

Asepsis during periodontal surgery involving oral implants and the usefulness of peri-operative antibiotics: a prospective, randomized, controlled clinical trial

Mahmoud Abu-Ta'a¹,
Marc Quirynen¹, Wim Teughels¹
and Daniel van Steenberghe^{1,2}

¹Department of Periodontology, School of Dentistry, Oral Pathology and Maxillofacial Surgery, Faculty of Medicine; ²Holder of P-I Brånemark Chair in Osseointegration, Catholic University of Leuven, Leuven, Belgium

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Abstract

Objectives: This randomized clinical trial compares the usefulness of pre- and post-operative antibiotics while strict asepsis was followed during periodontal surgery.

Material and Methods: Two groups of 40 consecutive patients each with fully or partially edentulous jaws were enrolled. Antibiotics group (GrAB⁺): 23 men, mean age 60, 128 implants, received oral amoxicillin 1 g, 1 h pre-operatively and 2 g for 2 days post-operatively. Non-antibiotics group (GrAB⁻): 20 men, mean age 57, 119 implants, received no antibiotics. Bacterial samples were taken from the peri-oral skin before and at the end of surgery. In 12 patients in each group, samples were also taken from the nares. A VAS questionnaire evaluated symptoms of infection/inflammation by both the patient and the periodontologist at suture removal.

Results: There were no significant differences between both groups, neither for the clinical parameters nor for the microbiota. *Staphylococcus aureus* was detected in the nares of one patient only. The patients' subjective perception of post-operative discomfort was significantly smaller in the group receiving antibiotics. Three patients lost one or two implants.

Conclusions: Antibiotics do not provide significant advantages concerning post-operative infections in case of proper asepsis. It also does not reduce peri-oral microbial contamination. It does on the other hand reduce post-operative discomfort.

Key words: antibiotic prophylaxis; implant surgery; nose cap; periodontology; post-operative infection; *Staphylococcus aureus*

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Clinical disinfection appeared in surgery in the 19th century when Semmelweis

suggested that it was the medical personnel who infected patients by moving from the autopsy to the delivery rooms without performing proper clinical aseptic measures. Around the same time Lister, influenced by the work of Louis Pasteur, believed it was possible to reduce post-operative infections by using carbolic acid to purify the air during surgery (Salvi et al. 2006).

Periodontal surgical procedures carry with them an inherent risk of developing complications such as infections.

It is especially important to avoid peri-operative infection of the wound during surgery, when foreign bodies are implanted (Haanaes 1990). Indeed, biofilm-shielded microbial colonization on the surface of the latter is much more resistant to antimicrobials than their planktonic form (Gristina et al. 1989).

Conflict of interests and source of funding statement

The authors declare that they have no conflict of interests.

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Even though periodontologists and oral surgeons often prescribe antibiotics routinely following gingivectomy (Stahl et al. 1969), osseous resective (Kidd & Wade 1974), regenerative (Cortellini & Bowers 1995), and implant-related surgery (Dent et al. 1997), the validity of such tradition remains unsubstantiated. The side-effects of antibiotic therapy are well documented and can be serious, including anaphylaxis and the possibility for development of resistant microbial strains (Dent et al. 1997). Health authorities tried to convince doctors to limit the use of antibiotics as much as possible because of possible side effects and budget implications.

Some reports have shown that antibiotic prophylaxis offers no advantage in preventing post-operative infections or affecting the outcomes of periodontal surgery involving gingivectomy (Pack & Haber 1983), mucogingival procedures (Checchi et al. 1992), osseous grafts (Pack & Haber 1983), or the insertion of endosseous implants (Gynther et al. 1998). The rate of infections following periodontal surgery, when no antibiotics were used, ranges from less than 1% (Pack & Haber 1983) to 4.4% (Checchi et al. 1992) for routine periodontal surgery and 4.5% when endosseous implants are installed (Gynther et al. 1998).

Several sources of infection during surgery in the oral cavity have been identified: instruments, the hands of surgeon and assistants, the air of the operatory room (OR), patients' nostrils and saliva, and the peri-oral skin (van Steenberghe et al. 1997). In orthopaedic surgery, on the other hand, the air and the skin, that of both the patient and the surgeon, are the prime vehicles of infection (Altemeier 1983, Garner & Favero 1985). During intra-oral surgery, reduction of salivary flow can be achieved by atropine and of the microbial flora by pre-operative rinsing with chlorhexidine (Altonen et al. 1976, Veksler et al. 1991). The supine position of the patient and the use of two independent suction tips (one for the mouth and one only for the wound) can further decrease the chances of wound contamination (van Steenberghe et al. 1997). The use of a meshed nose guard prevents contact with the highly contaminated nares while it was demonstrated that the expired air does not contain more bacteria than the surrounding air of the OR (van Steenberghe et al. 1997).

