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CONSENSUS REPORT

CLINICAL ORAL IMPLANTS RESEARCH WILEY

# Group 3 ITI Consensus Report: Materials and antiresorptive drug-associated outcomes in implant dentistry

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## Abstract

**Objectives:** The aim of Working Group 3 was to address the influence of both material- and anti-resorptive drug- related factors on clinical and biological outcomes and complications in implant dentistry. Focused questions were addressed on (a) implant materials other than titanium (alloy)s, (b) transmucosal abutment materials and (c) medications affecting bone metabolism were addressed.

**Materials and Methods:** Three systematic reviews formed the basis for discussion in Group 3. Consensus statements and clinical recommendations were formulated by group consensus based on the findings of the systematic reviews. Patient perspectives and recommendations for future research were also conveyed. These were then presented and accepted following further discussion and modifications as required by the plenary.

Bilal Al-Nawas and France Lambert contributed equally to this work and share primary authorship.

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**Results:** Zirconia is a valid alternative to titanium as material for implant and transmucosal components, allowing soft and hard tissue integration with clinical outcomes—identified by implant survival, marginal bone loss and peri-implant probing depths—up to 5-years comparable to titatnium. However, most of the evidence for zirconia implants is based on 1-piece implants limiting the indication range. Furthermore, based on expert opinion, zirconia transmucosal components might be preferred in the esthetic zone. In patients receiving low-dose bisphosphonate therapy, the rate of early implant failure is not increased, while the long-term effects remain poorly studied. Although it has not been sufficiently addressed, similar outcomes can be expected with low-dose denosumab. A drug holiday is not recommended when considering implant placement in patients treated with low-dose ARD. However, the specific therapeutic window, the cumulative dose and the administration time should be considered. Access to peri-implant supportive care is mandatory to prevent peri-implantitis-related medication-related osteonecrosis of the jaw (MRONJ) or implant-related sequestra (IRS). In patients receiving low-dose anti-resorptive drugs (ARD) therapy, the risk of complications related to implant placement is high, and implant procedures in this specific population should be strictly treated in a comprehensive multidisciplinary center. Finally, healthy dental implants should not be removed before low or high-dose ARD.

**Conclusions:** Zirconia implants can be an alternative to titanium implants in selected indications. However, the current state of evidence remains limited, especially for 2-piece implant designs. Administration of low-dose ARD did not show any negative impact on early implant outcomes, but careful follow-up and supportive care is recommended in order to prevent peri-implant MRONJ and IRS. Implant placement in high-dose patients must be strictly considered in a comprehensive multidisciplinary center.

**KEYWORDS**
anti-resorptive drugs, biomaterials, drug delivery, peri-implant tissue integration, pharmacology, structural biology, tissue implant interactions, tissue physiology, wound healing

## 1 | INTRODUCTION

The objectives of Group 3 of the 7th ITI Consensus Conference were to provide statements and recommendations for clinicians and researchers relating to the **material- and antiresorptive drug-associated outcomes in implant dentistry**. Additionally, considerations from a patient perspective were also addressed. Three systematic/narrative reviews formed the basis for discussion within the working group and were prepared and reviewed before the consensus conference. The reviews were discussed within the group, and consensus statements, clinical recommendations and patient considerations were formulated and then presented to the plenary for approval. The working group also prepared recommendations for future research. The three systematic reviews are listed below.

## 2 | SYSTEMATIC REVIEW PAPER 1

### 2.1 | Manuscript title

Clinical and radiographic outcomes of zirconia dental implants—a systematic review and meta-analysis.

### 2.2 | Preamble

Currently, zirconia is the only (commercially available) material other than titanium (alloy) used for fabricating ceramic dental implants with 1- and 2-piece designs. Evidence-based data has shown that physical properties and ongoing market availability significantly influenced the reported zirconia implant survival

rates. So far, meta-analyses investigating zirconia implants are limited to a follow-up of up to 2 years. The present review aimed to evaluate in clinical studies implant survival, marginal bone loss, probing depths and technical and biological complications of commercially available zirconia implants after at least 5 years of function.

The primary outcome of this systematic review was to investigate implant survival.

Secondary outcomes were peri-implant marginal bone loss (MBL), peri-implant probing (PD) depths, and technical and biological complications.

## 2.3 | Consensus statements

### 2.3.1 | Consensus statement 1

Based on the review, only zirconia was found to be a commercially available alternative material to titanium or titanium alloy implants.

### 2.3.2 | Consensus statement 2

The data after 5 years mainly applies to 1-piece zirconia implants for single crowns and 3-unit implant fixed dental prostheses (iFDP). Regarding 2-piece zirconia implants, only limited data is available.

