Immediate Placement and Provisionalization of Implants Into Sites With Periradicular Infection With and Without Antibiotics: An Exploratory Study

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This study explored the necessity of perioperative antibiotics on survival rates of implants immediately placed and provisionalized into sites with infection. Subjects were randomly assigned into antibiotic or placebo groups. Extraction, immediate placement, and provisionalization of an implant were performed. Eight subjects received placebo and five subjects received both a pre- and postoperative antibiotic regimen. One implant from each group failed. Perioperative antibiotic therapy may not be needed in selected immediate implant therapy.

Key Words: antibiotics, apical infection, dental implants, immediate provisional restoration, immediate placement, randomized controlled trial

INTRODUCTION

The practice of placing and immediately provisionalizing dental implants has been studied extensively and has become a common procedure under certain clinical situations.1–5 Advantages to placing and immediately loading dental implants include immediate restoration of function and appearance, decreased morbidity as a result of reduced surgical visits, and a reduction in the amount of resorption of soft and hard tissues adjacent to the implant.2 Several clinical studies have demonstrated survival rates comparable to those of implants placed in a conventional manner; that is after osseous and gingival tissues have undergone an appropriate period of healing.4 There is a concern by some practitioners that implants should not be placed immediately within sites that demonstrate periradicular pathology.7–9 While no evidence exists to support this claim, there is a growing body of literature to suggest that the immediate placement of implants into such sites is possible, and limited data to suggest that immediate loading of implants placed into such sites is possible as well.10–23 In one prospective, controlled clinical study by Sigenthaler et al, implants (n = 34) were placed into sites with (n = 17) and without (n = 17) infection.18 A delayed loading protocol (after 3 months) was utilized. Of the 34 implants that were placed, 5 were lost early due to inability to obtain primary stability. Of the remaining 29 implants, all were functional at the 12-month follow-up, yielding a 100% success rate. Of importance to note is that 3 of the 29 implants (2 experimental and 1 control) showed signs of infection during the first 13 weeks of healing, requiring therapeutic intervention.

Only one clinical trial exists which tested the possibility of immediate loading of immediately placed implants into sites with infection.19 A total of 100 implants were placed, 76 being placed into sites with infection, and 24 into normal healthy tissue. Of the implants placed in this study, 2 failed due to periodontal involvement, representing an overall success rate of 97.4%. Some of the limitations of this study include the lack of identification of health status of patients (eg, whether the...
common antibiotics can no longer be used.\textsuperscript{28–30} As well as additional costs for more sophisticated antibiotics when antibiotic, the development of resistant microorganisms, as inexpensive may lead to potential adverse reactions to the misuse of common antibiotics that are currently relatively no clinical evidence to support such a protocol.\textsuperscript{24–27} Overuse or potential for successful osseointegration of the implant, there is no clinical evidence to support such a protocol.\textsuperscript{24–27} Overuse or misuse of common antibiotics that are currently relatively inexpensive may lead to potential adverse reactions to the antibiotic, the development of resistant microorganisms, as well as additional costs for more sophisticated antibiotics when common antibiotics can no longer be used.\textsuperscript{28–30}

To our knowledge, there have not been any studies completed which have attempted to determine the need for prophylactic antibiotic coverage under such conditions. Gynther et al\textsuperscript{26} looked at the effect of administration of preoperative systemic antibiotics on the success rates of implants placed within healthy sites. According to results from their study, implants that were placed in subjects who did not receive preoperative antibiotics exhibited similar rates of success as implants that were placed in subjects receiving preoperative antibiotics. Irrespective of the practice and belief that administration of antibiotics prior to placement of an implant into a site with a localized infection increases the potential for successful osseointegration of the implant, there is no clinical evidence to support such a protocol.\textsuperscript{24–27} Overuse or misuse of common antibiotics that are currently relatively inexpensive may lead to potential adverse reactions to the antibiotic, the development of resistant microorganisms, as well as additional costs for more sophisticated antibiotics when common antibiotics can no longer be used.\textsuperscript{28–30}

It would be helpful for clinicians to know from an evidence-based perspective whether the presence of periapical infection would preclude the successful outcome of dental implants placed and loaded immediately after an extraction. It would also be helpful for clinicians to know whether prophylactic administration of antibiotics during such procedures is necessary for a successful outcome in healthy subjects. We also hypothesized that the use of systemic antibiotics when placing implants according to this protocol would not provide any additional benefit in terms of implant survival.