Indeed the main carriage sites of *Staphylococcus aureus* in healthy indi-

viduals are the nares and 20–30% of normal people are nasal carriers (Ayliffe & Lowbury 1982). It has been reported that *S. aureus* carriers have a two- to nine-fold increased risk of development of surgical-site infections (Wenzel & Perl 1995) and that *S. aureus* causes 25% of health care-related infections and contributes substantially to the morbidity and costs of hospitalizations (Engemann et al. 2003).

The aim of this randomized, controlled clinical trial was to compare the usefulness of pre- and post-operative antibiotics while strict asepsis was followed during periodontal surgery. Further aims were to investigate the effect of peri-operative antibiotics on the peri-oral skin microbial flora and to detect its impact on *S. aureus* from the nares of the patients involved.

Material and Methods

This prospective, randomized, controlled clinical trial involved 80 consecutive patients (fully or partially edentulous maxillas or mandibles or both) treated by means of endosseous oral implants in the OR of the Department of Periodontology of the University Hospital of the Catholic University Leuven. These patients were randomly assigned into one of two groups (with and without antibiotics = AB) of 40 patients each using random sampling with masking of the person performing the randomization. The study was approved by the Ethics Committee of the University Hospital of the Catholic University Leuven.

The antibiotics group (GrAB⁺) consisted of 40 patients: 23 men and 17 women, mean age 60 years, range 27–82

years. In patients of GrAB⁺, 128 endosseous implants were installed.

The non-antibiotics group (GrAB⁻) consisted of 40 patients: 20 men and 20 women, mean age 57 years, range 26–88 years. In this group, 119 endosseous implants were placed.

The exclusion criteria for the study were allergy to penicillin, need for endocarditis prophylaxis, any systemic or local immunodeficiency, uncontrolled diabetes mellitus, or previous radiation therapy in the head and neck area. Such patients would systematically receive prophylactic antibiotics and were not considered for randomization.

Patients in the GrAB⁺ group received amoxicillin 1 g per os, 1 h pre-operatively and 500 mg four times per day, 2 days post-operatively. Patients in the other group received no antibiotics. All patients were instructed to rinse with chlorhexidine digluconate, PerioAid (0.12 solution without alcohol) for 1 min. just before surgery. Post-operatively they all rinsed with the same agent twice a day for 1 min. up to the follow-up visit (stitch removal), which was 7–10 days later. Furthermore, the peri-oral skin of all patients was disinfected for 30 s using cetrimumbromide 0.5 and chlorhexidine 0.05 in water (UZ Leuven pharmacy, Leuven, Belgium). Both the surgical team and the patients were blinded to the groups.

Measures of asepsis and prevention against infection from the oral cavity included the use of sterile drapes around the patient's mouth, head, and a large sterile drape over the supine body of the patient as usually done during periodontal surgery in addition to the use of a meshed nose guard (van Steenberghe et al. 1997) to prevent contact with the



Fig. 1. Patient with nose mesh (cap) during surgery.

highly contaminated nasal skin (Fig. 1) in addition to the use of two suction tips (one for the mouth and one only for the wound). The team of periodontologists and nurses are all thoroughly trained in high-end asepsis.

Bacterial samples were taken using dry sterile plain swabs (COPAN innovation, Copan Italia S.P.A.); by streaking the peri-oral skin and the sterile drapes 15 times; just before and at the end of surgery; from every patient, i.e. two bacterial samples from every patient. Moreover, bacterial samples were taken from the nares of the last 12 patients from each group, i.e. a total of 24 samples. The swabs were transferred into a conical tube containing 2 ml of RTF and were delivered to the microbiological laboratory.

The dilutions 1/10 to 1/1000 were plated in duplicate by means of a spiral plater (Spiral Systems Inc. Cincinnati, OH, USA) onto a non-selective blood agar plate (Blood Agar Base II, Oxford, Basingstoke, UK) and a selective mannitol salt agar plate. After 7 days of anaerobic (80% N₂, 10% CO₂, and 10% H₂) and aerobic incubation at 37°C, the total number of CFU/ml of aerobic and anaerobic bacteria was counted and *S. aureus* was identified (after fermentation of mannitol); once identified (*S. aureus*, which is coagulase-positive), the coagulase test, which is regarded as the gold standard for the detection of *S. aureus*, was additionally used to confirm its presence and to differentiate it from other coagulase-negative staphylococci. In order to calculate the CFU/ml, every counted CFU number was multiplied by the corresponding dilution factor, then the total was multiplied by the volume in millilitre of the conical tube (2 ml), and the result was then divided by the volume plated on the agar plate.

