COMPARATIVE SOFT AND HARD TISSUE RESPONSES TO TITANIUM AND POLYMER HEALING ABUTMENTS

By

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For my wife Cyndi.
ACKNOWLEDGMENTS

I would like to thank Theofilos Koutouzis and Tord Lundgren. They are my mentors and friends. I am a better clinician and person because of their tireless commitment to my education.
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A dental implant at the time of placement is a direct communication from the oral cavity to the alveolar crest. Fortunately, soft tissue components exist that protect the implant structure within the bone. It is known that connective tissue fibers align parallel to the titanium surface circumferentially in order to "seal" the communication of the junctional epithelium from the alveolar crest. To our knowledge there is limited information from human studies assessing the soft tissue interface for abutments with different material composition using clinical outcome measures.

In order to test this hypothesis, sixteen patients were randomly assigned to either the experimental group (PEEK healing abutments) or the control group (Titanium healing abutments). Standard surgical protocols were applied to install Straumann Bone Level implants. Buccal and lingual cortical plate thickness (post-osteotomy) and alveolar ridge thickness (post-implant placement) were measured surgically during implant placement. Other clinical parameters used for comparative analysis were measured at 14 and 90 days postoperatively. They included plaque levels and bleeding on probing at four surfaces as well as probing depth and recession at six sites. In
addition, width of keratinized mucosa around the healing abutment was measured from the three buccal surfaces. Lastly, radiographs were exposed at placement and 90 days postoperatively and subjected to comparative analysis to determine bone loss.

The study was completed after 90 days and patients were referred for final abutment placement and restoration. Results demonstrate statistically significant differences regarding plaque accumulation between test and control groups (20.5% vs. 48.5%) at the two week examination. Secondly, implants of the test group had a significantly higher proportion of sites with probing depths ≤3mm (87.9% vs. 47%) and lower proportion of sites with probing depths 4-5mm (12.1% vs. 48.5%) compared to the control group at fourteen days. No other notable clinical differences were observed between the test polymer abutments and the control titanium abutments.

Findings of the current clinical study utilizing implants temporarily restored with PEEK or titanium healing abutments indicate that PEEK healing abutments do not render an increased risk for marginal bone loss and soft tissue recession during the initial healing period.
CHAPTER 1
INTRODUCTION

Tissue integration to dental implants is a wound healing process that involves several stages of tissue formation and degradation.\textsuperscript{1,2} The establishment of the mucosal barrier around the implant is characterized by the gradual shift from a coagulum to granulation tissue followed by the formation of a barrier epithelium and the maturation of the connective tissue.\textsuperscript{3}

The soft tissue around implants was described in a series of experimental studies.\textsuperscript{4,5,6,7} Thus, the peri-implant mucosa consisted of a 2mm long barrier epithelium and a 1-1.5 mm “connective tissue integration”.\textsuperscript{4} Collagen fibers occurred in large proportions and were mainly aligned in a direction that was parallel to the implant surface. Furthermore, the connective tissue integration zone had a low density of blood vessels and a large number of fibroblasts.\textsuperscript{8}

Additional animal studies\textsuperscript{9} documented that the material used in the abutment portion of the implant was of decisive importance for the quality of the attachment that occurs between the mucosa and the implant. Hence, abutments made of titanium or highly sintered aluminum based ceramic established similar conditions for mucosal healing to the abutment surface and allowed the formation of an attachment that included one epithelial and one connective tissue portion that were about 2 mm and 1-1.5 mm high respectively. On the contrary, at sites where the abutments made of gold alloy or dental porcelain were installed at second stage surgery, no proper attachment seemed to form at the abutment level, but the soft tissue margin receded and bone resorption occurred. The abutment-fixture junction was hereby occasionally exposed and the mucosal ‘seal’ was established to the fixture portion of the implant.
There is limited information from human studies assessing the soft tissue interface for abutments with different material chemistry using clinical outcome measures\textsuperscript{10}. To our knowledge there is limited data evaluating the effect of materials such as polymers that are commonly used for implant provisionalization on the peri-implant soft tissue interface.