**This statement is based on six clinical cohort studies (four prospective studies, two retrospective studies). A single retrospective study investigated 2-piece implants.**

### 2.3.3 | Consensus statement 3

Zirconia implants show a mean survival rate of 97.2%, range: 93.8%–100% at 5 years, comparable to published data for titanium-based implants.

**This statement is based on a meta-analysis (95% CI: 94.7%–99.1%) of six clinical cohort studies (four prospective studies, two retrospective studies).**

### 2.3.4 | Consensus statement 4

Over 5 years, zirconia implants show similar peri-implant tissue health compared to published data for titanium implants (mean MBL of 1.1 mm – range: 0.7–1.2 and mean PD of 3 mm – range: 2.2–3.3). Bleeding on probing could not be compared because of the heterogeneity of the used indices.

**This statement is based on a meta-analysis (95% CI: 0.9–1.3 mm for MBL and 2.5–3.4 mm for PD) on five clinical cohort studies.**

### 2.3.5 | Consensus statement 5

Over 5 years, 1- piece zirconia implants for single crowns and 3-unit implant fixed dental prostheses (iFDP) do not show higher fracture risk than titanium implants.

**This statement is based on six clinical cohort studies (four prospective studies, two retrospective studies).**

## 2.4 | Clinical recommendations

### 2.4.1 | Clinical recommendation 1

Can zirconia implants be recommended in daily practice?

Zirconia implants can be an alternative to titanium implants in selected indications. Based on available data for up to 5 years, 1-piece zirconia implants for single crowns and 3-unit implant fixed dental prostheses (iFDP) can be recommended as a treatment option. In clinical indications that require the positioning of the restoration margin submucosally, the cementation process has to be controlled.

It has to be considered that various types and generations of zirconia implants exist today, exhibiting differences in mechanical properties and not all have been validated in clinical studies.

## 2.5 | Patient perspectives

### 2.5.1 | Patient perspective 1

Question: Are all implants made of titanium, or are there alternatives?
Answer: In addition to titanium implants, zirconia implants have been available for 20 years (2004).

### 2.5.2 | Patient perspective 2

Question: What is the difference between titanium and zirconia implants?
Answer: Titanium is a metal and is gray. Zirconia is an oxide ceramic and has a tooth-like color. However, both materials integrate with bone and gums in the same way.

### 2.5.3 | Patient perspective 3

Question: Do zirconia implants perform as well as titanium implants?
Answer: Studies show that the performance of zirconia implants in terms of survival rate and integration with the bone and gum is the same as titanium implants for up to 5 years. These studies are, however, based on the first type of one-piece zirconia implants. Zirconia

implants have evolved to offer us more options, but there are only limited studies to date on how these newer two-piece designs perform over time. **This statement is based on six clinical cohort studies (four prospective studies, two retrospective studies). A single retrospective study investigated 2-piece implants.**

#### 2.5.4 | Patient perspective 4

Question 5: I have an intolerance to various materials, including metals. Would you recommend that I have a ceramic rather than a titanium implant?
Answer: Intolerance to titanium is scarce. If you prefer a non-metallic material, you can choose a zirconia implant instead. If you do so, you must know that an internal metal screw is needed in some of the newer two-piece zirconia implants to connect the different components. This metal screw will not come into contact with your bone or gums. **This statement is based on six clinical cohort studies (four prospective studies, two retrospective studies). A single retrospective study investigated 2-piece implants.**

#### 2.5.5 | Patient perspective 5

Question: I lost a titanium implant because of peri-implantitis. Is a ceramic implant a better solution to prevent these complications?
Answer: Currently, there is no clinical evidence that zirconia implants perform better than titanium implants to prevent peri-implantitis.

### 2.6 | Recommendations for future research

After 5 years, there is data on commercially available zirconia implants. However, the evidence is limited (low sample size, lack of RCTs comparing zirconia and titanium implants).

#### 2.6.1 | Recommendation 1 for future research

Further prospectively designed long-term clinical studies and randomized clinical trials investigating titanium and zirconia implants are needed to confirm the presently evaluated promising outcomes.

#### 2.6.2 | Recommendation 2 for future research

More clinical data is needed on the short and long-term clinical performance of 2-piece zirconia implant designs.

#### 2.6.3 | Recommendation 3 for future research

Additional clinical examinations investigating zirconia implants in specific patient populations are needed (e.g., patients with a history of periodontitis and auto-immune diseases…).

