Immediate placement and loading of dental implants into infected sites with and without antibiotic prophylaxis: An exploratory study

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ABSTRACT

EDWARD GIVENS JR, DDS: Immediate placement and loading of dental implants into infected sites with and without antibiotic prophylaxis: An exploratory study.
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The objective of this prospective clinical trial was to evaluate the influence of pre- and post-operative antibiotic therapy on the survival rate of implants immediately placed and loaded into sites with infection. Fifteen subjects were enrolled in the study. All subjects underwent extraction of an infected tooth. All but two received an implant, abutment, and provisional crown at the same visit. Follow-up visits at week 1, 4, and months 6 and 12 were completed. Of the thirteen implants placed, two failed to integrate. Of the two failed implants, one subject received antibiotic, whereas the other received placebo. Within the limitations of this study, it appears that pre- and post-operative antibiotic use does not have a beneficial effect on the outcome of implants placed into sites with periradicular infection. Additionally, implants placed into sites with infection have comparable success rates to implants placed in sites without infection

This work is dedicated to those of whom are the anticipated beneficiaries of the clinical research that is conducted in the world of academia on a daily basis: The patients who entrust us with the care of their oral health.

ACKNOWLEDGEMENTS

The successful completion of the research contained herein could not have been possible without assistance and support from the following individuals: Dr's Sompop Bencharit, Donald Tyndall, Ceib Phillips, Lyndon Cooper, and Carlos Barrero. I would also like to recognize the American College of Prosthodontics Foundation for their monetary support and Zimmer Dental for their material support of the project.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

I. INTRODUCTION:

The practice of placing dental implants, and immediately loading them after placement 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, as well as 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 limited data to suggest that the immediate placement of implants into such sites is possible, and very limited data to suggest that immediate loading of implants placed into such sites is possible as well[10-23].

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 appears to be insufficient evidence to support such a claim[24-27]. The risks for potential adverse reactions to an antibiotic, the development of resistant microorganisms at both an individual and population level, as well as additional costs associated with use of the medications, are issues that could be avoided if it is determined that such coverage is not necessary[28-30].

II. REVIEW OF THE LITERATURE:

Endosseous dental implant therapy has become a widely accepted treatment modality for replacement of missing teeth. From the early beginnings of osseointegration, the field of implant dentistry has witnessed a number of paradigm shifts from the original implant placement protocols. At that time, whenever a tooth was deemed hopeless and extraction the recommended course of therapy, the tooth would be removed, and a period of healing would be recommended prior to placement of an implant. Once healed, the clinician would then place the implant, submerging it under the gingival tissues, allowing integration of the implant prior to restoring. A second stage surgery would then be performed to expose the implant, and prepare it for restoration. Due to a desire to increase the overall efficiency of the process, as well as an idea that outcomes may be improved, the concept of immediate placement and loading of implants began to emerge. By placing an implant immediately after extraction, the overall treatment time would be shortened, theoretically increasing patient satisfaction and possible acceptance of treatment, as well as reducing overall costs incurred by the treating dentist. Soon, investigators began to discover that placement of a temporary restoration (immediate loading) might improve the overall esthetic outcome of implants placed in such a manner, as well as further shorten treatment time, by eliminating the need for an additional procedure to expose the implant (second stage surgery).

Currently, the concept of placing and immediately loading implants has become a routine procedure, under certain clinical circumstances. The presence of infection around a tooth, however, has been considered a contraindication to implant placement by some

clinicians. This concept has recently been challenged, however, by a number of clinical trials, as well as a few case reports. The purpose of this review will be to systematically review relevant studies that have been completed evaluating placement of implants into sites with infection, as well as identify what the current literature states regarding the use of antibiotics in dental implant therapy,.

A comprehensive search of the literature initially revealed 53 articles related to implant placement into sites with the presence of infection. Of those articles, thirteen have been included for review here[10-23].

2.1 Animal Studies

Preliminary studies involving animal models have investigated the outcomes associated with implant placement into sites with infection. Each of the four studies included for review here used a beagle dog model, and either induced periodontal lesions prior to placing implant fixtures, or induced a periradicular type lesion, prior to placing implant fixtures. In all four studies, a split-mouth design was utilized, with approximately half of all implants in the study being designated to either the control or experimental group. Table 2.1 lists each study, as well as the important variables and experimental design.

