Prospective Clinical Trial of Survival Rate for Two Different Implant Surfaces Using the Osstem® SS II Non-submerged Implant System in Partially Edentulous Patients

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• Abstract

Objective : This study sought to investigate the clinical survival rate of two implants with different surfaces: resorbable blasting media (RBM)-treated and calcium metaphosphate (CMP)-coated implant.

Study design : SSII non-submerged implants (Osstem, Seoul, Korea) were placed in a total of 48 patients with mean age of 38.8. At least 31 patients in the experimental group had a CMP-coated implant, and 1 patient in the control group received a, RBM surface implant. The evaluation period was between April 2006 and December 2007. Radiographs, periotest, clinical periodontal examination, and prosthetic adjustment and occlusion were used.

Results : The survival rate of the experimental and control groups after 1 year was 97.2% and 100%, respectively. The Wald confidence interval reported for the experimental group was not inferior to the control group.

Conclusion : No significant differences were found between the RBM and CMP groups. The observed data suggest that CMP-coated methods can provide favorable clinical results for the functioning and healing of dental implants.

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Introduction

Ongoing research has shown that the surface morphology of the implant is an important factor in accelerating osseointegration. Titanium implants such as Branemark implants have a smooth machined surface. As the oldest type of implants with known excellent biocompatibility and tissue stability, they have been used most commonly. Note, however, that numerous studies are now exploring the effect of different surface treatments of implants on shortening the healing period. The variables considered in these studies include the type of implants, expansion of the direct contact surface of the implant and bone, surface roughness, and surface treatment methods.

Two different surface treatments for increasing the surface roughness of commercially available implants were performed by either blasting with resorbable blasting media (RBM) or coating with calcium metaphosphate (CMP). The RBM surface treatment creates a rough implant surface by spraying biocompatible materials such as oxidated aluminum (Al₂O₃), oxidated titanium (TiO₂), calcium phosphate, and hydroxyapatite powder to the implant surface. In this study, the clinical survival rate of RBM surface implants was compared to CMP-coated implants after a one-year prospective study.

Materials and Methods

Surgery was performed after the patient provided written informed consent. The protocol was approved by the Institutional Review Board (CDIRB2004-1) at Chosun University Dental Hospital prior to its initiation.

Patient Population and Implants Used

A prospective clinical trial was conducted from April 1, 2006 to December 31, 2007 on the 48 patients who visited the Department of Oral and Maxillofacial Surgery of Chosun University Dental Hospital. The patients selected met all the following exclusion criteria:

1. Pregnancy
2. Disease history or recent episode of myocardial infarction
3. Uncontrolled medical diseases
4. Hemorrhagic disease
5. Psychological diseases or patients suspected to have psychological diseases
6. Allergy to implant materials
7. Ethical reasons for exclusion as determined by the investigators

The patients were divided into two groups based on the type of implant surface treatment; 31 patients were assigned to the experimental group (CMP-coated surface), and 17 patients, to the control group (RBM surface). The experimental group consisted of 16 males and 15 females with mean age of 41.2 years. The control group was made up of 10 males and 7 females with mean age of 34.1 years. The gender distribution of the total population was 26 males and 22 females, and the mean age was 38.8 years (Fig. 1). The assignment of patients to the control group and the experimental group was planned at a 2:1 ratio; every effort was made to assign the subjects without differences in other conditions.

The SSII implants (Osstem, Seoul, Korea) used in this study had an internal 8° morse taper connection and a straight body. It was used for the one-stage procedure. Since the screws of the body are triangular with a 0.8 pitch, early stability can be obtained readily in poor bone-quality cases. In addition, the distribution of the masticatory force was good, hence its usefulness in immediate loading. The roughness of the RBM surface was measured to be 1.2 ~ 1.8 μm. The collar area (1.8/2.8) of the implant was treated to create a machined surface, with surface roughness Ra of 0.1 ~ 0.3 μm.