## 3 | SYSTEMATIC REVIEW PAPER 2

### 3.1 | Manuscript title

The effect of different transmucosal abutment materials on peri-implant tissues – a systematic review and meta-analysis

### 3.2 | Preamble

In the last decades, alternative abutment materials were introduced on the market. This systematic review collected data from randomized clinical trials examining the effect of these materials—compared to titanium (alloys)—on peri-implant tissues.

The primary outcome of this systematic review and meta-analysis was marginal bone loss and probing pocket depths.

The secondary outcomes were:

- Abutment survival
- Biological complications
- Aesthetic outcomes.

Thirteen randomized clinical trials could be included. Nine examined titanium abutments versus zirconia abutments, three studies examined titanium versus alumina and two titanium versus gold. Sufficient information was provided for meta-analyses of the data on marginal bone loss, pocket probing depth and abutment survival. The other outcomes could only be described descriptively. Similar marginal bone loss, probing depth and abutment survival were found for the examined materials after 1 year and 5 years of follow-up.

### 3.3 | Consensus statements

#### 3.3.1 | Consensus statement 1

Bone-level implants with zirconia and titanium transmucosal abutments demonstrate comparable peri-implant parameters (MBL and PD) after 1 and 5 years. Bleeding on probing could not be compared because of the heterogeneity of the used indices.

**This statement is based on meta-analyses of six RCTs.** (mean diff and 95% CI after 1-year: MBL: −0.24 mm [−0.65,0.16], PD: −0.06 [−0.41,0.30] and after 5 years: MBL: [], PD: −0.06 []).

#### 3.3.2 | Consensus statement 2

Both zirconia and titanium transmucosal abutments are clinically comparable regarding biological complications, esthetic outcomes and patient satisfaction.

**This statement is based on descriptive data from nine RCTs.**

#### 3.3.3 | Consensus statement 3

Limited data regarding peri-implant tissue parameters were found for gold and alumina transmucosal abutments. Thus, a direct comparison with titanium is not possible.

**This statement is based on descriptive data of respectively two and three RCTs.**

### 3.4 | Clinical recommendations

#### 3.4.1 | Clinical recommendation 1

**Do zirconia abutments provide additional biological esthetic or patient satisfaction benefits over titanium implants?**

Based on biological peri-implant parameters and patient satisfaction, titanium and zirconia can be recommended as transmucosal abutment materials. However, even though the scientific evidence remains unclear, zirconia abutments might be preferred in the esthetic region.

#### 3.4.2 | Clinical recommendation 2

**What material allows for adequate peri-implant soft tissue integration?**

Titanium (alloy) and zirconia are well-documented biocompatible restorative materials for final restorations allowing cell adhesion. If ceramic glaze or other restorative materials are considered, placing these materials submucosally as coronal as possible is recommended.

### 3.5 | Patient perspectives

#### 3.5.1 | Patient perspective 1

Question 1: Are zirconia abutments more esthetic than titanium ones?

Answer: Yes. We can achieve good esthetic results with titanium abutments, but where esthetics are critical, zirconia abutments are usually preferred. This avoids the risk of the metal showing through the gums in the places that become visible when you smile. **This patient's perspective is based on expert opinions.**

### 3.6 | Recommendations for future research

#### 3.6.1 | Recommendation 1 for future research

Standardization for reporting clinical, biological and technical outcomes is needed in clinical trials to facilitate data comparison and future systematic reviews and meta-analyses.

#### 3.6.2 | Recommendation 3 for future research

Randomized clinical trials examining abutment materials should consider/avoid confounding factors that may influence the results (e.g., using screw-retained and cemented restorations).

#### 3.6.3 | Recommendation 2 for future research

Further investigation is needed to consider newly developed restorative materials as biocompatible for peri-implant soft tissue integration (e.g., lithium disilicate, composite CAD-CAM materials, …). Both ex-vivo and clinical studies are necessary to make further clinical recommendations.

## 4 | SYSTEMATIC REVIEW PAPER 3

### 4.1 | Manuscript title

Effect of medications affecting bone metabolism on short- and long-term implant failure: a narrative review.

### 4.2 | Preamble

Patients on low-dose bisphosphonates (BPs) or denosumab (e.g., osteoporosis therapy) are considered low-risk for medication-related osteonecrosis of the jaw (MRONJ). Those who are on high-dose antiresorptive drugs (ARDs) due to or prevention of, skeletal related events and skeletal metastasis (e.g breast or prostate cancer) and treatment of multiple myeloma are considered high-risk groups for MRONJ. The typical dosage for high and low dose ARD are displayed in Table 1.

