) OAT medication should not be discontinued during standard implant therapy. In this case and when placing dental implants in specific anatomic situations, such as in the mandible symphisis, and due to the specific vascular risk of these areas, the implant surgeon must have enough training and needed materials to proceed in case of the occurrence of a hemorrhage in the floor of the mouth.
- The topical application of hemostatic agents (tranexamic acid mouthrinses, gelatin sponges and fibrin glue) is recommended to reduce the risk of postoperative bleeding.
- The interruption of OAT medication bridging with low-molecular-weight heparin or reducing the warfarin dosage may expose patients to an increased risk for thrombo-embolic events and therefore, if the patient is recommended this regime by his/her physician, this OAT strategy should be documented by the physician.
- In patients with OAT (INR $\geq$ 3.5) the patient should be referred to his/her physician for dose adjustment before any oral implant therapy. If the INR is unstable and at the higher range, ambulatory implant therapy is not recommended.

Implications for research

- Prospective clinical studies evaluating the bleeding risk of different implant surgical protocols (advanced flaps, bone harvesting, sinus lift, etc.).
- RCTs on the efficacy of different hemostatic agents to prevent postoperative bleeding in implant surgical protocols.

References

Blanes, R. (2009) To what extent does the crown–implant ratio affect survival and complications of implant supported restorations. *Clinical Oral Implant Research* **20** (Suppl. 4): 67–72.

Madrid, C. & Sanz, M. (2009a) What is the impact of systemic bisphosphonates on patients undergoing oral implant therapy? *Clinical Oral Implant Research* **20** (Suppl. 4): 87–95.

Madrid, C. & Sanz, M. (2009b) What is the impact of anticoagulants on patients undergoing oral implant therapy? *Clinical Oral Implant Research* **20** (Suppl. 4): 96–106.

Schneider, D., Marquardt, P., Zwahlen, M. & Jung, R.E. (2009) A systematic review on the accuracy and the clinical outcome of computer-guided template based implant dentistry. *Clinical Oral Implant Research* **20** (Suppl. 4): 73–86.

Zurdo, J., Romao, C. & Wennström, J. (2009) To what extent do cantilevers affect survival and complications of implant supported restorations in partially dentate patients. *Clinical Oral Implant Research* **20** (Suppl. 4): 59–66.