Length and diameter of implants

The experimental group consisted of 31 patients implanted with SSII implants coated with CMP. A total of 36 implants were placed. The control group included 17 patients, with a...
total of 20 implants placed. The length and diameter of implants used in this study are shown in Table 1.

**Evaluation Methods**

Before surgery, the clinical index of surgery area was assessed, and the surgery area was expressed as dentition. The diameter and length of implants were measured. The bone quality was determined by combining the feeling of the drilling procedure of the surgeon and result of panorama radiographs. The findings were classified into 4 types (Types I~IV).

The evaluation of clinical efficacy was based on multiple factors. One of the most important factors for clinical efficacy was zero implant loss or fracture reported. The clinical examination should reveal that implants that were not connected to each other did not move. On radiographs, clinical efficacy was based on penetration imaging in the vicinity of implants on unmodified radiographs. In the evaluation of prosthesis, compatibility/incompatibility was evaluated using articulating paper (approximately 20 ~ 40㎛ thick, Articulating paper BK09, Bausch, Köln, Germany) and shimstock (approximately 8㎛ thick, Altstätten, Switzerland).

For a total of 9 visits over a 12-month period, the following variables were measured: mobility, bone resorption level on radiographs, presence or absence of abnormal reactions, occlusion condition, and patient satisfaction. The specific time intervals for evaluations are shown in the Table 2. At the follow-up examination, the following evaluation methods were used:

a. **Mobility**: This was measured thrice using a Periotest® (Siemens AG, Bensheim, Germany); the average was used as a final value.

b. **Bone Loss**: The amount of bone loss was evaluated by a single reader. Radiographs of the root apex were taken using a parallel method, with the amount of vertical as well as horizontal bone loss measured.

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**Table 1. Implant length and diameter distribution**

<table>
<thead>
<tr>
<th>D</th>
<th>L</th>
<th>Experimental group</th>
<th>Control group</th>
<th>Experimental group</th>
<th>Control group</th>
<th>Experimental group</th>
<th>Control group</th>
<th>Experimental group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0mm</td>
<td>8.5mm</td>
<td>10.0mm</td>
<td>11.5mm</td>
<td>13.0mm</td>
<td>15.0mm</td>
<td>4.1mm</td>
<td>2</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

**Table 2. Clinical evaluation manual**

<table>
<thead>
<tr>
<th>Number of visits</th>
<th>Observation period*</th>
<th>Observation items &amp; clinical exam. items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>-4 week ~ 0 day</td>
<td>Signature on subject consent, Demographic study, Medical history/Dental history taking, Intra / Extra oral exam., Evaluation of subject suitability, Identification code invest., of subject, Diagnosis impression taking, Panoramic view taking, Clinical index measurement of surgical site</td>
</tr>
<tr>
<td>Visit 2</td>
<td>0 day (base line)</td>
<td>Implant surgery, Clinical index measurement of surgical site, Mobility check, Allergy reaction check</td>
</tr>
<tr>
<td>Visit 3</td>
<td>2 week ± 1 week</td>
<td>Stitch out, Standard view taking, Preliminary impression taking, Allergy reaction check</td>
</tr>
<tr>
<td>Visit 4</td>
<td>13 week ± 2 week (Max.)</td>
<td>7 week ± 2 week (Man.)</td>
</tr>
<tr>
<td>Visit 5</td>
<td>26 week ± 2 week (Max.)</td>
<td>14 week ± 2 week (Man.)</td>
</tr>
<tr>
<td>Visit 6</td>
<td>27 week ± 2 week (Max.)</td>
<td>15 week ± 2 week (Man.)</td>
</tr>
<tr>
<td>Visit 7</td>
<td>28 week ± 2 week (Max.)</td>
<td>16 week ± 2 week (Man.)</td>
</tr>
<tr>
<td>Visit 8</td>
<td>9 month ± 4 week (Max.)</td>
<td>6 month ± 4 week (Man.)</td>
</tr>
<tr>
<td>Visit 9</td>
<td>9 month ± 4 week (Man.)</td>
<td>Mobility check, Standard view taking, Allergy reaction check</td>
</tr>
</tbody>
</table>

