Effects of Antibiotics on Bone and Soft-Tissue Healing Following Immediate Single-Tooth Implant Placement Into Sites With Apical Pathology

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Overprescription of antibiotics can cause bacterial resistance problems, leading to life-threatening illnesses and public health crises. Clinicians often believe antibiotics can prevent dental implant failure and postoperative complications. In conjunction with implant surgery, antibiotics are therefore routinely prescribed for all cases. In this double-blind, randomized controlled trial, the effects of antibiotics on the clinical outcomes of immediate implant placement upon replacing a tooth with an apical pathology were examined to compare antibiotics (n = 10) and placebo (n = 10). In each subject, a tooth with a chronic apical lesion was extracted, thoroughly curetted, irrigated, and replaced with single implant with a screw-retained custom provisional abutment/crown. Postoperative pain/discomfort was measured at 1- and 4-week postsurgical follow-up visits using visual analog scales. Facial alveolar bone and soft-tissue changes were measured using pre- and postoperative cone-beam computerized tomography and impressions. We found survival rates of 100% (antibiotics) and 78% (control). However, there was no statistical difference in means for any clinical outcome (t tests with Bonferroni adjustment for multiple testing), except for midfacial soft-tissue changes: 0.43 mm (SD, 0.76) in the antibiotics group and 1.70 mm (SD, 1.06) in the placebo group (t15 = 2.89, P = .011). The average change of the midfacial alveolar plate was 0.62 mm (SD, 0.46) and 1.34 mm (SD, 0.91) for the antibiotic and placebo groups, respectively, which did not significantly differ statistically. No significant correlation (Spearman correlation) existed between the changes in facial alveolar bone and the facial gingival margin. Antibiotics appear to have little effect on immediate implant treatment outcomes.

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

INTRODUCTION

One common treatment modality when replacing a nonrestorable tooth in the esthetic zone is the use of an immediate implant. However, in most instances, the affected tooth has often developed an apical pathology. This can create controversy as to whether clinicians should or should not prescribe antibiotics in conjunction with immediate implant placement into an extraction site with apical pathology. Endodontic treatment of a tooth with an apical pathology does not normally require antibiotics. Fouad et al.1 reported that most of the time, antibiotics are not indicated in conjunction with endodontic therapy and the infection of endodontic origin is usually resolved by only using localized endodontic therapy. Abbott2 further discouraged the use of antibiotics in conjunction with endodontic therapy. He found that antibiotics are often overprescribed and suggested there are only a limited number of indications for antibiotics for endodontic infection.2 Similar recommendations of limited prescription of antibiotics for extraction of a tooth with a chronic apical lesion are widely accepted.3 In implant dentistry, however, it is almost universally accepted that antibiotics are needed in every case of implant surgery.4

Recently, “superbugs,” or antibiotic-resistant bacteria, have become a major public health crisis and a common life-

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threatening problem for individual patients. Overprescribing antibiotics is known to create new strains of bacteria that resist common antibiotics. Moreover, the manufacturing of new antibiotics has not kept up with the resistant bacteria that are developing.\(^7\) This increase in antibiotic resistant bacteria has been described as a threat to both global stability and national security.\(^6\) Antibiotic resistance is, in many cases, an irreversible phenomenon and difficult to manage. The World Health Organization emphasizes the unnecessary use of antibiotics with minor infections is perhaps one of the main etiological factors for antibiotic resistance.\(^6\) The World Health Assembly resolution of 1998 urged health care organizations to develop a protocol for the appropriate use of antibiotics to improve and prevent the spread of resistant bacteria and thus avoid a potential health care crisis.\(^7\)

Immediate implants have traditionally been contraindicated in sites with periapical pathology, but recent trends have moved away from this concept. Recently, the potential benefit of systemic antibiotic therapy to manage surgical complications after implant placement into sites with apical pathology has been a subject of debate. In a systematic review by Waasdorp et al,\(^8\) this issue was explored in both animal and human models. Combining two animal and 3 human studies, 100% and 98.9% survival rates of the implant fixtures were found, respectively.\(^8\) Waasdorp and colleagues\(^8\) suggested that, although controversial, the use of systemic antibiotics is recommended for this procedure until future evidence proves otherwise.\(^1-3\) In a randomized controlled trial, Givens et al\(^9\) compared the survival rate and the clinical outcomes including postoperative pain and discomfort of immediate implants placed in sites with apical pathology. Their findings suggested that systemic antibiotics may not play a role in the survival of the dental implant. However, in this study, there was no direct measurement of soft- or hard-tissue changes around the implant.