All four studies utilized a pre- and post-operative course of antibiotic coverage. There were no implant failures in any of the four studies, however, in the study by Marcaccini, delayed healing was noticed initially, however, after 12 weeks, there was no statistical significance. These studies were important, as they were able to demonstrate the plausibility of placing implants under these circumstances. It may be suggested that one of the limitations to each of the studies is the short follow-up period, however, it seems

reasonable to suggest that if the presence of an infection precludes an implant to failure, then such a failure would occur within the early phases of the healing and integration processes.

Study	Animal Model	Number of Subjects	Number of Implants	Type of Infection	Treatment	Outcomes
Novaes, et al 1998	Dog	4	28	Periradicular vs healthy socket	Debridement, rinse with tetracycline solution, and antibiotic coverage	Zero failures and NSD in BIC in the experimental group
Novaes, et al 2003	Dog	5	40	ligature-induced periodontitis	Curretage of alveolus and antibiotic coverage	Zero failures and NSD in BIC in the experimental group
Marcaccini, et al 2003	Dog	5	40	ligature-induced periodontitis	Curretage of alveolus and antibiotic coverage	Slower healing initially and NSD after 12 weeks
Chang, et al 2009	Dog	4	24	Periradicular vs healthy socket	Osteotomy and curettage, placement with or without membranes and antibiotic coverage	Zero failures, less BIC in experimental groups, and less BIC in the non-membrane group

Table 2.1 Animal Studies BIC-Bone-Implant Contact NSD-No Significant Difference

2.4. Human Studies

One of the first reports of placement of implants into sites with the presence of infection in humans was a case report published in 1995 by Novaes, et al[14]. A total of 3 patients were treated, 2 patients with teeth exhibiting radiographic signs of infection, with clinical signs of root fracture, and 1 patient with a combined periodontal-endodontic lesion. Each of the patients were treated according to the same protocol: Extraction of the involved tooth, careful debridement of the remaining infected osseous tissue, irrigation with sterile saline solution, and administration of pre- and post-operative antibiotics (Penicillin V every 8 hours, for 10 days, beginning 24 hours prior to the procedure, as well as doxycycline once

per day, for 21 days). All implant placements were conducted using a two-stage approach. The follow-up time reported for each case was: 7 months for case report 1, 2 years for case report 2, and 11 months for case report 3. At each follow-up period, an exam and periapical radiograph was taken, to confirm integration of the implant.

The first clinical trial, published in 2005, can be credited to Villa and Rangart[16]. The objective of their study was to observe implant survival rates for dental implants that were placed into sites with infection, in the interforaminal region of the mandible. A total of 20 patients were enrolled in their study, and received from 4-6 implants. A provisional prosthesis was inserted 3 days later, conforming to an early loading protocol. The final restorations were delivered between 3 and 12 months. The total follow-up time was 44 months. There were no implant failures, accounting for a 100% survival rate.

A number of clinical trials followed the Villa and Rangart paper. The largest of these was a randomized, controlled trial published in 2010 by Crespi, et al[23]. In their study, a total of 37 patients were enrolled, with the placement of 275 implants. 197 implants were placed in periodontally infected sites, and 78 were placed in native, healthy tissues. Parameters that were evaluated were marginal bone levels, plaque accumulation, and bleeding indices. Evaluations were made at baseline, 12, 24, and 48 months. The authors found no statistically significant difference between the experimental and control groups at the 48 month follow-up period.