The aim of the present study was to comparatively evaluate soft and hard tissue responses to titanium and polymer provisional implant abutments over a three-month period.
CHAPTER 2
BACKGROUND

Indication for Dental Implants in Modern Dentistry

Records of ancient civilizations indicated that dental diseases such as tooth decay and periodontal diseases have affected mankind for thousands of years. As the initial stage in the gastrointestinal cascade of nutritional procurement, the action of teeth set the stage for subsequent enzymatic activity required for breakdown of a food bolus. This bolus travels through the body to be broken down for essential nutrients that all animals require to survive.

Secondly, teeth play an important role in communication. Specifically in the English language, the approximation of the teeth, lips and tongue provide the appropriate phonetic sounds required to annunciate a vast majority of words.

There is history-long evidence of the importance of teeth from an esthetic and interpersonal perspective. In biblical times, written words have expressed the importance and acknowledge concepts of tooth color, evenness, alignment, bilateral symmetry, and completeness. It is with these concepts that the value and appreciation of these attributes are expressed. These very same concepts could not be more exaggerated today.

Dental implants provide a means for the replacement of missing teeth that have surpassed the traditional concepts and drawbacks of removable and fixed partial dentures. Dental implants also allow the restoration and prevention of further breakdown in a severely deteriorated alveolar complex.
History of Root-Form Endosseous Dental Implants

The Glossary of Prosthodontic Terms\textsuperscript{13} defines an implant as a prosthetic device or alloplastic material implanted into the oral tissues beneath the mucosal and/or periosteal layer, and/or within the bone to provide retention and support for a fixed or removable prosthesis. There are several forms of implants that have been used throughout history including transosteal, eposteal and endosteal. With the exception of the endosteal implant, all other types were short-lived and are not considered the standard of care. For the purposes of this discussion, only the endosteal implant will be discussed further.

Endosteal Implants

Endosteal implants include those that approximate the size and form of a tooth root. These are frequently referred to as “endosseous root form implants”. Plates of metal called “blade implants” and metal frameworks designed to fit the mandible with intraosseous components referred to as “ramus frame implants” also fall within the category of endosteal implants; however, as referred to previously, only the endosseous root form implant as we know it today will be discussed further.

A variety of materials have been described to fabricate early dental implants including gold by Maggiolo in 1809, porcelain with roughened lead lining by Harris in 1886, platinum foil covered with lead and soldered with silver by Edmunds in 1889, iridio-platinum soldered with gold by Greenfield in 1909 and rubber pins by Brill in 1936.\textsuperscript{14} Continuing on through the 1900’s, clinicians and engineers continued to study these materials and the body’s reaction to them. Nonetheless, it wasn’t until the 1950’s and 1960’s that the work of Per-Invar Brånemark and his colleagues completed
experiments with bone healing around titanium surfaces, that the most widely used implant in the world today was invented.\textsuperscript{15} To date, there are over 1,300 varieties of endosseous root form implants to choose from in the United States alone.\textsuperscript{16} All varieties are structurally and functionally similar to those invented by Brånemark almost 60 years ago.

**Osseointegration**

In order to provide long term structural support under the masticatory forces in the oral cavity, a dental implant must be inserted carefully and undergo a process termed osseointegration. Osseointegration refers to the direct structural and functional connection between ordered, living bone and the surface of a load-carrying implant.\textsuperscript{17} This definition supports the idea that under proper conditions, there is an absence of connective tissue or any non-bone tissue in the interface between the implant and the bone. However, it is important to note that bone-to-implant contact (BIC) is only expected under light microscopy. Schroeder reports an amorphous, cell-free layer, ranging in width from 20 to 1000nm and composed of glycosaminoglycans and proteoglycans interposed between the bone and the titanium.\textsuperscript{18}

**Implant Design and Surfaces**

The surgical process of implant placement requires initial fixation and lack of macromovement during the initial phases of the development of the implant-bone interface in order to achieve osseointegration. It is important to emphasize that multiple factors play a role in proper integration and long term success of dental implant therapy. These factors include surface topography, thread design, implant material, bone quality, surgical technique and implant loading conditions.\textsuperscript{17} Implant material and surface topography will be discussed in more detail as they are more relevant to this project.
Implant material

Since its biocompatibility was noted by Brånemark in 1982, titanium is the most widely used material to fabricate dental implants in the world. Titanium is a metal that presents low weight, high strength-weight ratio, low modulus of elasticity, excellent corrosion resistance, excellent biocompatibility, and easy shaping and finishing.\textsuperscript{19} Titanium is used as a commercially pure variant (cpTi) or as an alloy. The most common alloy used for dental implants is composed of 90% titanium, 6% aluminum and 4% vanadium.\textsuperscript{20} Although there are many studies that compare the two materials, the alloy is most often used today due to its mechanical advantages of cpTi. The titanium alloy is estimated to be four times stronger than grade-1 cpTi and 2.4 times stronger than grade-3 cpTi.\textsuperscript{21} Due to similar values in BIC and reverse torque, the alloy is often used to decrease complications such as implant fracture.