It is a duty of health care providers to prescribe antibiotics properly for the management and treatment of dental infections. There is, however, some disconnect in clinical understanding when dealing with immediate implant placement into sites with chronic apical lesions. In this study, we explore the need for antibiotic use with immediate implants into sites with apical pathology as well as whether antibiotics have any positive effects on clinical outcomes, in particular, the facial alveolar bone and soft tissue.

**Materials and Methods**

**Subject recruitment, selection, and randomization**

Subject selection and treatment protocol was similar to our previous study.\(^9\) The study protocol was approved by the University of North Carolina at Chapel Hill (UNC) Institutional Review Board (study No. 10-0286). Written consents were obtained from all subjects. A total of 20 subjects were recruited at the UNC School of Dentistry. All subjects were required to have a current dental provider and to have all active caries and periodontal disease treated and controlled. Subjects were in good periodontal health with proper periodontal recalls. The subject was required to have a current anterior or premolar tooth with an apical radiolucency evident with a periapical radiograph. The tooth in question was deemed to be nonrestorable by the subject’s current dental providers. A treatment plan for extraction and dental implant was indicated and prescribed by the dental provider. The tooth could be either in the maxillary or mandibular arch with intact adjacent teeth and appropriate opposing dentition.

Each subject’s general health history was thoroughly reviewed to ensure there was no contraindication for dental implant therapy. Only American Society of Anesthesiologists (ASA) class 1 or 2 patients were selected. Subjects with a compromised medical history (ASA class 3 or higher) that would require a physician’s consultation and alteration to surgical treatment or protocol were excluded. Subjects who were currently taking or require antibiotics, steroids, and or any immunsuppressive drugs on a regular basis or in conjunction with dental appointments were excluded. Table 1 shows the inclusion and exclusion criteria, which were similar to our previous study.

Periapical radiographs were used for initial screening (Figure 1a). Preoperative small-volume cone-beam computerized tomography (CBCT) scans (Kodak 9000, Kodak Dental Systems, Rochester, NY) were taken for all potential subjects (Figure 1b). The CBCT scans were used to determine whether the subject would fit the radiographic criteria for the study (Table 2). Note that the availability and integrity of facial alveolar bone and the extent of the apical lesions that would allow for ideal positioning of the implant with minimal or no grafting were used as the major criteria for case selection (Figure 1c). The CBCT scans were also used for the determination of the appropriate implant diameter and length (Figure 1b).

Subjects were randomly allocated to the antibiotic or placebo group. This was a double-blind study in which neither the subject nor the operator knew which group the patient was assigned. A computer-generated randomization sheet was given to the UNC drug investigational pharmacy at the UNC Hospital. The pharmacist was the only individual who had access to the allocation of subjects. An initial loading dose of antibiotics or placebo 1 hour prior to surgery and then 4 doses per day postoperatively for 7 days was instructed. The antibiotic selection was based on the most commonly used antibiotics in the field of dentistry. Patients were to receive amoxicillin (n = 25 capsules) if they did not have a penicillin allergy or clindamycin (n = 23 capsules) if they did not report a history of penicillin hypersensitivity (Table 3).

**Treatment protocol**

Written informed consent was obtained from all subjects. All subjects were instructed to take the initial loading dose of either antibiotics (2 g of amoxicillin or 600 mg of clindamycin) or placebo 1 hour prior to surgery. Immediately before the surgery, the subject was instructed to rinse for 2 minutes with 0.12% chlorhexidine. An initial preoperative impression was made with polyvinyl siloxane (Regisil, Dentsply Caulk, Milford, Del). The patient was properly anesthetized with 2% lidocaine with 1:100 000 epinephrine (Xylocaine, Dentsply, York, Penn). The tooth was extracted using periosteums and small straight elevators to ensure the facial alveolar bone was not damaged (Figure 2a and b).\(^9\)\(^10\) The socket was thoroughly curetted, and...
TABLE 1
Inclusion and exclusion criteria based on subject’s general health history