Study	Number of patients	Number of implants	Type of infection	Follow-up Time (months)	Treatment	Outcome
Novaes, et al-1995	3	3	Periapical	7-14	Debridement, saline rinse, 31 days of antibiotics	100% survival
Villa and Rangart-2005	20	97	Periapical and periodontic	15-44	Socket debridement, curretage, antibiotic (local), cortisone injection, and post surgical antibiotics	100% survival
Lindeboom, et al-2006	50	50	Periapical	12	Antibiotics, 1 hour prior to surgery, socket degranulation	92% survival-test group 100% in control group
Siegenthaler, et al-2007	29	29	Periapical	12	Antibiotics 1 hour prior to surgery, CHX rinse, socket debridement, GBR, and anti-biotics 5 days post-surgery	100% survival
Villa and Rangart-2007	33	100	endodontic, periodontic, or root fracture	12	Socket debridement, currettage, irrigation with antibiotic, cortisone injection into soft tissue, post-surgery antibiotics	97.4% survival
Casap, et al-2007	20	30	Periodontal and periapical	12-72	Systemic antibiotics pre- and post-operative intrasocket ostectomy, and GBR	97.7% survival
Naves, et al-2009	1	3	Periapical	36	Antibiotics 1 hr prior to surgery and 7 days post-surgery, Apical access flap, with debridement	100% survival
Del Fabbro, et al-2009	30	61	Periapical	10-21	Socket debridement and PRGF coating of implant	98.45% survival

Crespi, et al-2010	37	275	Periodontal	48	systemic antibiotics pre- and post-operatively, 0.12% CHX rinse, Immediate load protocol	98.9%-test group 100%-control group

Table 2.2 Human Studies CHX-Chlorhexidine, GBR-Guided Bone Regeneration

2.3 Antibiotics and Implant Therapy

It has traditionally been the standard of practice to provide a pre-loading dose of antibiotic prior to implant placement, and in some instances, a post-operative course of antibiotic therapy subsequent to implant placement. The rational for administration of antibiotics has been the belief that such administration will reduce bacterial loads intra-orally, and thus create an environment that will allow an implant fixture a better opportunity to integrate within the host tissue, at least during the early phase of healing. Becker and Becker have described this in their paper, in addition to a number of other authors[24-27]. A number of clinical controlled studies have been completed, which have evaluated the efficacy of such practice (Table 2.3). The results have been equivocal.

In a large scale, multi-center prospective analysis, Laskin, et al, compared the efficacy of a pre-operative dose of antibiotic versus no antibiotic[24]. A total of more than 2900 implants were evaluated in the study, and a minimum follow-up period of 3 years was completed. There were 387 patients (1,743 implants) in the group that received preoperative antibiotics and 315 patients (1,287 implants) in the group that did not receive preoperative antibiotics. Postoperative antibiotics were used in 96% of the total cases. At four different time points, or stages, the implants were assessed for survival status. These time points were as follows: 1) period between the time of implant placement and uncovering (Stage 1); 2) at uncovering (Stage 2); 3) before loading of the prosthesis (Stage 3); and 4) from loading of

the prosthesis to 36 months post-placement (Stage 4). Failure was defined as the need to remove the implant at any time for any reason, including clinical mobility, the presence of infection, persistent pain, or the radiographic presence of pathology. In making their comparison, the authors looked at three different regimens of pre-operative antibiotic regimens: 1) preoperative antibiotic regimen of any type versus no preoperative antibiotic coverage; 2) a sufficient level of preoperative antibiotics as defined by Peterson et al., which is twice the therapeutic level or greater, versus a smaller dose or no preoperative antibiotics; and 3) a sufficient level of preoperative antibiotics as defined by the American Heart Association (AHA)1 versus an insufficient AHA dose or no preoperative antibiotics. Survival of implants in patients with preoperative antibiotic coverage was 95.4% compared to 90% for those implants placed without coverage. A higher implant survival rate also occurred at each stage of treatment from the time of placement to 36 months. In conducting their statistical analysis, authors found a statistically significant difference between the survival rates among the two groups, stating that the P-value was less than .05. They concluded that a single pre-operative dose of systemic antibiotic administration has a positive effect on the survival rate implants that are placed.

In another large scale, multi-center study, Morris, et al, placed a total of 1,500 implants, and followed their rate of failure over a 3-5 year period[25]. 1175 of those implants were placed with the use of a pre-operative antibiotic regimen, while 354 were placed without a preoperative antibiotic regimen. Of those placed with antibiotics, the survival rate was calculated to be 96.3%, and for those without, the survival was calculated to be 95.2%. The difference was not statistically significant. The author's concluded that the

administration of a pre- or post-operative antibiotic regimen has no positive effect on the outcome of implant survival.