Surface topography

**Turned surfaces.** The turned or machined surfaces were the most commonly used surfaces in the past. They were machined and only sterilized prior to placement. Although this surface was sometimes referred to as “smooth”, this terminology was not accurate because the machining process left grooves in the titanium surface. The machined implant was used universally until it was proposed that a shift be made from turned implants to purposefully roughened implants.

**Roughened surfaces.** It was observed that the implant surface morphology plays a role in stabilization of the implant (due to friction) and provides more surface area.\textsuperscript{22} This leads to a increased interaction between the surface of the implant and the cellular behavior that initiates osseointegration.\textsuperscript{23} With this in mind, a variety of surface roughening methods were and continue to be developed. The ideal roughness for
optimal bone formation is debatable and in fact, other characteristics such as wettability and free energy have since been studied to understand their role in osseointegration.  

**Peri-Implant Mucosa**

Although dental implants characteristically differ from teeth in multiple perspectives, both entities are secured within the alveolar bone and pass transgingivally (or in the case of implants transmucosally) into the oral cavity. Natural teeth erupt from the alveolar bone through the mucosa and into the oral cavity with a physical barrier or attachment of the epithelium and connective tissue directly to the supracrestal root surface. In healthy cases, this attachment prevents subgingival bacterial invasion beyond the epithelial sulcus. Similar conditions must be replicated in transmucosal dental implant therapy so that a seal is formed between the oral cavity and the alveolar crest that is securing the stability of the implant body. Presumably, a higher quality seal will result in greater longevity of the implant.

**Characteristics of the peri-implant mucosa**

**Anatomy of peri-implant mucosa.** The anatomy of the peri-implant mucosa around a dental implant is widely based on evidence originally obtained from histological experiments in dogs and monkeys.  

The peri-implant mucosa is established during wound healing that occurs subsequent to surgical flap closure at implant placement (or implant uncovering and abutment attachment). It is compositionally similar to the macroscopic gingival complex around teeth including an epithelium and what appears to be a connective tissue “attachment”. Microscopically; however, the cellular composition and orientation are much different.

**Composition and collagen fiber orientation.** Schroeder *et al* in 1981, analyzed the soft tissue around implants placed in monkeys and reported the presence of
“functionally oriented” fibers in the connective tissue.\textsuperscript{26} In agreement with Schroeder, Berglundh \textit{et al} also noted the orientation of the collagen fibers and that they aligned parallel to the surface of the implant as opposed to bundles of fibers that project lateral, coronal, and apical directions from the tooth root.\textsuperscript{4,26} Furthermore, it was also noted in the same article that there was a higher concentration of collagen fibers but fewer fibroblasts and vascular structures compared to the gingival apparatus around a tooth. This was further validated in a dog study by Moon \textit{et al} in 1999, where two zones were described by their distance from the implant surface. The “inner” 40\textmu m zone of connective tissue contained a higher density of fibroblasts and lower volume of fibroblasts than the adjacent outer 160\textmu m zone.\textsuperscript{8} They also suggested that the thin fibroblast-rich barrier next to the titanium surface plays a role in the maintenance of proper seal between the oral environment and the peri-implant bone. It is concluded from the above mentioned studies that the transmucosal attachment that occurs at implants is composed from a 2mm barrier epithelium (that is functionally similar to a junctional epithelium) and a 1-1.5mm connective tissue zone that adheres to and runs a course parallel to the surface of the implant.