Additionally, some of the periopathogenic species namely *Porphyromonas gingivalis*, *P. intermedia*, and *black pigmented species* were identified, primarily based on colony morphology.

All 80 patients were seen at a follow-up visit (stitch removal appointment) 7–10 days after fixture installation. At the end of this appointment both the periodontologist, who removed the stitches, and the patient were asked to fill in a 10-cm visual analogue score (10 cm VAS score) consisting of five questions, in Dutch, to evaluate symptoms of infection/inflammation, which were spontaneous and/or evoked pain,

erythema, swelling and pus. A score of 10 meant no pain, no swelling, etc.

Criteria of infection

A post-operative infection was defined as the presence of purulent drainage (pus) or fistula in the operated region, together with pain or tenderness, localized swelling, redness and heat or fever (>38°C) (Sawyer & Pruett 1994). These signs were observed and reported by patients by looking into a mirror. A failed implant was defined as the presence of signs of infection and/or radiographic peri-implant radiolucencies that could not respond to a course of antibiotics and/or judged a failure after performing an explorative flap surgery by an experienced periodontologist. This incidence was checked up to the finalization of this study where the time lapse of evaluation for all implants was 5 months.

Statistical analysis

Data were statistically analysed by means of STATISTICA software version 7 for windows (StatSoft® Inc., Tulsa, OK, USA). To evaluate the differences in means between both groups, a *t* test for independent unpaired variables was used. The *p* value was set at the 0.05 level to detect significance. The null hypothesis was the absence of significant differences between groups.

Results

All 80 patients randomly allocated to one of the groups completed the study and all of them were controlled at the follow-up visit by a post-graduate resident in periodontology (Fig. 2). Table 1 shows the distribution of implants in GrAB⁺ while Table 2 shows the distribution of implants in GrAB⁻.

All participants were included in the statistical analyses (GrAB⁺, *n* = 40;

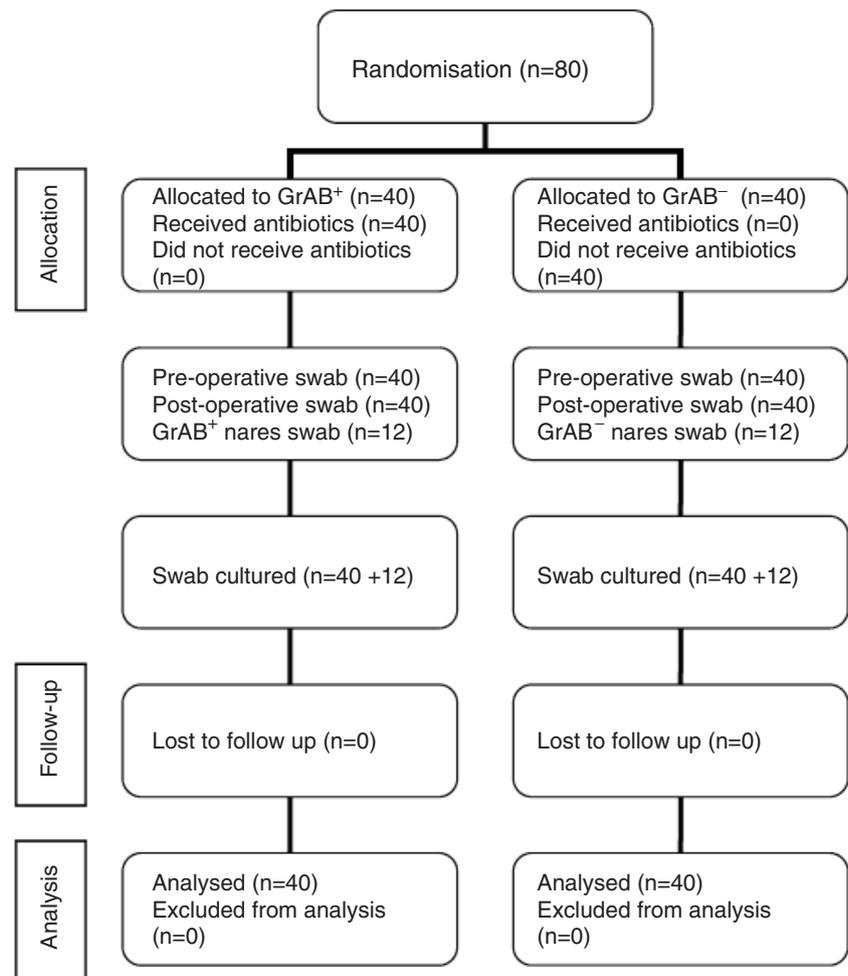


Fig. 2. Flow chart of patients' flow throughout the phases of the study.