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
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<tbody>
<tr>
<td>American Society of Anesthesiologists (ASA) class 1 or 2 individuals,</td>
<td>ASA class 3 or 4 individuals or who have other contraindications for oral surgery</td>
</tr>
<tr>
<td>to include those with controlled hypertension, diabetes, etc</td>
<td>Age less than 19 y, more than 80 y</td>
</tr>
<tr>
<td>Female/male, ages 19–80 y</td>
<td>Smokers (more than 1 pack/d) or smokeless tobacco users</td>
</tr>
<tr>
<td>Nonsmokers or smokers with a reported use of less than 1 pack/d</td>
<td>Patients who are on antibiotic therapy, steroids, or immunosuppressive drugs</td>
</tr>
<tr>
<td>Not taking any antibiotics or steroids or immunosuppressive drugs</td>
<td>Patients who exhibit gross infection/facial space infection with purulent discharge</td>
</tr>
<tr>
<td>A premolar, canine, or incisor tooth with a nonrestorable tooth with periapical</td>
<td>Insufficient alveolar bone for the placement of dental implant</td>
</tr>
<tr>
<td>pathology</td>
<td>or insufficient primary stability of dental implant during the placement</td>
</tr>
<tr>
<td>Patients with sufficient bone quantity for implant placement, irrespective of</td>
<td>Patients unable to tolerate implant placement with local anesthesia</td>
</tr>
<tr>
<td>infective lesion, and as determined by initial examination, preoperative periapical</td>
<td>Patients who are unable/unwilling to return for follow-up appointments</td>
</tr>
<tr>
<td>radiograph, and cone-beam computerized tomography scans</td>
<td></td>
</tr>
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</table>

**Figures 1 and 2.**

**Figure 1.** Preoperative radiographs and immediate implant protocol. (a) A preoperative periapical radiograph of the tooth with a periapical lesion. (b) An example of cone-beam computerized tomography scans of the affected area. (c) Implant placement protocol showing the placement of an implant by engaging the palatal bone and the bone apical to the extraction socket. **Figure 2.** Clinical treatment protocol showing a series of an immediate implant surgery. (a) Preoperative view of the nonrestorable tooth. (b) The extraction socket after curettage and irrigation. (c) The implant drill in the extraction socket showing the angulation of the osteotomy site. (d) The implant in place. (e) Occlusal view of the implant fixture showing no contact to the facial bone.
and discomfort. The scale ranged from 0 to 10, with 10
analog scale at each appointment to assess the level of pain
following implant surgery. Each subject completed a visual
implant placement position.

If the implant was deemed close to the maxillary sinus, the inferior alveolar canal,
or root of an adjacent tooth, small-volume CBCT scans similar to
preoperative ones were also taken to ensure appropriate
placement of an immediate implant (eg, maxillary sinuses,
inferior alveolar canals, roots of adjacent teeth).

No narcotic prescriptions were given. A postop-
management. Over-the-counter analgesics (acetaminophen or ibuprofen)
were recommended to the subject to use as needed for pain
relief. The fabrication of the definitive restoration was performed
at least 12 to 16 weeks after the implant was placed (Figure 4a
and b). All implants were restored with a custom zirconia
abutment (Atlantis, Dentsply, Cambridge, Mass) or zirconia
prefabricated abutment (Zimmer Dental). The selection of the
abutment was based on the size of the tooth and the
angulation of the implant placed. All implants were restored
with lithium disilicate with esthetic layered feldspathic porce-

Facial alveolar bone and soft-tissue measurements

Subjects were seen at a 6-month recall after the placement of
the implant for a CBCT scan (Kodak 9000, Kodak Dental
Systems) and a polyvinyl siloxane impression of the implant
area. The vertical change in the alveolar bone was measured by
comparing the pre- and postoperative CBCT scans using
Simplant software (Materialise Dental, Waltham, Mass). To
ensure the similar linear plane of reference was used in the 2
different CBCT scans, the long axis of the tooth mesial to
the implant site was used as a reference plane (Figures 5a and 6a).
In both CBCT scans, the same panoramic curve was drawn
using the center of each tooth at the level of the cement-