\textbf{Biologic width.} Traditionally, the term biologic width refers to the minimum soft tissue dimension around teeth required to maintain the current alveolar bone level and is comprised of approximately 1mm of connective tissue and 1mm of junctional epithelial attachment to the root surface.\textsuperscript{28} First, Berglund and Lindhe tested the hypothesis that a “biologic width” existed around implants.\textsuperscript{27} The invaded what they believed to be the minimum distance between the peri-implant mucosa margin and the alveolar crest in five dogs and observed bone loss in those respective sites compared to
an unchanged control side in each dog. Since the bone loss observed in the test sites was approximately the distance invaded, it was confirmed that there was a minimum “biologic width” around implants. These findings were further confirmed by Cochran et al in 1997, when a similar dimension as described by Berglundh and Lindhe was observed when non-submerged placement of implants resulted in an implant-soft tissue junction that had a physiologic dimension that persisted despite being loaded.

**Effect of materials on peri-implant mucosa**

**Implant surface.** In further attempt to understand the characteristics of the peri-implant mucosa, Abrahamsson in 1996 and 2002 observed the previously described mucosal attachment in multiple implant systems. He concluded that the attachment was the same despite the implant system used (and the their respective surface characteristics) as well as whether or not the implants were submerged.

**Abutment material.** In a continuing effort to identify the factors that affect peri-implant mucosa dimensions, Abrahamsson in 1998 performed a study where the material composition of the transmucosal abutment was tested. Abutments made of aluminum-based sintered ceramic (Al₂O₃), gold and dental porcelain were inserted and tested against titanium abutments. It was observed that the Al₂O₃ allowed for the establishment of a mucosal attachment similar to that which occurred at titanium abutments; however, the gold alloy and dental porcelain provided inferior conditions for mucosal healing and apical repositioning of the bone and soft tissue apparatus occurred until the proper dimension could be re-established on the titanium surface of the implant. This simply exemplifies the decisive importance of the material that is to be chosen for the transmucosal abutment.
Biomedical Application of PEEK

Following confirmation of its biocompatibility two decades ago\textsuperscript{31}, polyaryletherketones (PAEKs) have been increasingly employed as biomaterials for orthopedic, trauma, and spinal implants. Two PAEK polymers, used previously for orthopedic and spinal implants, include poly(aryl-ether-ether-ketone) (PEEK) and poly(aryl-ether-ketone-ether-ketoneketone) (PEKEKK). Numerous studies documenting the successful clinical performance of polyaryletherketone polymers in orthopedic and spinal patients continue to emerge in the literature\textsuperscript{32,33} but very few reports exist about application of PEEK in dental implant therapy.

Evaluation of oral mucosal integration at implant abutments made from PEEK material has not been performed in an animal model. However, several in vitro and animal studies have been performed confirming the biocompatibility of PEEK materials. Williams \textit{et al.}\textsuperscript{31} reported the first animal studies of PEEK in the literature. Neat PEEK and carbon-fiber reinforced samples were subcutaneously implanted in rabbits for 6 months and submuscularly implanted in rats for 30 weeks. Williams stated that PEEK elicited a “minimal response” in both animal models. The growth and attachment of osteoblasts and fibroblasts to PEEK was evaluated by Hunter \textit{et al.}\textsuperscript{34} in a series of cell culture experiments. 450G PEEK resin was employed and Ti alloy, CoCr alloy were used as controls. No significant differences were observed for fibroblast and osteoblast attachment among the various materials evaluated. The results of this study suggested that PEEK did not appear to deleteriously affect osteoblasts and fibroblasts.
CHAPTER 3
MATERIALS AND METHODS

This study was designed as a prospective, randomized, controlled clinical trial. Sixteen patients who had at least one tooth missing posterior to the maxillary or mandibular canine were enrolled in the study.

The following conditions were reasons for excluding a subject from participating in the study: insufficient bone volume at the recipient sites for placement of an implant with a diameter of at least 4.1mm and length of at least 8mm, active infection or severe inflammation in the areas intended for implant placement, uncontrolled diabetes mellitus, hemophilia, metabolic bone disorders, history of renal failure, current chemotherapy and pregnancy, treatment with therapeutic radiation to the head region within the past 12 months, alcohol or drug abuse and smoking of more than 10cig/day.

The study protocol was reviewed and approved by the Institutional Review Board of University of Florida. All subjects received detailed information on the study and signed a written consent before the start of the treatment.

Control of periodontal infection, if applicable, was achieved by an initial treatment phase consisting of scaling and root planing, motivation and oral hygiene instructions. If indicated, supplement mechanical debridement with periodontal surgery was performed. The initial therapy was completed 30–60 days before the time of patient entry into the study.