Influencing factors are:

- Underlying diseases
- Anti-resorptive drug
- Dose, duration and frequency
- Other medication/therapy: hormone therapy, immune or antibody therapy, chemotherapy anti-angiogenic therapy, head and neck radiotherapy
- Prior osteonecrosis of the jaw.

**TABLE 1** Typical therapeutic dosage of ARDs.

| Type of ARDs | Low-dose | High-dose |
|---|---|---|
| Alendronate | 70 mg/week per os. | N/A |
| Risedronate | 35 mg/week per os. | N/A |
| Ibandronate | 150 mg/month, per os or 3 mg/3 months i.v. | 50 mg/day, per os. |
| Pamidronate | 30 mg/3 months i.v. | 90 mg/3 ~ 4 weeks i.v. |
| Zoledronate | 5 mg/year i.v. | 4 mg/3 ~ 4 weeks i.v. |
| Denosumab | 60 mg/6 months s.c. | 120 mg/3 ~ 4 weeks s.c. |

## 4.3 | Consensus statements

### 4.3.1 | Consensus statement 1

In patients receiving low-dose BP therapy (e.g. for osteoporosis therapy), the rate of early implant failure after implant placement is not increased compared to patients without BP therapy. Nevertheless, the history of BP administration (cumulative dose) is not sufficiently investigated.

**This statement is based on 12 cohort studies. (22 implant failures out of 1202 implants).**

### 4.3.2 | Consensus statement 2

The influence of low-dose BP therapy on long-term implant survival has not been sufficiently documented to allow conclusions. **This statement is based on expert opinions.**

### 4.3.3 | Consensus statement 3

The influence of low-dose denosumab therapy on failure after implant placement and failure of existing implant has not been sufficiently reported to allow conclusions.

### 4.3.4 | Consensus statement 4

In patients receiving low- or high-dose ARD, prognosis and complications of augmentation procedures are not sufficiently reported to allow conclusions.

### 4.3.5 | Consensus statement 5

In patients receiving high-dose ARD, the early and late implant failure rate is not sufficiently documented to allow conclusions.

**This statement is based on a case series (no early failures, 49 implants in 27 patients).**

### 4.3.6 | Consensus statement 6

In patients receiving low-or high-dose ARD, implant-related sequestration (IRS)/MRONJ is reported. The incidence of IRS/MRONJ after implant insertion or around an existing implant is unknown.

**This statement is based on retrospective case series. (168 patients from 20 case series).**

### 4.3.7 | Consensus statement 7

Implant supported-rehabilitation after resective treatment and healing of MRONJ is not sufficiently reported to allow conclusion.

### 4.3.8 | Consensus statement 8

The influence of other drugs affecting bone metabolism (e.g. methotrexate (MTX), corticosteroid (CS), anti-angiogenic agents, or romosozumab) on failure after implant placement or failure of existing implants has not been sufficiently addressed to allow conclusions.

### 4.3.9 | Consensus statement 9

The potential effect of temporary withholding of ARD (drug holiday) on implant failure or MRONJ development after implant insertion has not been sufficiently documented to allow conclusions.

## 4.4 | Clinical recommendations

All clinical recommendations are based on expert opinions.

### 4.4.1 | Clinical recommendation 1

**What has to be considered by the dentist before ARD Therapy?**

A dentist should be involved when ARD therapy is planned.

Present and potential intraoral infections should be resolved to prevent MRONJ.

Existing dental implants without peri-implant pathology should not be removed.

Pressure sores should be avoided to reduce the risk of MRONJ.

### 4.4.2 | Clinical recommendation 2

**Is it safe to perform dental implant therapy *during or after ARD* therapy?**

Proceed with caution in specialized comprehensive centers.

In patients treated with *low-dose ARDs*, dental implant therapy is relatively safe. However, cumulative dose and administration time should be considered. Straightforward Direct implant placement in native bone and alternatives to bone augmentation procedures should be preferred.

### 4.4.3 | Clinical recommendation 3

In patients treated with *high-dose ARD* or *after resection of MRONJ lesion*, straightforward implant placement in the native bone can be considered only under rigorous risk evaluation.

- Strength of indication (no alternative to implant therapy, including no treatment)
- Specialized comprehensive center
- Patients' motivation
- Periodontal maintenance
- Patient awareness of specific risks (implant-related sequestration, MRONJ)
- Cooperation with ARD prescribing physicians (e.g. oncologists)
- Careful evaluation of co-morbidities, additional risk factors, and other medications.