all granulation tissue was removed. The socket was irrigated
with about 10 mL of 0.12% chlorhexidine, and then with
copious amounts of normal saline solution (about 20 mL). The
socket was then inspected to ensure there was an intact facial
plate at least at the cervical half of the socket (Figure 1c).
Osteotomy was made using the final 1 or 2 drills following the
manufacturer’s recommended protocol for drill sequence and
speeds (Figure 2c). The use of only the final 1 to 2 drills (largediameter drills) was to control the implant angulation and
minimize misalignment for the osteotomy. Copious irrigation
with saline was used throughout the drill sequence. A root-
form endosseous implant (tapered-screw vent [TSV]; Zimmer
Dental, Carlsbad, Calif) was placed into the osteotomy (Figure
2d and e). Each implant had good primary stability at about 50
N-cm insertion torque. The implant was then provisionalized
with a screw-retained provisional crown fabricated from
provisional abutment (Zimmer Dental) and bis-acryl acrylic
resin (Integrity, Dentsply, York, Penn). The occlusion of the
provisional crown was adjusted until there were no contacts in
the maximum intercuspal position or in lateral excursive
movements (Figure 3a and b). The subject was instructed to
continue use of the antibiotics or placebo for the next 7 days.

<table>
<thead>
<tr>
<th>TABLE 2</th>
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<tbody>
<tr>
<td>Inclusion and exclusion criteria based on preoperative cone-beam computerized tomography (CBCT) scans</td>
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<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
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<tbody>
<tr>
<td>1. Apical radiolucency present</td>
<td>1. No apical radiolucency present with associated tooth in question</td>
</tr>
<tr>
<td>2. Adequate bone to support dental implant</td>
<td>2. Extensive apical lesion that has resulted in loss of bone that would not allow for stability of immediate implant</td>
</tr>
<tr>
<td>3. Adequate facial plate to allow immediate implant placement</td>
<td>3. Not ideal facial plate that would compromise an immediate implant placement and the esthetic outcome</td>
</tr>
<tr>
<td>4. No anatomic landmarks that would not allow appropriate placement of an immediate implant (eg, maxillary sinuses, inferior alveolar canals, roots of adjacent teeth)</td>
<td>4. Extensive bone loss that would require major bone grafting</td>
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Subjects were seen at 1 week and then at 4 weeks
following implant surgery. Each subject completed a visual
analog scale at each appointment to assess the level of pain
and discomfort. The scale ranged from 0 to 10, with 10
representing the worst pain ever experienced. At each
appointment, the extent and location of inflammation, edema,
and erythema were noted. The clinical measurement was
recorded as none, mild, moderate, or severe.

TABLE 3

<table>
<thead>
<tr>
<th>Antibiotics vs Placebo Selection</th>
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<tr>
<td>Not Allergic to Penicillin</td>
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<tr>
<td>Amoxicillin 0 (placebo)/500 mg cap</td>
</tr>
<tr>
<td>Sig: Take 4 capsules by mouth 1 h before the procedure, then take 1 capsule 3 times daily for 7 d</td>
</tr>
<tr>
<td>Dispensed: 25 capsules</td>
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apex of the root in the sagittal plane (Figure 5a). This long axis was used as a reference line, allowing us to have a common and predictable reference plane to measure the facial alveolar height of the facial plate, preoperatively (Figure 5b) and postoperatively (Figure 6b). A common horizontal line was drawn in the axial view at the root apex of this mesial tooth. This horizontal line was stationary and could be used as a common reference line to measure the facial plate. The vertical measurement of the facial alveolar bone was made from the midfacial of the tooth in the preoperative CBCT scans and the implant in the postoperative CBCT scans, to the stationary horizontal in the axial plane of the apex of the tooth mesial to the implant site (Figures 5b and 6b). The difference between the pre- and postoperative facial bone height was recorded, with a positive value indicating bone resorption and negative value indicating bone gain.