Patients were randomly assigned to a test or control treatment groups by a computer-generated list. In the test group, following standard placement of the dental implant, a polymer healing abutment (PEEK) was connected to the implant (test n=8). In the control group, following a similar dental implant installation procedure, a titanium
healing abutment was connected to the implant (control n=8). Figure 3-1 illustrates components used for test and control groups. The characteristics of the patients of the test and control groups are given in Table 3-1.

**Implant Treatment**

The implants used in the current study were Straumann Bone Level Implants with a diameter of 4.1mm or 4.8mm and with lengths varying from 8mm to 12mm. The selection of implant type was based on existing bone dimensions. Figure 3-2 illustrates the structural characteristics of Straumann Bone Level Implant system. The surgical treatment performed under local anesthesia and according to manufacturer’s manual by two periodontists (J.R. and T.K.). Immediately following local anesthesia, an endodontic file with a rubber stop was inserted into the buccal mucosa perpendicularly at a point 5mm apical to the crest of the edentulous ridge until bone contact was perceived. The rubber stop was positioned at the mucosal surface and the distance from the rubber stop to the tip of the endodontic file was measured to the lowest half millimeter to determine mucosal thickness (Figure 3-3).

Crestal incisions were used and full thickness flaps were elevated to expose the bone. The recipient sites were enlarged according to the protocol of the manufacturer.

Subsequent to osteotomy preparation, the thickness of buccal and lingual bony plates was measured at a point 2mm apical to the crest of the ridge with a caliper instrument at the lowest half-millimeter (Figure 3-4). Dental implants were installed in the edentulous segments according to patient needs.

Healing abutments, either titanium (Straumann RC Healing Abutment, conical shape D 4.5mm, H 6mm) or polymer (Straumann RC Healing Abutment, customizable, D 7mm,polymer) were placed according to the randomization protocol (Figures 3-5). All
abutments extended transmucosally and remained completely out of occlusion. After abutment installation, the flaps were closed with interrupted sutures. Each patient received 1 g amoxicillin twice daily from the day of the implant surgery for seven days and chlorhexidine 0.12% rinse twice daily for two weeks.

Three months following implant installation the prosthetic treatment was performed according to manufacturer’s manual.

**Clinical Examinations**

At the 2-week and at the 3-month re-examinations, the following clinical parameters were recorded at the implant sites: presence of visible plaque (mesial, distal, buccal and lingual surfaces), probing depth (PD), bleeding on probing (BoP), peri-implant mucosa height (PMH) at six sites of each implant (mesiobuccal, buccal, distobuccal, distolingual, lingual and mesiolingual). Peri-implant mucosa height was recorded as the distance between the peri-implant mucosa margin and the most coronal part of the healing abutment (Figure 3-6). In addition, the width of buccal keratinized mucosa was recorded as the linear distance from the mucosal margin to the mucogingival line (Figure 3-7). All measurements performed with a manual probe (Hu-Friedy PCP 15) to the lowest half-millimeter.

**Examiner Variability**

The two periodontists that performed the surgical procedures also performed all clinical examinations. Each subject was assigned to one examiner. Before the start of the study, the examiners were trained to adequate levels of accuracy and reproducibility for the various clinical parameters to be used. The mean inter-examiner difference between repeated measurements was 0.14 (95% CI -0.02 to 0.3) for PD and 0.08 (95% CI-0.09 to 0.24) for PMH.
Radiographic Examination

Radiographic examinations were performed immediately after the surgical procedure and at the 3-month follow-up visit (Figure 3-8). The periapical radiographs were taken in a standardized manner using a paralleling device (Dentsply Rinn, York, PA, USA) and a digital imaging software system (MIPACS, USA). One periodontist (T.L.) that was not involved in the implant therapy interpreted the radiographs. Measurements of the marginal bone level (distance between the abutment/fixture junction and the marginal bone to implant contact level) were made at the mesial and distal aspects of the implants. All measurements were determined using a magnification (x7) of the images. The radiographs were downloaded as 16-bit, JPEG files and analyzed with an image processing system29 on a laptop computer. The known geometry of each implant was used to assess the distortion of the images. The error of the method used for appraising the measurements on the radiographs was calculated by reassessing 10 randomly selected cases including 40 sites. The mean difference between repeated measurements of the 40 sites was found to be 0.04mm (SD 0.33 mm).