Gynther, et al, found similar results in their study[26]. A total of 1454 implants were placed at two different time periods. A total of 790 implants, which were used to support both fixed and removable prostheses, were placed with a pre- and post-operative course of antibiotics. These implants were followed for a range of 1-6 years, with a mean follow-up of 3 years. A total of 664 implants were placed, almost a decade later, without any type of antibiotic regimen. These implants were followed for a range of 1-5 years, with a mean follow-up period of 3 years. Survival rates for the antibiotic group was 88% in the maxilla, 99% in the mandible, and for the non-antibiotic coverage group, 95% in the maxilla, and 95% in the mandible. The differences were not statistically significant.

Esposito, et al, conducted a meta-analysis of four large clinical trials[31]. Each of the studies, individually, failed to find a statistically significant difference in implant survival outcomes, when comparing antibiotic administration versus placebo. Their meta-analysis of the four studies together did show that a pre-load dose of 2g of Amoxicillin may be beneficial in preventing failure of an implant to integrate during the early phases of healing. According to the author of that review, one out of every 33 patients that receive a pre-operative dose of 2g of Amoxicillin, would prevent early failure of an implant.

Although the administration of a preoperative dose of antibiotics, prior to the placement of a dental implant is common practice, the evidence to support this protocol has been weak at best. Clearly there is no consensus in the literature regarding whether or not the administration of antibiotics prior to the placement of an implant improves implant survival rates. More well-designed, larger scale studies are needed to definitively answer the

question: Should we give our healthy patients a pre or post-operative course of antibiotics to improve the outcome of their implant surgery? If we are able, through well-controlled studies, definitively say no, then we can potentially avoid the negative outcomes associated with overuse of antibiotics, such as the creation of strains of bacteria resistant to antibiotic therapy, as well as the potential for development of allergic reactions.

Author	Study Design	Sample Size	Interventions	Outcomes Assessed	Results
Laskin, et al-2000	Non-randomized trial	3130 implants	pre-operative antibiotics of clinician's choice vs no antibiotic	3 year implant survival rate	Pre-operative antibiotics improves survival
Morris, et al-2004	Correlational	1500 implants	Pre-operative and post-operative	3-5 year implant survival rate	NS difference for all regimens
Gynther, et al-1998	Retrospective	1454 Implants	Pre-op and post op antibiotic vs no antibiotic	1-6 year implant survival rate	NS difference for implant survival
Mazzocchi, et al-2007	Retrospective	736 implants	no antibiotic therapy	4-6 months post-op	Implant survival rate-96.2%

Table 2-3 Studies Comparing Antibiotic Efficacy

2.4 Discussion

The immediate placement of implants into sites with the presence of infection has become an increasingly common procedure. Data from studies that have been published in the past two decades seem to suggest implant survival rates that are equivalent to implants that are placed in native, healthy osseous tissue. While it is not known exactly why the rates are equivalent, some explanations can be proposed. First, when a tooth exhibiting signs of

infection is removed, most of the source of that infection is also removed. In some cases, granulation tissue associated with the lesion is also removed with the root of the offending tooth. Any remaining or residual infection is subsequently removed with curettage and irrigation of the socket. Additionally, upon completion of the osteotomy for placement of the implant, more of the infected tissue is removed.

While it has been shown that survival rates for implants placed into sites with infection are high, it is not known whether administration of a pre- and post-course of antibiotic therapy is able to exert any beneficial effect on those rates. In all of the studies included in this review, a course of antibiotic therapy, both a pre-loading dose and post-operative dose were prescribed. Considering that most, if not all, of the infection is removed when a tooth is removed, then it may stand to reason that antibiotic therapy may not be needed when performing immediate placement of implants into such sites. Future studies with larger sample sizes should be completed in order to evaluate the effect of prophylactic antibiotic coverage when immediately placing implants under these circumstances.

Additionally, consideration should be given to conducting trials evaluating the effects of the administration of localized antibiotics. It is possible that the use of local versus systemic antibiotics could provide a beneficial effect on the outcome, while potentially minimizing the risks that are associated with the use of systemic antibiotics.