\textbf{MATERIALS AND METHODS}

All work related to this study was carried out at the University of North Carolina-Chapel Hill, and conformed to the appropriate standards for research with human subjects, as well as guidelines delineated by the school’s Institutional Review Board (IRB Study # 10-0286). Subjects were recruited via approved announcements posted within the school, as well as in select dental offices within the community. Prior to enrollment, patients were given appropriate informed consent for the procedure. Table 1 lists the inclusion and exclusion criteria used as the basis for enrollment into the study. Note that the presence of mostly-intact facial and lingual alveolar plates in the cervical 1/2 of the alveolar socket was required for including the subjects into the study. Only cases with chronic periapical infection were enrolled. In addition, primary stability of implant at placement (at least 50 N-cm) was also required for our loading protocol for the implant.

\textbf{Placement of implants}

Upon acceptance into the study, subjects were randomly allocated to either the experimental or control groups via block randomization. Full-arch alginate impressions were acquired, and used to record baseline soft tissue levels, as well as provide a matrix for the provisional restoration. For those subjects whose tooth was severely broken down, a direct mock-up of the crown was completed using flowable resin. Baseline small volume cone-beam computerized tomography (CBCT) scans (Kodak dental systems, Rochester, NY) of each site were acquired prior to extraction and implant placement, and were used to evaluate the extent of infection and presence of remaining osseous tissue (Figures 1 and 2). All sites needed to have intact facial and lingual plates in the cervical half. However, the apical fistula tract was not an exclusion factor. One hour prior to the surgical procedure, each subject received either antibiotic or placebo. Antibiotic coverage consisted of amoxicillin, 2 g, PO 1 hour before the procedure, and then 500 mg tid, for 7 days following placement. For those patients who were allergic to amoxicillin, clindamycin, 600 mg 1 hour prior to surgery, and then 300 mg three times a day, for 7 days was administered. Placebo consisted of sucrose enclosed within a capsule that mimicked the antibiotic. Antibiotic or placebo was administered by the first author, who was blinded to the randomization schedule.

\begin{table}[h]
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\begin{tabular}{|c|c|}
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\textbf{Inclusion Criteria} & \textbf{Exclusion Criteria} \\
\hline
ASA Class 1 or 2 individuals, to include those with controlled HTN, diabetes, etc. & ASA Class 3 or 4 individuals, or those who are pregnant \\
Nonsmokers and smokers with a reported use of less than 1 pack/d & Age less than 19, over 70 \\
Female/Male, ages 19–70 & Patients who are on continuous antibiotic therapy for any medical condition \\
Presence of at least 1 pre-molar, canine, or incisor tooth with site of infection, either of periodontal or endodontic origin & Patients who exhibit gross infection/facial space infection with purulent discharge \\
Premolar, canine, or incisor tooth deemed nonrestorable secondary to vertical root fracture & Patients who use smokeless tobacco, who are unwilling/unable to cease for enrollment into study \\
Patients with sufficient bone quantity for implant placement, irrespective of infective lesion, and as determined by initial exam and small-volume CBCT scan & Patients unable to tolerate implant placement with local anesthesia \\
Presence of stable posterior contacts, bilaterally, and distal to the infected site & Patients who are unable/unwilling to return for follow-up appointments \\
\hline
\end{tabular}
\caption{Inclusion/exclusion criteria}
\end{table}
In addition to the preoperative antibiotic/placebo, all subjects were instructed to rinse for 2 minutes with 0.12% chlorhexidine. Anesthesia was administered, and the infected tooth was extracted (Figure 3), with curettage and irrigation with sterile saline solution and a very copious amount of 0.12% chlorhexidine. All implants were placed utilizing a flapless procedure (Figures 4 and 5). Implants (Zimmer TSV, Zimmer Dental Inc, Carlsbad, Calif) were placed lingually to the facial plate with minimal or no contact to the facial plate in the cervical 1/2 of the socket. There was an approximated gap of 1–3 mm between the most cervical part of the facial plate to the implant. No grafting was performed; however, our treatment protocol was to graft if there was more than a 3-mm gap between the implant and the socket wall. Note that we had the bone grafting protocol in place prior to the study, but none of the subjects included in this study required additional bone graft. All implants had at least 50 Ncm of primary stability.