Data Analysis

For description of data, mean values, standard deviations and cumulative frequencies were calculated. The primary outcome variable was the marginal bone level changes from the time of implant installation to the three-month follow-up examination. Fisher’s exact test was used to evaluate differences in frequencies of plaque, bleeding on probing and pocket depth categories between the treatment groups. Differences in changes of peri-implant mucosa height, buccal width of keratinized mucosa and marginal bone levels between the groups were analyzed by using the Student’s t-test.
for unpaired observations. Pearson’s correlation analysis performed with respect to thickness of the bone wall following the osteotomy (buccal and lingual) and changes in peri-implant mucosa height (buccal and lingual) and thickness of buccal mucosa before implant placement and changes of buccal peri-implant mucosa height. In all analysis a p-value of <0.05 was considered to represent a statistically significant difference.
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<td>Gender (male/female)</td>
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<td>4/4</td>
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<tr>
<td>Mean age (SD)</td>
<td>59.1 (12.6)</td>
<td>54.2 (13.6)</td>
</tr>
<tr>
<td>Smokers</td>
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</tr>
<tr>
<td>Number of implants</td>
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Table 3-1. Demographics of patients included in the study. Table indicates number of patients, gender, mean age, number of smokers, and total number of implants placed for each treatment group. There were no statistical differences between group demographics.
Figure 3-1. This figure illustrates two types of healing abutments used in the study. The control group (A) is a standard titanium healing abutment. The experimental group (B) is a PEEK healing abutment. Both components are currently commercially available by the Straumann Company.
Figure 3-2. The structural and thread design of the Straumann Bone Level implant.
Figure 3-3. Measurement of mucosal thickness. Endodontic file with rubber stopper was inserted approximately 5mm from the mucosal margin. A rubber stopper was placed to the tissue. The file was removed and mucosal thickness was measured with a periodontal probe.
Figure 3-4. The thickness of buccal and lingual bony plates was measured at a point 2mm apical to the crest of the ridge with a caliper instrument at the lowest half-millimeter.
Figure 3-5. Healing abutments, either titanium (Straumann RC Healing Abutment, conical shape D 4.5mm, H 6mm) labeled (A & B) or polymer (Straumann RC Healing Abutment, customizable, D 7mm, polymer) labeled (B & C) were placed according to the randomization protocol.
Figure 3-6. Peri-implant mucosa height was recorded as the distance between the peri-implant mucosa margin and the most coronal part of the healing abutment (denoted by blue bracket). This measurement was performed at 6 sites around implant (MB, B, DB, DL, L, ML).
Figure 3-7. The width of buccal keratinized mucosa was recorded as the linear distance from the mucosal margin to the mucogingival line (denoted by the blue bracket). This measurement was performed at DB, B, and MB surfaces.
Figure 3-8. Radiographic examinations were performed immediately after the surgical procedure and at the 3-month follow-up visit. A and B represent PEEK healing abutments at placement and 3 months respectively. C and D represent titanium healing abutments at placement and 3 months respectively.
CHAPTER 4
RESULTS

The distribution of diameter, length and position in the jaw of implants placed in the two groups is illustrated at Figure 4-1. For both test and control groups 5 patients received one implant and three patients received two implants. The results of the clinical measurements are illustrated in Table 4-1 and Table 4-2. There was a statistically significant difference regarding plaque accumulation between test and control groups (20.5 % vs 40.9%) at the 2-week examination. Secondly, the test group implants had a significantly higher proportion of sites with PD ≤3mm (87.9% vs 47%) and a lower proportion of sites with PD 4-5mm (12.1% vs 48.5%) compared to control group at the 2-week examination. There were no significant differences between the two groups regarding plaque, BoP and frequencies of sites with different PD categories at the 3-month examination. No differences were detected between the different groups in changes of peri-implant mucosa height and width of keratinized mucosa from 2 weeks to 3 months.

For the test implants, the mean marginal bone level change at the 3-month follow-up examination was -0.09 (0.2)mm for the mesial site and 0.04 (0.2) mm for the distal site. The corresponding numbers for the control group were -0.21 (0.40) mm and -0.28 (0.75) mm respectively. The mean marginal bone level change calculated with an implant level analysis was -0.02 (0.2)mm for the test group and -0.25(0.4)mm for the control group. There were no statistical significant differences between the two groups.