2.6 Conclusions

Limited data from animal and human studies suggest that immediate placement of implants into sites previously occupied with an infection can be a predictable treatment modality. Implant survival rates placed under these conditions have been in the mid- to high-ninety percentile range. It is unclear as to whether the administration of antibiotics provides

any positive outcome on these rates of survival, and future work should be directed at determining the need for prophylactic antibiotic coverage in these circumstances. Careful debridement and irrigation of such sites can be considered an important part of this treatment protocol.

III. PROSPECTIVE CLINICAL TRIAL

3.1 INTRODUCTION

The practice of placing dental implants, and immediately loading them after placement 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, as well as 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 limited data to suggest that the immediate placement of implants into such sites is possible, and very limited data to suggest that immediate loading of implants placed into such sites is possible as well[10-23].

Controlled clinical trials demonstrating the success/failure rates of placing implants into infected extraction sites are scarce. 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 (two experimental and one control) showed signs of infection during the first 13 weeks of healing, which required 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, which represented an overall success rate of 97.4%. Some of the limitations of this study include the lack of identification of health status of patients (i.e., whether patient had controlled or uncontrolled systemic disease, smoker vs. non-smoker, etc), a lack of definition of lesion size/location, the varying types of prosthesis use to restore the implants, such as single crowns, fixed partial dentures, and full arch restorations, and a limited number of implants within the control group.

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[26], et al 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[24-27]. The risks for potential adverse reactions to an antibiotic, the development

oresistant microorganisms, as well as additional costs associated with use of the medications, are issues that could be avoided if it is determined that such coverage is not necessary[28-30].

It would be helpful for clinicians to know, from an evidence-based perspective, whether or not the presence of periradicular 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 or not prophylactic administration of antibiotics during such procedures are necessary for a successful outcome. Thus, one aim of this prospective controlled clinical trial will be to evaluate the rate of success of endosseous dental implants placed into sites with infection, and immediately loaded. A secondary aim will be to evaluate the influence of systemic prophylactic antibiotics on the success rate of implants placed under such circumstances.

We hypothesized that implants placed and immediately loaded within sites that are infected will perform as well as implants that are placed and immediately loaded within healthy sites. We also hypothesized that the use of systemic antibiotics when placing implants according to this protocol would not provide any additional benefit.

3.2 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. 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 3.1 lists the inclusion and exclusion criteria used as the basis for enrollment into the study.

Inclusion Criteria	**Exclusion Criteria**
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
Non-smokers and smokers with a reported use of less than 1 pack/day	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 one 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 non-restorable 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

Table 3.1 Inclusion/Exclusion Criteria

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 CT (CBCT) scans (Kodak dental systems, Rochester, NY) of each site were acquired prior to extraction and implant placement, and used to evaluate the extent of infection, and presence of remaining osseous tissue. One hour prior to the surgical procedure, each subject received either antibiotic or placebo. Antibiotic coverage consisted of Amoxicillin 2g, PO 1hr before the procedure, and then 500 mg tid, for 7 days following placement. For those patients who were allergic to Amoxicillin, Clindamycin 600mg 1 hour prior to, and then 300mg 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. In addition to the pre-operative antibiotic/placebo, all subjects were instructed to rinse for two minutes with 0.12% Chlorhexidine. Anesthesia was administered, and the infected tooth was extracted, 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. Guided bone regeneration (Bio-Oss,) with or without barrier membrane (Biomend, Osteohealth, Shirly, NY) was used when it appeared that there was a horizontal deficiency between the implant and alveolus of greater than 2mm.

Loading of implants

After placement, each implant received a pre-fabricated abutment and screw-retained provisional crown (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 (non-occlusal loading). Subjects were given a prescription of 0.12% Chlorohexidene mouthrinse, and instructed to rinse twice per day, for 1 week following placement of the implant. The provisional crowns were replaced with an all-zirconia abutment (Zimmer) and cement retained permanent all ceramic restoration (Emax-Ivoclar) no later than 8-12 weeks after placement of the implant.