**Provisionalization of implants**

After placement, each implant received a prefabricated abutment and screw-retained provisional crown (Figure 6, Integrity, Dentsply International, York, Pa). The occlusal surface of each crown was adjusted, such that there was no contact during maximum intercuspation or excursive movements of the mandible (nonocclusal loading). There was no occlusal contact and therefore this protocol is not an immediate load protocol by definition. Subjects were given a prescription of 0.12% chlorhexidine mouth rinse, and instructed to rinse twice per day for 1 week following placement of the implant. The provisional crowns were replaced with a prefabricated zirconia abutment (Figure 7, Zirconia abutment, Zimmer, Carlsbad, Calif) and a cement-retained lithium disilicate CAD/CAM crown (Figure 8, IPS e.max, Ivoclar Vivadent, Amherst, NY) no later than 8–12 weeks after placement of the implant.

**Follow-up and success criteria**

Follow-up periods were conducted at weeks 1 and 4 to assess for the presence of postoperative infection, pain, or other complications. Assessments at 6 and 12 months post-implant placement were completed to evaluate parameters related to implant survival (Figures 9–11). Another small-volume CBCT volumetric image was exposed at the 6-month follow-up visit. The criterion used to determine implant survival was a modified version of the Smith-Zarb criteria (Table 2). Analysis of the effectiveness of antibiotic coverage was completed using a Chi-
square analysis and Fisher’s exact test, with a probability value set at 0.05.

RESULTS

A total of 13 implants were placed in a total of 13 patients (1 implant/patient). Of the 13 implants that were placed, 2 fixtures were deemed to have failed by the 4-week follow-up period and were removed. The remaining 11 implants, at the 12-month follow-up recall appointment were in function, representing an overall survival rate of 84.7%. A descriptive analysis was completed (Table 3–7). Of the 8 subjects who received placebo, 1 implant failed to integrate, resulting in an implant survival rate without antibiotic of 87.5%. Of the 5 subjects who


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received antibiotic therapy, 1 implant failed to integrate, resulting in an implant survival rate with antibiotic therapy of 80%. Note that there are slightly more males than females; however, the 2 failed implants are in the male group (Table 3). There is 1 failure in each group based on antibiotic assignment (Table 4). Both failed implants are in the anterior region (Table 5), in the location of lateral incisor (Table 6). Finally, both failed implants had a diameter of 4.1 mm (Table 7). However, the failed implant in the placebo group had a length of 8 mm, while the failed implant in the antibiotic group had a length of 16 mm.

**DISCUSSION**

Results from this study are similar to results from other studies investigating placement of implants into sites exhibiting signs of infection: they seem to suggest that the immediate placement of implants into sites exhibiting signs of infection is a viable treatment modality. Of the 15 subjects enrolled, 2 were unable to receive implants at the time of surgery due to lack of the buccal plate of bone. It was determined that the possibility to obtain primary stability would be low, and subsequent integration of the implant unlikely to occur. Eleven of the 13 implants, at their respective 6- and 12-month follow-up periods satisfied the criteria for success established within this paper, demonstrating an overall survival rate of 84.7%. Note the triple-threaded design of the Zimmer TSV implants may allow high insertion torque (all implants achieved over 50 N-cm). Note that 2 subjects were excluded (Subject #14 and 15; see also Table 7). One subject (Subject #14) had lost a significant portion of the facial bone. An immediate implant was placed; however, due to the size of the graft, we decided clinically not to provisionalize the implant. For the other subject (Subject #15), there was a vertical root fracture as well as vertical bone fracture of both facial and palatal bone plates. We were unable to place an immediate implant.

While the survival rates that have been demonstrated in this study are slightly lower than those from other studies, we believe there may be a few variables that account for the differences in rates. We are in the process of expanding the study in a larger population. Both failures resulted in loss of an implant. We do not know for sure if the reason was periodontal or endodontic in nature. Our speculation is that failure in the placebo group was from overloading of a short implant. In one of the placebo group subjects, it was noted preoperatively that the roots of the adjacent teeth were converging and that a short implant fixture would be required. The use of a shorter implant in this case altered what would be considered an ideal crown-to-root ratio, resulting in an increased potential for undesirable forces on the implant fixture during the period of osseointegration. In general, it appeared to us that about 3 mm beyond the apex of the socket is needed to gain primary stability in the anterior teeth; however, the larger implants (in our case, 4.7 mm in diameter) are needed for the posterior (premolar) sites. While we do not have statistical power, there seems to be a trend that larger diameter of implants appear to have a higher survival rate.