The cumulative distribution of mesial and distal implant surfaces according to marginal bone level changes at the 3-month follow-up examination is illustrated in
Figure 4-2. None of the implant surfaces in the test group and 10% of the implant surfaces in the control group have marginal bone level reduction ≥1mm.

There were no significant correlations between the thickness of the bone wall following osteotomy preparation (buccal and lingual) and changes in peri-implant mucosa height (buccal and lingual) (r=0.14, p=0.37) nor between thickness of buccal mucosa before implant placement and changes of buccal peri-implant mucosa height (r=0.24, p=0.27).
Table 4-1. Measurements recorded at 2 weeks and 3 months. Frequencies (%) of sites with plaque, BoP, PD≤3mm, 4-5mm and ≥6mm.

<table>
<thead>
<tr>
<th></th>
<th>Test (2 weeks)</th>
<th>Control (2 weeks)</th>
<th>Test (3 months)</th>
<th>Control (3 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque (%)</td>
<td>20.5*</td>
<td>40.9*</td>
<td>18.2</td>
<td>6.8</td>
</tr>
<tr>
<td>BoP (%)</td>
<td>31.8</td>
<td>36.3</td>
<td>4.5</td>
<td>12.1</td>
</tr>
<tr>
<td>PD≤3mm (%)</td>
<td>87.9*</td>
<td>47*</td>
<td>93.9</td>
<td>87.9</td>
</tr>
<tr>
<td>PD4-5mm (%)</td>
<td>12.1*</td>
<td>48.5*</td>
<td>6.1</td>
<td>12.1</td>
</tr>
<tr>
<td>PD≥6mm (%)</td>
<td>0</td>
<td>4.5</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Fisher’s exact test P<0.05 ; Test vs Control at 2 weeks

Table 4-2. Changes in peri-implant mucosa height (M, D, B, L) and width of keratinized mucosa between 2 weeks and 3 months. Mean values and standard deviations are provided.

<table>
<thead>
<tr>
<th></th>
<th>Mesial</th>
<th>Distal</th>
<th>Buccal</th>
<th>Lingual</th>
<th>Keratinized Mucosa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>0.04(0.8)</td>
<td>-0.13(0.8)</td>
<td>-0.09(0.5)</td>
<td>-0.27(0.6)</td>
<td>0.01(0.8)</td>
</tr>
<tr>
<td>Control</td>
<td>-0.13(1.2)</td>
<td>-0.36(0.7)</td>
<td>-0.27(1.0)</td>
<td>-0.18(0.6)</td>
<td>0.24(1.0)</td>
</tr>
</tbody>
</table>

Independent sample T-test, P-value non significant
Figure 4-1. Distribution of implant sizes used for test and control patients is labeled with “A”. Distribution of posterior implant locations in test and control patients is labeled with “B”.
Figure 4-2. The cumulative distribution of mesial and distal implant surfaces according to marginal bone level changes at the 3-month follow-up examination. “A” denotes the mesial bone level changes and “B” denotes the distal bone level changes.
CHAPTER 5
DISCUSSION

The results of the present study failed to demonstrate that the material of the healing abutment (PEEK or titanium) significantly influences soft tissue and bone level changes for the period of 3 months following implant installation.

The soft tissue barrier around dental implants serves as a protective seal between the oral environment and the underlying peri-implant bone. The integration of oral mucosa to implant components of different materials was examined in few studies. Abrahamsson et al.⁹, in an experimental study in dogs, reported that the abutment material was of decisive importance for the quality of the attachment that formed between the mucosa and the implant abutment. While abutments made of aluminum-based ceramic provided conditions for a mucosal attachment that was similar to that of titanium, no proper mucosal attachment was formed to abutments made of gold-alloy and dental porcelain. At such sites, recession of the mucosal margin and bone resorption occurred. Similar findings reported from Welander et al.³⁰ that healing to abutments made of gold-alloy was different than that at ceramic and titanium abutments. Although these studies demonstrate optimal soft tissue healing and dimensions for abutments made from titanium, aluminum-based ceramic and zirconium, they do not provide information regarding abutments made from polymer materials that are very frequently used as healing abutments.