The facial soft-tissue height was measured using polyvinyl siloxane impressions of the affected tooth preoperatively and the implant at the 6-month follow-up visit. The impressions were digitally scanned using Ortho Insight 3D, (Motion View Software, LLC, Chattanooga, Tenn), which then allowed for the fabrication of digital 3-dimensional casts in an STL format. The digital cast was used to measure the soft-tissue changes. Five common reference points were used (Figure 7a and b), including top of the facial-proximal line angle of incisal edges or cusps of adjacent teeth (2 reference points), height of mesial and distal papillae (2 reference points), and the lowest level of the midfacial gingival margin of the tooth or implant (1 reference point). The change in the mesial papilla height, distal papilla height, and the facial gingival margin was determined. Positive values were used as soft-tissue height reduction and negative values were used as soft-tissue height gained.

Hotelling’s $T^2$ was applied to simultaneously compare the differences in mean changes between the antibiotic and the placebo group for the 4 outcomes corresponding to facial alveolar bone and the 3 soft-tissue measures. The between-group difference in mean change for each outcome was also examined univariately with pooled 2-sample $t$ tests, with a Bonferroni-adjusted significance level defined at the $0.05/4 = 0.0125$ significance level. Satterthwaite’s $t$ test assuming unequal group variances and Mann-Whitney $U$ test for ranks were applied as sensitivity analyses. The Spearman rank correlation coefficient test was used to examine if there was a correlation between the changes of the underlying facial alveolar bone and the midfacial marginal gingiva.

**Results**

**Implant survival and reported complications**

A total of 20 immediate implants were placed in a total of 20 subjects (1 implant per subject). The subject’s ages ranged from 33 to 72 years. Eleven women and 9 men were enrolled. Race demographics included 12 Caucasians, 4 African Americans, 2 Asians, 1 Hispanic, and 1 Native American. Subjects were mostly recruited from DDS and graduate endodontic and urgent care clinics. A few referrals came from DDS and graduate prosthodontic clinics. Ten subjects were in the antibiotic group, and 10 subjects were in the placebo group. Nine implants were
FIGURES 5 AND 6. FIGURE 5. Preoperative measurement of facial alveolar bone. (a) Measurements at the reference site, tooth mesial to the implant site, in the sagittal plane (upper) and frontal plane (lower). (b) Measurements at the affected tooth site in the sagittal plane (upper) and frontal plane (lower). FIGURE 6. Postoperative measurement of facial alveolar bone. (a) Measurements at the reference site, tooth mesial to the implant site, in the sagittal plane (upper) and frontal plane (lower). (b) Measurements at the implant site in the sagittal plane (upper) and frontal plane (lower).
placed in men and 11 in women. With regard to implant site, implants were placed in the central incisor (n = 2), later incisor (n = 4), canine (n = 2), and premolar (n = 12) sites. Two implants in the placebo group were determined to have had an early failure. One subject, also in the placebo group, did not return for treatment after the 6-month follow-up. The survival rate was 78% (7/9) in the placebo group and 100% (10/10) in the antibiotic group.

Note that 1 of the failures was in a subject who did not come back after the second postsurgical visit. The provisional abutment screw became loose, which resulted in the provisional crown being in hyperocclusion, and thus, the subject overloaded the implant. When the subject came back about 4 months after surgery, the implant was loose. The second failure was noted in a subject when she came back for the final impression visit. We determined that there was an abscess and the implant was mobile. Once we removed the implant, a fragment of hard-tissue debris was found packed between the implant and facial alveolar bone.

In terms of postoperative pain and discomfort, 1 subject in each group reported mild pain (3) on the 0–10 visual analog scale, at the 1-week postsurgical visit (Figure 8a and b). However, none of the subjects reported any pain or discomfort at the 4-week postsurgical visit. Note also that clinical inflammation and swelling was not reported in any of the clinical visits. All subjects reported that they no longer used any analgesics at the 1-week postsurgical visit or thereafter.