For the antibiotic group, failure may be a result of compromised periodontal support of other teeth or overheating from implant site preparation. The second implant failure occurred in an antibiotic group patient who did not have sufficient posterior support, despite meeting the initial inclusion criteria. Furthermore, completion of disease control phase (which was to occur in coordination with another department within the school) did not occur as the patient failed to show for appointments. In both failed cases, careful adherence to the concept of nonocclusal loading (removal of all contacts on the tooth in maximum intercuspation and excursive movements) was followed; however, it is also possible that there was lack of adherence to the strict dietary instructions given to the subjects postoperatively. In addition, it is also possible that the implant site preparation to 16 mm in length could result in heat necrosis due to depth of osteotomy.

As was mentioned in the introduction, most studies investigating this topic employed systemic antibiotics, both pre- and postoperatively, as a part of their study design. Our study investigated whether or not pre- or postoperative antibiotics exert a beneficial effect on the outcome of implants placed into sites exhibiting signs of infection. From the limited data available in the present study, it appears that antibiotics do not provide any additional benefit when placing implants.
Prescribing Antibiotics for Immediate Implants in Infected Sites

into sites exhibiting signs of infection. Interestingly, the survival rate for implants in the placebo group (87.5%) was higher than for the group receiving antibiotics (80%). It is important to note, however, that the number of subjects enrolled in the present study is low and results should be interpreted with caution. To satisfy the odds-ratio analysis conducted prior to commencing with the study, it was determined that over 700 subjects would have needed to enroll to have an accurate assessment of the effects of prophylactic antibiotics on the outcome of survival rates of implants placed within sites previously occupied by infection.

It may be worthwhile for future studies to compare the influence of localized antibiotics, such as minocycline, versus no antibiotics on the outcomes of implant survival rates. It may be possible that the use of a localized, rather than systemic, antibiotics would have less propensity to cause some of the potential health concerns that the use of systemic antibiotics cause, such as life-threatening allergic reactions, development of bacteria that are resistant to the antibiotic, etc. It is also important to note that all cases included in this study had chronic periapical infection, most often with a facial fistula tract. None of these cases exhibited acute infection. More importantly, we used copious amounts of chlorhexidine irrigation postextraction in all cases. Chlorhexidine is known to be effective toward oral microorganisms including organisms associated with implant complications and graft contamination. A study done by Lambert et al suggests that perioperative oral rinse with chlorhexidine significantly improves implant surgical complications from bacterial infection.31 Young et al suggests that chlorhexidine rinse may effectively reduce bacterial contamination in autogenous bone graft materials.32 Rinsing an extraction socket with chlorhexidine may help reduce bacterial contamination from the previous periapical lesion.

Our goal in this exploratory study is not to prove that antibiotic resistance can occur from the use of antibiotics in conjunction with implant surgery; however, the study aimed to address the common belief that antibiotics are needed for all implant surgeries and that antibiotic use may help improve treatment outcome.33 Only healthy subjects with a presumably intact immune system were enrolled in this study. While the results suggest that antibiotics do not affect the implant surgical treatment outcome in healthy subjects, we do think, however, that patients with a potentially compromised immune system (eg, those with poorly controlled diabetes, use of immunosuppressive medications, or having other conditions that may compromise immunity) should have antibiotics prescribed in conjunction with implant surgery. While the main limitation of this study is the small sample size and a relatively short follow-up period, the most important point of this study is that perioperative antibiotic therapy, used almost universally in all dental implant surgery, may not be necessary. This study demonstrated that peri-operative antibiotics might not be necessary in selected cases, including single tooth immediate implant placement and provisionalization with flapless procedure and no grafting. Limited use of antibiotics and careful selection of cases for antibiotics in implant dentistry may in the future prevent the development of bacterial resistance to antibiotics, and may help save individual patients and prevent this potential public health crisis.29,33–35

**Conclusions**

The immediate placement and provisionalization of implants into sites previously exhibiting apical pathology appears to be a viable treatment modality. Results from this study are similar to results from other studies evaluating a similar protocol. Prophylactic antibiotic administration in healthy subjects does not appear to have a positive effect on the survival rates of implants placed into such sites, although further large-scale trials are needed to validate these findings.

**Abbreviation**

CBCT: cone-beam computerized tomography

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REFERENCES