### 4.4.4 | Clinical recommendation 4

**How can the risk for complications around existing or newly inserted implants in patients receiving ARD be reduced?**

Supportive periodontal therapy is highly recommended in patients receiving ARD to avoid peri-implantitis-related MRONJ/IRS.

### 4.4.5 | Clinical recommendation 5

**Is a "drug holiday" recommended for implant placement in patients receiving ARD?**

Withholding ARD (drug holiday) for implant placement is not recommended. Based on the general effects and pharmacokinetics of ARDs, surgery should be scheduled according to the specific therapeutic windows of the last administration.

### 4.4.6 | Clinical recommendation 6

**Are there other relevant medications with a possible impact on implant success?**

Clinicians should be aware of medications affecting bone metabolism, including methotrexate (MTX), corticosteroid (CS), anti-angiogenic agents, or romosozumab, which might impair wound healing leading to complications.

## 4.5 | Patent perspectives

All clinical patient perspectives are based on expert opinions.

### 4.5.1 | Patient perspective 1

Question: What can I do to avoid complications if I take medication that affects my bones?
Answer: Regularly check with your dentist even if you have no teeth, and tell them about your bone-modifying medication. Resolving oral infections is crucial for you because infections may lead to severe bone healing problems and even the death of bone tissue. Therefore careful daily oral hygiene and regular professional maintenance are strongly recommended. It is also essential to look out for and seek to prevent pressure sores under dentures.

### 4.5.2 | Patient perspective 2

Question 2: Does anti-resorptive treatment affect my existing implants?
Answer: Regular dental care during anti-resorptive drug treatment is essential to spot existing or potential infections around your implants. The goal is to avoid problems around implants that could lead to necrosis of the jaw bone (dead bone). Equally, if your existing implants are healthy, they pose no risk of necrosis, and there is no reason to remove them.

### 4.5.3 | Patient perspective 3

Question: Is it too risky to have implants if I am taking anti-resorptive drugs for osteoporosis?
Answer: Treatment for osteoporosis usually involves a low dose of antiresorptive drugs, and we know this carries only a low risk for bone necrosis. In this situation, dental implant therapy is possible. However, we should consider how long you have been taking the

medication because we also know that the risk of problems with bone healing and necrosis increases when the drugs are taken over the years.

#### 4.5.4 | Patient perspective 4

Question: Is it too risky to have implants if I am taking anti-resorptive drugs as part of cancer therapy?
Answer: In cancer treatment where you receive a high drug dose, for example, in cases of bone metastases or multiple myeloma, there is an increased risk of bone necrosis. In this situation, dental implant therapy can only be performed after a thorough risk evaluation by a specialized multidisciplinary team. If you proceed with the implants, you need an ongoing regular dental follow-up to reduce the risk of bone necrosis.

### 4.6 | Recommendations for future research

#### 4.6.1 | Recommendation 1 for future research

Prospective comparative studies to investigate the outcome of dental implants in patients on low and high dose denosumab.

#### 4.6.2 | Recommendation 2 for future research

Prospective clinical studies to investigate the cause-effect relationship between some medications affecting bone metabolism and the outcome of implant therapy.

#### 4.6.3 | Recommendation 3 for future research

Large-scale cohort studies to evaluate the effect of confounders, such as cancer and osteoporosis, co-morbidities, and multiple medications that may alter tissue metabolism, on the outcome of implant therapy.

#### 4.6.4 | Recommendation 4 for future research

Although peri-implantitis and impairment of bone remodelling seemed to be risks of IRS, well-designed studies are required to confirm this.

## AUTHOR CONTRIBUTIONS

Bilal Al-Nawas: Conceptualization; Methodology; Supervision; Project administration; Writing - original draft; Writing - review & editing; Validation. France Lambert: Conceptualization; Methodology; Supervision; Project administration; Writing - original draft; Writing - review & editing; Validation. Sanne Werner Møller Andersen: Writing - review & editing. Michael Bornstein : Supervision ; Writing - review & editing. Michael Gallert: Investigations; Writing - review & editing. Asbjorn Jokstad : Writing - review & editing. Junho Jung: Investigations; Writing - review & editing. Yong-Dae Kwon : Investigations; Writing - review & editing. Isabelle Laleman: Investigations; Writing - review & editing. Giacomo Oteri: Writing - review & editing. Stefan Roehling: Investigations ; Writing - review & editing. Eik Schiegnitz: Writing - review & editing. Yukihiro Takeda: Writing - review & editing. Hendrik Terheyden: Writing - review & editing.

## CONFLICT OF INTEREST STATEMENT

The authors reported all conflits of interest at the ITI Consensus Meeting.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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