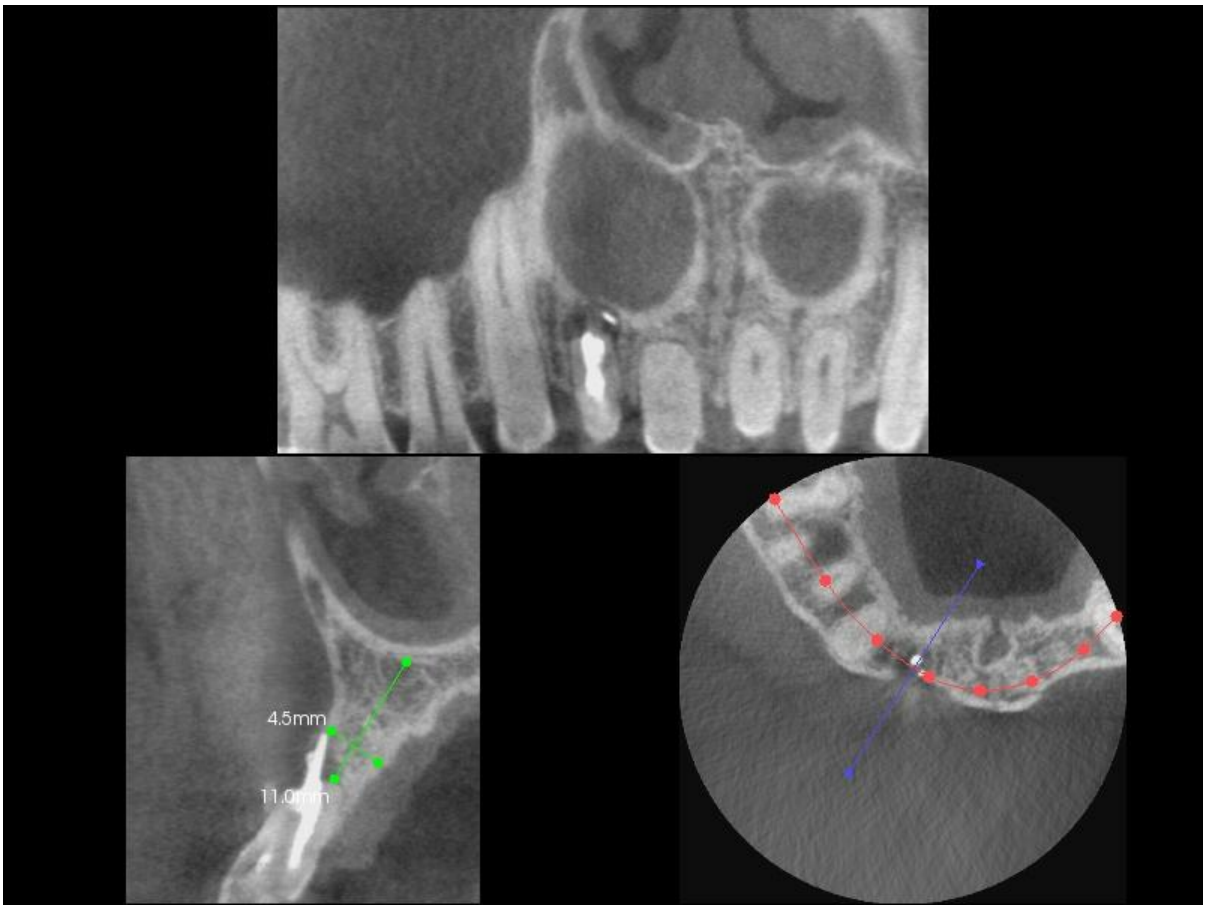

Fig. 3.1 Pre-extraction CBCT of Tooth #7

Fig 3.2 Pre-extraction Clinical Photo

Fig. 3.3 Extraction Socket

Fig 3.4 4.1mm x 11.5mm Zimmer TSV Implant

Fig 3.5 Implant Placement

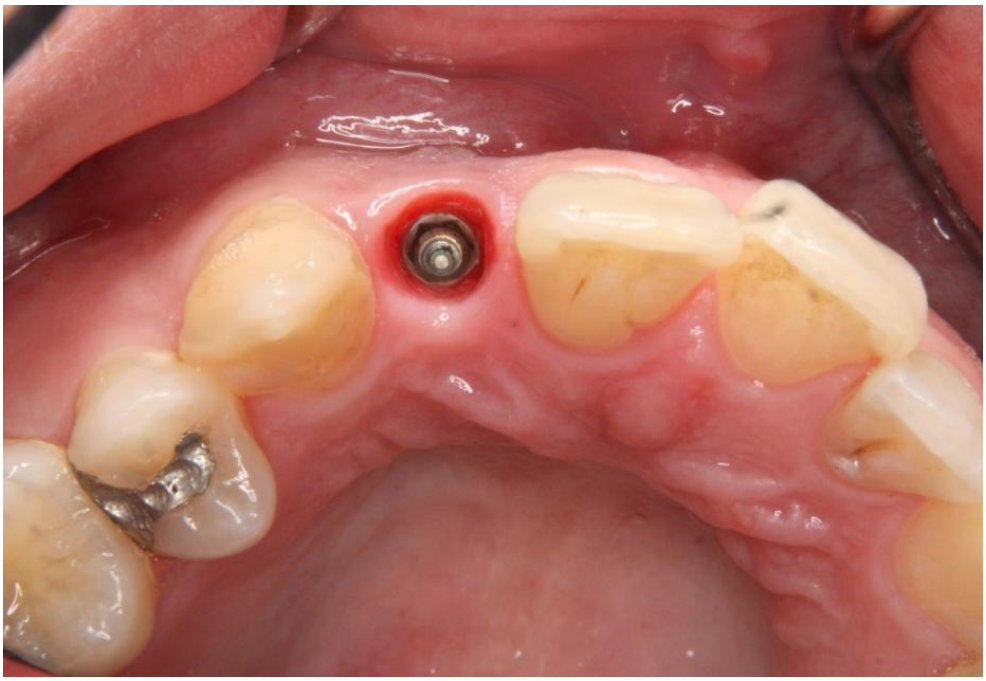

Fig 3.6 Occlusal View of Implant Placement

Fig 3.7 Provisional Restoration in Place

Fig 3.8 Definitive All-Zirconia Abutment

Fig 3.9 All-Ceramic Definitive Restoration

Fig 3.10- 6 Month Follow-Up Photograph

Fig 3.11-12-Month Follow-Up Photograph

Fig 3.12 Baseline Radiograph

Fig 3.13 12-Month Follow-Up Radiograph

Follow-up and Success Criteria

Follow-up periods were conducted at weeks 1 and 4 to assess for the presence of post-operative infection, pain, or other complications. Assessments at 6 and 12 months post-implant placement were completed to evaluate parameters related to implant survival. Another small-volume CBCT volumetric image was exposed at the 6 month follow-up visit. 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. The criteria used to determine implant success was a modified version of the Smith-Zarb criteria (Table 3.2)

Criteria used to determine Implant Success **(Modified from Smith and Zarb)**
• **No mobility detected on implant at each follow-up interval**
• **Decrease in size of lesion, from baseline to 12 month follow-up, as determined by conventional PA radiograph**
• **Vertical bone loss not to exceed 1.5 mm**
• **No persistant pain, discomfort, or infection is attributable to the implant at each follow-up interval**

Table 3.2 Implant Success Criteria

3.3 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 failed to integrate, and were deemed early failures. This represents a survival rate of 84.7%. Table 3.3 lists the distribution of implants based on gender and implant failures. A descriptive analysis was completed, and results are displayed as follows: Table 3.4 lists the distribution of subjects based upon who received antibiotic versus who received placebo, and the distribution of failures among each group. Table 3.5 shows distribution of each subject, tooth number, whether or not the subject received antibiotic or placebo, and whether or not the implant was stable at the 6 month follow-up.