**Facial alveolar bone and soft-tissue changes**

To measure the soft-tissue changes, pre- and postoperative digital 3-dimensional casts were used to compare the vertical height of the mesial and distal papillae as well as the midfacial gingiva (Table 4). The tooth mesial to the implant site was used to determine the measurement error. The differences between the pre- and postoperative soft-tissue height (standard deviation) for this calibration tooth are on average 0.14 (0.09) mm, 0.19 (0.07) mm, and 0.21 (0.08) mm for the midfacial, distal papilla, and mesial papilla measurements, respectively. The Hotelling T² was statistically significant ($F_{4,12} = 3.39; P = .045$), indicating that means between the antibiotic and placebo groups were different for at least 1 of the 4 outcomes. The average mesial papilla height change (standard deviation) was 0.51 (1.10) mm for the antibiotic group and 1.51 (1.32) mm for the placebo group; however, this difference was not statistically significant. The average distal papilla height change was 0.47 (0.81) mm for the antibiotic group and 0.24 (0.44) mm for the placebo group; however, this difference was not statistically significant. When comparing the midfacial gingival margin change, the average change for the antibiotic group was 0.43 (0.76) mm, while for the placebo group, it was 1.70 (1.06) mm, which was statistically significant ($P < .0125$).

Regarding the hard-tissue changes, the height of the midfacial alveolar plate was measured from the apex of the tooth mesial to the implant site to determine the measurement error similar to the soft-tissue measurement (Table 5). The differences between the pre- and postoperative midfacial alveolar bone height (standard deviation) of the tooth mesial to the implant site was on average 0.16 (0.08) mm. The average change of the midfacial alveolar plate for the antibiotic group was 0.62 (0.46) mm and 1.34 (0.91) mm for the placebo group; however, this was not statistically significant ($P > .0125$). Sensitivity analysis results for both soft and hard tissues supported the use of 2-sample pooled t tests (Table 5).

To determine if there was a possible correlation between the midfacial alveolar bone and midfacial gingival soft-tissue changes, the Spearman rank correlation coefficient test was used. Our data show there is no correlation between the hard- and soft-tissue changes (Figure 9).
**Table 4**

Descriptive statistics* for average hard- and soft-tissue changes

<table>
<thead>
<tr>
<th></th>
<th>Antibiotic Group (n = 10)</th>
<th>Placebo Group (n = 7)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Min 25p Median 75p Max</td>
<td>Min 25p Median 75p Max</td>
</tr>
<tr>
<td>Mesial papilla</td>
<td>–2.10 0.20 0.70 1.20 1.80</td>
<td>0 0.10 2.10 2.40 3.30</td>
</tr>
<tr>
<td>Distal papilla</td>
<td>–0.50 –0.10 0.35 0.90 2.20</td>
<td>–0.30 –0.20 0.20 0.70 0.90</td>
</tr>
<tr>
<td>Facial gingival margin</td>
<td>–0.30 0 0.25 1.00 2.00</td>
<td>0.50 0.80 1.50 2.20 3.70</td>
</tr>
<tr>
<td>Facial plate</td>
<td>–0.41 0.57 0.72 0.89 1.18</td>
<td>–0.01 0.61 1.41 1.60 2.94</td>
</tr>
</tbody>
</table>

*Min indicates minimum value; 25p, 25th percentile; 75p, 75th percentile; Max, maximum value.

**Discussion**

The goal of this study was to address the clinical question of whether antibiotics are needed when replacing a tooth with a periapical lesion with an immediate implant in the esthetic zone. In addition, we explored the effects of perioperative antibiotics for immediate single implants in terms of implant survival, postoperative complications, and, most importantly, changes in facial soft and hard tissue. While we share the same clinical protocol (double-blinded randomized controlled trial protocol, antibiotics, and implant placement/restoration protocol) with our previous study, we found the placebo group showed a lower survival rate than the Givens et al results. Note, however, that the 2 failures in the placebo group were caused by overloading of the implant due to screw loosening in 1 patient and by the root/bone fragment wedged between the tooth and the socket in the other patient. Antibiotics likely would not have helped in either case.

The question remains: are antibiotics needed if there is any infection remaining in the extraction socket? In this study, implants were placed into extraction sockets that were thoroughly curetted and irrigated with chlorhexidine as well as saline. All teeth with lesions were chronic in nature. There were no flap or large grafting procedures performed. We believe that in select cases of replacing a tooth with a chronic apical lesion with an immediate implant, antibiotics are not necessary. This study is, however, only an exploratory study with a small sample size. A larger study of this type is required to provide us with a more definitive answer. We need to keep in mind that the unnecessary use of common antibiotics may result in both expensive antibiotics in the future and an increase in bacterial resistance. This may pose a significant risk for patients in the future and could possibly develop into a public health crisis for the community at large.