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Su-Gwan Kim et al. Prospective Clinical Trial of Survival Rate for Two Different Implant Surfaces Using the Osstem® SS Non-submerged Implant System in Partially Edentulous Patients.
c. Occlusion: The evaluation of the occlusal condition after prosthesis was performed at the 7th visit immediately after the placement of the upper structure of the implant (prosthesis). Articulating paper (approximately 20 ~ 40µm thick) and shimstock (approximately 8µm thick) were used for the evaluation of occlusion.

d. Abnormal Finding/Reactions: The incidence of abnormal findings such as hemorrhage, subcutaneous hemorrhage, edema, blood clots, infection, hyperplastic gingivitis, fistula formation, invasions of maxillary and nasal sinus, invasions of mandibular canal, and mental foramen were recorded. Incidence of abnormal reactions such as inflammation in the soft tissue in the vicinity of implants, excessive resorption of marginal alveolar bone, destruction of abutment and other accessories, destruction of implant body as well as prosthesis, mandibular fracture, dysesthesia, and pain and failure of the oral hygiene maintenance were also recorded.

e. Patient Satisfaction: On the last visit, a questionnaire on patient satisfaction as developed by the patients was administered. It addressed five areas of concern: occlusal function, pain, discomfort, dysesthesia, and inflammation.

Statistical Analysis

The survival rate of each group was estimated using the maximum likelihood estimator (MLE). To determine the confidence interval of the survival rate, the likelihood-ratio confidence interval was used. The Wald confidence interval and the likelihood-ratio confidence interval were reported as the confidence interval of the difference of the survival rate of the two groups, and their significance was determined.

Results

Mobility level according to bone quality

Mobility levels for both groups on the day of surgery was type III and type IV, which suggested that early fixation was not indicated. Note, however, that the final evaluation of the mobility level on all cases showed decreased mobility level with the exception of implants placed in type V bone. This observation suggested that good osseointegration was achieved (Figs. 2, 3).

Mobility level

The difference in mobility level between groups was not statistically significant. Note, however, that the mobility value in the experimental group was smaller than that of the control group. As the observation period spanned 12 months, the mobility level continually decreased compared to the findings reported for the first evaluation (Table 3).

Volume of bone loss

A statistically significant volume of bone loss was not observed in both the control group and the experimental group.
Survival rate

The survival rate of the experimental group was 97.2% (95% CI: 91.7 ~ 99.5%), and that of the control group was 100% (94.8 ~ 100%). In the non-inferiority evaluation, by applying the Wald confidence interval, the lower value of the one-tail 95% confidence interval of the difference in survival rate between the groups (survival rate of the experimental group-survival rate of the control group) resulted in a value of -0.0597. In other words, the lower limit of the 95% Wald one-tail confidence interval was larger than the non-inferiority standard of -0.1. Thus, in the comparison of the control group and the experimental group, such was considered to be statistically non-inferior.

On the other hand, the estimation of the survival rate of the experimental group was 0.9722 or close to 1. The survival rate of the control group was estimated to be 1. In such cases, the likelihood ratio confidence interval may be more appropriate than the Wald confidence interval. The result of the lower limit of the one-tail 95% confidence interval using the likelihood ratio confidence interval was -0.0462; this value was also larger than -0.1 as the standard of non-inferiority. As such, in comparing the experimental group with the control group, the result was statistically non-inferior.