Table 1. Distribution of 128 implants in the upper and lower jaws in the prophylaxis group (GrAB⁺)

| With prophylaxis (n = 40) | Case | No. of patients | No. of implants |
|------------------------------|---------|-----------------|-----------------|
| | Sol UJ | 11 | 19 |
| | Sol LJ | 6 | 8 |
| | Od UJ | 6 | 24 |
| | Od LJ | 4 | 8 |
| | Full UJ | 8 | 44 |
| | Full LJ | 5 | 25 |
| | Total | 40 | 128 |

UJ, upper jaw; LJ, lower jaw; Sol, solitary implant; Od, overdenture; Full, edentulous.

Table 2. Distribution of 119 implants in the upper and lower jaws in the non-prophylaxis group (GrAB⁻)

| Without prophylaxis (n = 40) | Case | No. of patients | No. of implants |
|---------------------------------|---------|-----------------|-----------------|
| | Sol UJ | 14 | 34 |
| | Sol LJ | 8 | 16 |
| | Od UJ | 6 | 24 |
| | Od LJ | 6 | 12 |
| | Full UJ | 3 | 18 |
| | Full LJ | 3 | 15 |
| | Total | 40 | 119 |

UJ, upper jaw; LJ, lower jaw; Sol, solitary implant; Od, overdenture; Full, edentulous.

GrAB⁻, n = 40; GrAB⁺ nares, n = 12; GrAB⁻ nares, n = 12). Analysis of the data showed no significant differences between GrAB⁺ and GrAB⁻ with respect to aerobic and anaerobic peri-oral bacteria from the peri-oral skin and the sterile drapes (Table 3). Furthermore, there was no significant difference between both groups with respect to aerobic and anaerobic bacteria taken from the nares (Table 4). No side effects of the antibiotic were reported.

S. aureus was detected in one patient (nares) only. He belonged to the no-antibiotics group. Finally, none of the well-known periopathogens (*P. intermedia*, *P. gingivalis*, and black pigmented species) were detected.

Following the criteria of infection for this study, one patient from GrAB⁺ group and four patients from the GrAB⁻ group developed post-operative infections. Survival rate of implants in the GrAB⁺ group was 100% while in the GrAB⁻ group it was 96%. Three patients in GrAB⁻ lost a total of five implants (Table 5).

Four out of the five lost implants in the GrAB⁻ group were installed in the posterior mandibular region of two

Table 3. Results from microbiological tests of peri-oral samples

| | GrAB ⁺ | | n | GrAB ⁻ | | n | p-value |
|-------|-------------------|-------------------|----|-------------------|-------------------|----|---------|
| | mean CFU/ml | SD CFU/ml | | mean CFU/ml | SD CFU/ml | | |
| An Pr | 2.3×10^4 | 3.5×10^4 | 40 | 1.6×10^4 | 2.1×10^4 | 40 | 0.3 |
| An Po | 6.2×10^4 | 1.1×10^5 | 40 | 3.6×10^4 | 5.2×10^4 | 40 | 0.2 |
| Ae Pr | 5.0×10^3 | 6.5×10^3 | 40 | 4.6×10^3 | 4.5×10^3 | 40 | 0.7 |
| Ae Po | 8.5×10^3 | 9.7×10^3 | 40 | 1.1×10^4 | 1.3×10^4 | 40 | 0.6 |

Level of significance $p < 0.05$.

n, number of patients; CFU/ml, colony forming units/ml; An, anaerobic bacteria; Ae, aerobic bacteria; Pr, pre-operative peri-oral sample; Po, postoperative peri-oral sample; GrAB⁺, group with antibiotic; GrAB⁻, group without antibiotic; SD, standard deviation.