Following confirmation of its biocompatibility two decades ago³¹, polyaryletherketones (PAEKs) have been increasingly employed as biomaterials for orthopedic, trauma, and spinal implants. Two PAEK polymers, used previously for
orthopedic and spinal implants, include poly(aryl-ether-ether-ketone) (PEEK) and poly(aryl-ether-ketone-ether-ketoneketone (PEKEKK). Numerous studies documenting the successful clinical performance of polyaryletherketone polymers in orthopedic and spinal patients continue to emerge in the literature\textsuperscript{32,33} but very few reports exist about application of PEEK in dental implant therapy.

Evaluation of oral mucosal integration at implant abutments made from PEEK material has not been performed in an animal model. However, several in vitro and animal studies have been performed confirming the biocompatibility of PEEK materials. Williams et al.\textsuperscript{31} reported the first animal studies of PEEK in the literature. Neat PEEK and carbon-fiber reinforced samples were subcutaneously implanted in rabbits for 6 months and submuscularly implanted in rats for 30 weeks. Williams stated that PEEK elicited a “minimal response” in both animal models. The growth and attachment of osteoblasts and fibroblasts to PEEK was evaluated by Hunter et al.\textsuperscript{34} in a series of cell culture experiments. 450G PEEK resin was employed and Ti alloy, CoCr alloy were used as controls. No significant differences were observed for fibroblast and osteoblast attachment among the various materials evaluated. The results of this study suggested that PEEK did not appear to deleteriously affect osteoblasts and fibroblasts. The results of our study are in agreement with in vitro and animal reports for PEEK material since no adverse events were experienced by the patients and similar soft tissue and bone responses were observed compared to the titanium healing abutments.

In our study, we observed a statistically significant difference regarding plaque accumulation between PEEK and titanium abutments (20.5 % vs 40.9%) at the 2-week examination. During this period, the patients were instructed to use chlorhexidine 0.12%
rinse twice daily without brushing the operated area. This difference was not expected due to the fact that the abutments made from PEEK material are slightly more rough compared to abutments made from titanium (Sa value 0.4µm for titanium and 0.8µm for PEEK, data given from Straumann). These results are in contrast with the study by Wenneberg et al. They evaluated in a clinical study the amount of plaque collected at titanium abutments with different degree of roughness for a period of four weeks and reported greater amounts of plaque for abutments with rougher surfaces. However, the abutments used in our study have a roughness similar to the ones that Wenneberg et al. used as controls (0.259-0.430µm). The observed difference in plaque accumulation at the 2-week examination can be explained by the possible difference in compliance of the patients using the chlorhexidine rinse and not by the minimal differences in roughness between the abutment materials. It should be noted that no significant differences were observed for plaque accumulation between the two groups at the 3-month examination.

Implants for both groups showed minimal marginal bone loss during the 3-month healing period (-0.02mm test group vs -0.25 mm control group). One limitation of the study is the short follow-up period and one may assume that more bone loss might be expected for longer observational periods. However reports from both clinical and animals studies have shown that the largest amounts of marginal bone loss can take place following the first three months of implant installation with minor changes occurring subsequently. Donati et al. reported that the amount of bone loss using different installation protocols varied from 0.25mm to 0.38mm at one year with the major changes occurring at the first 3 months (0.2mm to 0.33mm). Cooper et al. in a study of
early loading on implants placed with one stage procedure reported that about 0.4mm bone loss occurred during an initial 6-week period, with no further bone level changes at the subsequent 12 months follow-up. Similarly Berglundh et al.\textsuperscript{38} in an animal study reported that the largest amount of bone loss occurred following implant installation and abutment connection with almost no bone level alterations during a 10 month period of functional load.

In conclusion, the findings of the current clinical study utilizing implants temporarily restored with PEEK or titanium healing abutments indicate that PEEK healing abutments do not render an increased risk for marginal bone loss and soft tissue recession during the initial healing period.
LIST OF REFERENCES


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BIOGRAPHICAL SKETCH

Joseph Philip Richardson was born in Lewiston, Maine in 1979. He grew up in Tavares, Florida and attended Wichita State University where he studied Chemistry. He graduated from the University of Florida College of Dentistry with a Doctor of Dental Medicine degree and attended the same institution for his specialty training in Periodontology. Upon graduation in the spring of 2010, he plans to join a private practice in Maitland, Florida and aspires to provide quality health care to all those who are in need.