In the comparison of the survival rate of each group according to bone quality (excluding type IV), in Types I ~ III bone, the survival rate of the two groups was estimated to be 100%. Thus, the confidence interval of the difference in the survival rate between the two groups could not be estimated. Nonetheless, this observation suggested that the survival rate of both groups was comparable. In Type IV bone, however, the survival rate of the experimental group was estimated to be 0% (95% confidence interval: 0.0 ~ 61.7%). The survival rate of the control group was estimated to be 100% (95% confidence interval: 61.9 ~ 100%), with a borderline significant difference in the survival rate between the two groups observed.

Discussion

Modifications of implant surface such as coatings with hydroxyapatite, acid etching, blasting, and sandblasting with larger-grit followed by acid etching (SLA) have been used to increase the surface roughness of commercially available implants. Nonetheless, there are equivocal reports on the effect of these modifications on osseointegration and the success rates. In a rabbit femur study, Piattelli, et al observed more osteoblasts and mature bones attached to the implants with RBM-treated surface compared to smooth implants 8 weeks after implantation. Recently, CPM-coated implants have been gaining popularity because of its chemical similarity to bone. Moreover, the degradation byproduct in the biological environments is in the form of fibers or porous rods.
CMP has the chemical structure \([\text{Ca(PO}_3\text{)}_2\text{]}\), and its molar ratio of calcium and phosphate is approximately 0.5. Coating commercially pure titanium with inorganic CMP polymers has been previously reported to be a good candidate technique for improving bone-to-implant osseointegration\(^\text{15}\). Yang\(^\text{16}\) reported that the addition of a thin layer of calcium phosphate coating to the implant surface promoted accelerated bone healing around porous-surface implants even after only 2 weeks of initial healing. Lee, et al\(^{19}\) demonstrated the potential for using a porous CMP matrix as a biodegradable scaffold in vitro along with attached marrow-derived mesenchymal cells for transplantation into a site for bone regeneration in vivo. Experimentally, El Sayegh, et al\(^{14}\) demonstrated that human gingival fibroblasts could attach to and spread on CMP. Using a rabbit tibia model, Yeo, et al\(^{17}\) concluded that there were no significant differences in early bone response to calcium metaphosphate-coated, anodic-oxidized, hydroxyapatite particle-blasted, and turned (control) implant surfaces; thus suggesting that various surface modification methods can provide favorable bone responses for the early functioning and healing of dental implants. Together with the surface characteristic of implants, bone quality in the area of implant placement is also a very important factor in achieving good osseointegration. Lekholm and Zarb\(^{19}\) classified the bone quality of jaws into 4 grades (from I to IV); this classification method has been commonly used for the classification of bone quality in clinics. Some investigators\(^{20,21}\) reported a major correlation between the implant success rate and bone quality, with high implant failure rate in cases wherein implants were placed in type IV bone consisting primarily of cancellous bone. Jaffin and Berman\(^{22}\) reported that Branemark implants placed in type I ~ III bones showed a 97% success rate, whereas implants placed in type IV bone showed a 65% success rate. In other words, bone quality is the most important factor in determining the failure of implants. In addition, Hutton, et al\(^{20}\) reported that implants placed in type I ~ III bones showed a 91% success rate, whereas implants placed in type IV bones showed a 55% success rate. Similarly, Goodacre, et al\(^{22}\) and Bryant\(^{23}\) reported high implant failures in type IV bones. Other bone volumes and bone quality-mediated adverse effects on the stability of implants. Such studies provide evidences on the importance of bone quality in the success of implant. These studies also suggest that placing implants in jaws with good bone quality enables obtaining a high success rate regardless of the type of implants. In this study, the survival rate of both groups studied was highest for type II bone (66.1%), followed by type III bone (25.0%), type IV bone (5.4%), and finally type I bone (1.8%). In addition, in cases excluding type I and type II bone quality at the final evaluation, a reduced level of mobility was observed.

In this study, no significant differences in implant success were found between the RBM and calcium metaphosphate coated groups. The data observed in this study suggested that CMP surface modification methods can provide favorable clinical results for the functioning and healing of dental implants.

References

References