Table 4. Results from microbiological tests for nasal samples

| | GrAB ⁺ | | n | GrAB ⁻ | | n | p-value |
|----|-------------------|-------------------|----|-------------------|-------------------|----|---------|
| | mean CFU/ml | SD CFU/ml | | mean CFU/ml | SD CFU/ml | | |
| An | 3.7×10^3 | 7.4×10^3 | 12 | 3.4×10^3 | 5.6×10^3 | 12 | 0.9 |
| Ae | 7.8×10^3 | 9.6×10^3 | 12 | 8.6×10^3 | 7.6×10^3 | 12 | 0.8 |

Level of significance $p < 0.05$.

n, number of patients; CFU/ml, colony forming units/ml; An, anaerobic bacteria; Ae, aerobic bacteria; GrAB⁺, group with antibiotic; GrAB⁻, group without antibiotic; SD, standard deviation.

Table 5. Infection and failure rates after fixture installation with (GrAB⁺) or without (GrAB⁻) peri-operative antibiotics

| | No. patients with post-operative infection | Survival rate of implants (%) | Position of failed implant(s) | Confounding factors |
|----------------------------|--|-------------------------------|--|--------------------------------|
| GrAB ⁺ (n = 40) | 1/40 | 128/128 (100) | None | Blood-clotting problems |
| GrAB ⁻ (n = 40) | 4/40 | 114/119 (96) | Four in posterior mandible, one in anterior mandible | Parafunctions or heavy smoking |

GrAB⁺, group with antibiotic; GrAB⁻, group without antibiotic.

female patients. One of them, in whom placement of short implants together with immediate placement of the abutments was performed, demonstrated extensive clenching habits. No signs of infection could be observed. But there was noticeable marginal bone loss and apical radiolucency just before rehabilitation by the final prosthetic work (2 months after fixture installation). The fifth failed implant in this group was installed in the anterior mandible of a female patient who smokes more than 40 cigarettes/day. Two months after fixture installation the patient presented mobility of the implant together with an abscess, a fistula and suppuration around the implant site. A radiograph demonstrated a radiolucency surrounding the implant.

There were no significant differences regarding the assessment of symptoms of infection/inflammation by the post-

graduate resident at the time of suture removal with respect to spontaneous pain (Spont) ($p = 0.1$), evoked pain by pressure (Evok) ($p = 0.3$), swelling (Swel) ($p = 0.1$), redness (Red) ($p = 0.5$), and pus (Pus) ($p = 0.6$) (Fig. 3). On the other hand there were significant differences regarding the assessment of symptoms of infection/inflammation by the patient at the time of suture removal with respect to Spont ($p = 0.01$), Evok ($p = 0.02$), Swel ($p = 0.02$), Red ($p = 0.01$) but no significant difference with regard to Pus ($p = 0.08$) (Fig. 4). Standard deviations and the presence of any outliers are included in the box and whisker plots.

Discussion

Although the use of peri-operative prophylactic antibiotics is inconsistent and

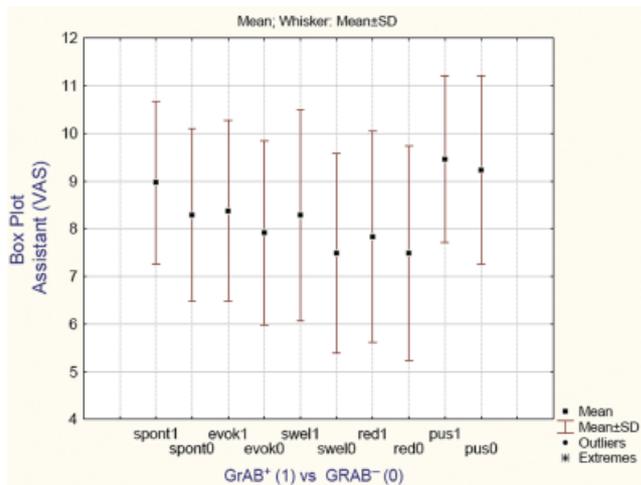


Fig. 3. Box and whisker plot of the assistants' visual analogue scores for the antibiotics group (GrAB⁺) and the non-antibiotics group (GrAB⁻). Ten means no pain, no swelling etc., 0 means severe pain, severe swelling, etc.