Gender	Implants	Failures
Male	7	2
Female	6	0

Table 3.3 Implant Distribution and Survival by Gender

	Implants	Failures
Antibiotic	5	1
Placebo	8	1

Table 3.4 Implant Survival by Antibiotic or Placebo

Site	Total	Failed
Anterior	9	2
Posterior	2	0

Table 3.5 Implant Survival by Anterior-Posterior Position

Site	Total	Failed
Maxillary	8	2
Mandibular	3	0

Table 3.6 Implant Survival by Jaw Location

Subject	Tooth #	Antibiotic /Placebo	Integrated?	Implant Diameter (mm)	Implant Length (mm)
1	7	A	Yes	4.1	11.5
2	28	A	Yes	4.7	11.5
3	7	P	Yes	4.7	16
4	10	P	Yes	4.7	13
5	7	P	Failed	4.1	8
6	29	P	Yes	4.7	11.5

7	7	P	Yes	4.7	13
8	7	A	Yes	4.7	16
9	7	P	Yes	4.7	16
10	4	A	Yes	4.7	16
11	26	P	Yes	3.7	13
12	7	A	Failed	4.1	16
13	10	P	Yes	4.1	16
14	29	P	n/a	n/a	n/a
15	8	A	n/a	n/a	n/a

Table 3.7 Data Set by Subject

Discussion:

Results from this study are similar to results from other studies investigating placement of implants into sites exhibiting signs of infection, and 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. For these patients, thorough debridement and irrigation was completed, followed by socket augmentation with Puross Putty and Collagplug. These patients were then given an essix retainer, and informed that they could return after a sufficient period of healing for placement of an implant fixture. Eleven of the thirteen implants, at their respective 6 month follow-up period, have satisfied the criteria for success established within this paper, demonstrating a rate of 84.7%.

While the survival rates that have been demonstrated in this study are slightly lower than those from other studies, there are some variables that may account for the discrepancy. One reason might be attributable to the study design, in that the implants in the present study were immediately placed and provisionalized. This can be considered a substantial difference between this and the majority of the studies that have been published. While careful adherence to the concept of non-occlusal loading (removal of all contacts on the tooth in maximum intercuspation, as well as excursive movements) was followed, it is possible that the implant failures were due to lack of adherence to the strict dietary instructions given to the subjects post-operatively.

In one of the failures, the implant chosen for placement was shorter than average (4.1mm x 8mm). This was chosen, because of the convergence of the adjacent teeth. While we did feel that we were able to obtain primary stability, an objective measure of that stability was not obtained, and thus it is possible that the amount of stability may not have been adequate. Failure of the second implant was determined at the 1 and 4 week follow-up period. This second failure we feel may be attributed to the lack of completion of the control phase of treatment, as well as lack of some posterior support of teeth. Completion of the control phase (i.e., caries, some periodontal pocketing of 4-5mm's) was to be completed shortly after placement of the implant, however, due to extenuating circumstances (appointments for treatment were not completed by provider or patient), this did not occur.

In regard to the administration of pre- and post-operative antibiotic therapy, there did not appear to be a difference between the antibiotic and placebo group. Of both implants that had failed, one received prophylactic antibiotic coverage, while the other received placebo. For the implants that did integrate, four received a pre-operative dose of antibiotics, while

seven received placebo. This is particularly interesting, as this seems to suggest that prophylactic antibiotic administration for implant placement may not provide any positive effect on the survival rate of implants placed under these conditions.

It is important to note that the number of subjects enrolled in the present study is low, and that while an exact analysis was performed, results should be interpreted with caution. To satisfy the odds-ratio analysis conducted prior to commencing with 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. Notwithstanding this limitation, we do feel that results from this exploratory study are encouraging, and recommend that future studies be completed with an identical design protocol, to provide an accurate analysis.

As mentioned in the introduction, most studies investigating this topic employed systemic antibiotics, both pre- and post-operatively, as a part of their study design. Our study asked the question: Are pre-operative antibiotics really necessary for placement of implants into sites exhibiting signs of 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. While it is still questionable whether or not antibiotics have any positive effect on implant integration, if future large scale trials in fact do determine that prophylactic antibiotic administration is beneficial, then consideration should be given to testing outcomes of the administration of localized versus systemic prophylactic antibiotics. It may be possible that the use of a localized rather than systemic antibiotic 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.

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 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.

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