Similar to Givens et al and other studies, we found that immediate implant therapy for a single tooth requires little pain management. In the study by Givens et al, narcotic analgesics and acetaminophen/codeine (Tylenol 3) were given to all subjects as our pain management protocol. We realized after that study that most of the patients did not take any narcotics prescribed. Therefore, we revised the protocol in this study, and none of our subjects were given narcotic analgesics. Only 1 subject in each group reported mild pain at the 1-week postsurgical visit, and none of the patients reported any pain after that. It is possible that placing an implant into a fresh extraction socket reduces the volume of the socket and creates only a small layer of clot. This would result in a smaller amount of inflammatory mediators. In addition, we fabricated a screw-retained provisional crown that was customized to fit the socket. This permitted primary closure of the socket, thus allowing stabilization of the clot and facilitating healing.

While the healing of the extraction socket is known to take up to 3 to 4 months, we know that the socket mineralization occurs within a few weeks at the periphery of the socket (close to the alveolar bone). In immediate single-implant placement, there is only a 2- to 4-mm gap between the implant and the facial alveolar bone. The gap appears to fill in completely in all cases at the 6-month postsurgical visit. It is plausible that immediate implant placement can facilitate bone healing simply by minimizing the bone-healing volume in the extraction socket. In addition, we suggested previously that perhaps antibiotics are not needed in cases of a single-tooth immediate implant even with periapical lesion when flap opening and graft were not performed.

**Table 5**

Average hard- and soft-tissue changes (mm)* (95% confidence intervals)

<table>
<thead>
<tr>
<th></th>
<th>Antibiotic group</th>
<th>Placebo group</th>
<th>Difference† (placebo – antibiotic)</th>
<th>Two-sample pooled t test P value‡</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mesial Papilla</td>
<td>Distal Papilla</td>
<td>Facial Gingival Margin</td>
<td>Facial Plate</td>
</tr>
<tr>
<td>Antibiotic group</td>
<td>0.51 (–0.28, 1.30)</td>
<td>0.47 (–0.11, 1.05)</td>
<td>0.43 (–0.11, 0.97)</td>
<td>0.62 (0.29, 0.95)</td>
</tr>
<tr>
<td>Placebo group</td>
<td>1.51 (0.29, 2.74)</td>
<td>0.24 (–0.16, 0.64)</td>
<td>1.70 (0.72, 2.68)</td>
<td>1.34 (0.49, 2.19)</td>
</tr>
<tr>
<td>Difference† (placebo – antibiotic)</td>
<td>1.00 (–0.33, 2.34)</td>
<td>–0.23 (–0.88, 0.43)</td>
<td>1.27 (0.23, 2.31)</td>
<td>0.72 (–0.14, 1.58)</td>
</tr>
<tr>
<td>Two-sample pooled t test P value‡</td>
<td>.11</td>
<td>.51</td>
<td>.011</td>
<td>.049</td>
</tr>
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</table>

*Change for soft tissues is postoperative minus preoperative. Change for facial plate is initial measurement minus 6-month measurement.
†Confidence interval for difference assumes Satterwaiet’s adjustment assuming unequal variances.
‡Pooled t test assumes equal variances. Satterwaiet’s t test assuming unequal variances gives P values of .13, .47, .021, and .091 for mesial papilla, distal papilla, facial gingival margin, and facial plate, respectively, whereas F tests for equality of variances gives P values of .60, .15, .36, and .066, respectively. Mann-Whitney test P values were .21, .70, .014, and .051, respectively.
One of the factors to consider in our study is the presurgical planning of the immediate implant. Using preoperative CBCT scans, we ideally selected an implant that was slightly longer than the socket. For instance, all implants placed were either 13 or 16 mm in length. We learned from our previous study that shorter implants may contribute to failure because of a lack of primary stability.\textsuperscript{8} The longer implants and the triple-thread design of TSV implants allow sufficient primary stability, which is one of the main requirements for immediate implant placement.\textsuperscript{8} We were also careful when placing an implant to keep a small gap (about 3 mm or less) from the implant fixture to the facial alveolar bone.\textsuperscript{16} For all subjects except one, we did not place any graft material. It has been suggested that the gap of 3–4 mm between immediate implant and extraction socket does not need grafting.\textsuperscript{17,18} We found that the facial bone in all cases regenerates into the gap. However, we also found that the apical fenestration from the previous lesion did not fully mineralize in all cases. This is most likely due to a short 6-month follow-up period, and it is likely that at 1 year, we would see more complete healing of the apical fenestration.