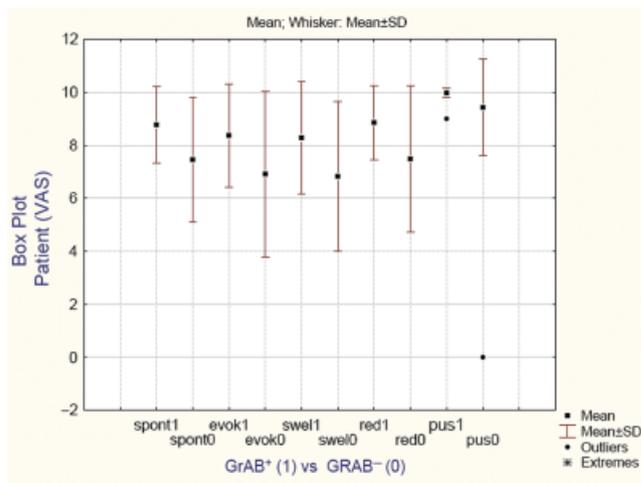


Fig. 4. Box and whisker plot of the patients' visual analogue scores for the antibiotics group (GrAB⁺) and the non-antibiotics group (GrAB⁻). Ten means no pain, no swelling etc., 0 means severe pain, severe swelling, etc.

varies widely among periodontologists and oral surgeons, the present study demonstrated that peri-operative antibiotic prophylaxis does not provide any significant advantages concerning post-operative infections. It should be pointed out that a high-end policy of asepsis was followed during this study. Indeed, often the use of sterile drapes is rendered futile because of improper behaviour of the operators and assistants because they did not have a proper training in the basics of surgery. This may explain why some papers report that the use of pre-operative antibiotics decreases the risk of implant failure two to three times (Dent et al. 1997). One should point out that because the incidence of infections following the

relatively atraumatic bone surgery associated with the insertion of oral implants is very low, the differences are difficult to assess.

Although the same surgical protocol was used consistently during this study, several surgeons, with different levels of experience, performed the surgeries.

The results of the present study also illustrate the following important points:

1. There is no correlation between peri-oral microbiology and post-operative infections.
2. There is no noticeable influence of pre-operative antibiotics on the peri-oral aerobic and anaerobic flora.
3. There is no effect for the prophylactic antibiotics on nasal aerobic and

anaerobic bacteria. The patients who reported adverse reactions such as swelling, pain, etc. have mainly experienced this during the first 1 or 2 days. This may explain the contrast between the questionnaires they answered and the VAS scores of the clinician at suture removal.

In the no-antibiotics (GrAB⁻) group three patients lost a total of five implants, while no implants were lost in the antibiotics (GrAB⁺) group. There were confounding factors in two of them, namely, heavy smoking (>40 cigarettes/day) or parafunctions. Four of the five failed implants were placed in the posterior mandible while the fifth was in placed in the anterior mandible.

According to the results of this clinical trial we suggest that thorough and careful evaluation of the benefits and risks of the use of peri-operative antibiotics should be considered before deciding to prescribe them for routine intra-oral surgery even when foreign materials are implanted. The administration of antibiotics carries the risk of adverse effects reaching from hypersensitivity to anaphylaxis; and from unwanted pregnancy complications to interactions with some medications. In addition to increased costs, it raises the risk of emergence of resistant microbial strains. Antibiotics should not be used as a cover-up for inappropriate asepsis techniques.

Conclusions

This paper reveals that when high-end asepsis is applied, the use of peri-operative antibiotic prophylaxis does not provide significant benefits concerning post-operative infections. The tendency for more implant failures in the group receiving no antibiotics did not reach significance and could be explained by confounding factors. The present findings also show that pre-operative antibiotics do not reduce peri-oral microbial contamination.

One must admit that the post-operative discomfort as assessed by the patients themselves during the first days was more limited when peri-operative antibiotics were given.

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Address:

Prof. Marc Quirynen
 Department of Periodontology
 Faculty of Medicine
 K.U.Leuven Kapucijnenvoer 7
 B-3000 Leuven
 Belgium
 E-mail: Marc.Quirynen@med.kuleuven.be

Clinical Relevance

Scientific rationale for the study: The present study is the first prospective randomized controlled study examining the eventual benefit of peri-operative antibiotics when performing intra-oral surgery involving the insertion of endosseous implants. *Principal findings:* The data indicate that antibiotics do not provide sig-

nificant benefits concerning post-operative infections in case of strict asepsis. It also does not reduce perioral microbial contamination. *Practical implications:* Except when specific systemic or local conditions render it beneficial, prophylactic antibiotics should not be routinely prescribed during elective surgery, such as the intra-oral placement of

implants. One should rather provide a proper training of the entire surgical team in asepsis. This should not be limited to the symbolic use of sterile gowns and drapes but in well-thought-of gestures. This will allow avoiding in most instances the unavoidable liabilities of antibiotic use.