When replacing a tooth with an implant in the esthetic zone, the primary goals of the treatment are to replace and restore the esthetics and function of the coronal portion of the tooth. In addition, we wish to preserve and restore the facial alveolar soft and hard tissues. Contemporary technology allows for fabrication of esthetic abutments and crowns to mimic natural adjacent teeth. In our study, we used zirconia abutments and lithium disilicate crowns (Figure 4a and b). More importantly, this study is one of the few that digitally measured the facial soft and hard tissue for the tooth preoperatively and the implant postoperatively. We found that only about 0.5 to 2 mm of soft and hard tissue is lost at the 6-month postsurgical recall visit. While this number is similar to that of other studies,\textsuperscript{18–21} we believe that antibiotics have little influence on hard- and soft-tissue change. While it is possible that antibiotics can reduce subclinical infection that may in turn reduce inflammation, soft-tissue recession, and bone resorption, only the midfacial soft-tissue change was found to be statistically significant in this study. It is also possible that the sample size of this study is too small to see the effects on soft-tissue changes.

Both the hard- and soft-tissue measurement techniques were tested to determine the accuracy of our method. For consistency of the measurement, we did not want to use any molars. Thus, we used the tooth mesial to the implant site as our reference because we included anterior and premolar teeth in this study. The measurement was done carefully with 1 operator. Our measurement error was found to be 0.18 ± 0.06 mm and 0.16 ± 0.08 mm for the soft and hard tissues, respectively. This is comparable to other studies.\textsuperscript{22} Hermann et al\textsuperscript{23} found precision of their radiograph technique to be 0.1 mm. The measuring errors for repeated measurements of the soft and hard tissues were 0.14 ± 0.02 mm and 0.13 ± 0.01 mm, respectively. Small-volume CBCT scans may be important research or clinical tools in monitoring facial bone changes.\textsuperscript{24}

Interestingly, we found no correlation between the midfacial soft- and hard-tissue changes. Several studies have examined the relationship between interproximal bone and interimplant–dental papilla and suggested certain correlations between the underlying bone and soft tissue. For instance, Tarnow et al\textsuperscript{25} reported that if the distance between the interproximal bone and contact is 5 mm or less, the papilla will be present 100% of the time, whereas if the distance is 7 mm or less, the papilla will be present only 25% of the time. There is very little information in the literature on the relationship between the facial alveolar bone and facial soft tissue of a dental implant.\textsuperscript{26,27} While in a single-tooth implant situation, the periodontal health of the adjacent teeth plays an important role in maintaining the mesial and distal papilla,\textsuperscript{19} the midfacial gingiva and its relevance to the facial plate is not clear.\textsuperscript{26,27} We believe that while the facial alveolar bone may be important for long-term survival of the implant, it plays a limited role in maintaining the soft tissue. We further propose that appropriate contouring of the abutment, the provisional abutment in particular, may have a crucial role in preserving the midfacial soft tissue of the implant. In our study, we fabricated a provisional abutment that fitted into the extraction socket with a concave emergence profile. The customized provisional abutment can potentially provide primary closure and protect the blood clot in the socket. More importantly, the provisional abutment also acts as a root contour and therefore preserves the facial soft-tissue contour.

**Conclusion**

The results of this study suggest that the use of perioperative antibiotics has little influence on replacing a tooth with apical pathology with an immediate implant in the esthetic zone. Furthermore, antibiotics were not shown to have a material effect on either postoperative pain/discomfort or facial alveolar bone preservation. However, antibiotics may have limited effects on the midfacial soft tissue. No correlation was observed between the midfacial alveolar bone and soft tissues. Immediate provisional abutments may play an important role in preserving the midfacial soft tissue. With careful treatment planning and execution, immediate implant therapy, even in a case with a periapical lesion, can be done successfully with an optimal esthetic and functional outcome.

**Abbreviations**

CBCT: cone-beam computed tomography
CEJ: cement-enamel junction
TSV: tapered-screw vent

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