Stability Development of Immediately Loaded Hybrid Self-Tapping Implants Inserted in the Posterior Maxilla: 1-Year Results of a Randomized Controlled Trial

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The objective of the present study was to elucidate stability development of immediately loaded hybrid self-tapping implants inserted in the posterior maxilla. Forty-eight hybrid self-tapping implants with a chemically modified surface (Ø4.1; length: 8 mm) were inserted bilaterally in the maxillary first and second premolar and first molar sites of 8 patients. In each patient, both sides of the maxilla were assigned randomly to either immediate (IL) or early (EL) loading group. Implant stability was evaluated by means of resonance frequency analysis immediately after implant placement and after 1, 2, 3, 4, 5, 6, 12, 26, and 52 weeks. High values of primary stability were found in both groups (71.91 ± 6.52 implant stability quotient [ISQ] in IL group; 73.87 ± 6.5 ISQ in EL group), with significant differences between the groups at the different time points. Initial decrease in stability was observed between the first and fifth weeks in the IL group and between the first and third weeks for the EL group. In the IL group 1 implant was removed after 3 weeks due to lack of stability. Early results of this study showed the ability of hybrid self-tapping dental implants with a chemically modified surface to achieve sufficient primary stability and to maintain high values of secondary implant stability in bone type 3 and 4, even when loaded immediately. Minimal alterations in stability were observed for both investigated groups, but the EL group showed faster recovery after an initial drop in stability.

Key Words: implant stability, hybrid self-tapping dental implants, immediate loading, posterior maxilla

INTRODUCTION

Dental implants are considered the standard of care procedure for replacement of lost teeth due to different pathologies (e.g., periodontal disease, caries, endodontic complications) and trauma. Over the last few decades, clinicians have begun to explore the possibilities of shortening treatment time, resulting in the introduction of early and even immediate loading protocols. A number of studies have shown similar survival rates for immediate and early loading as compared with standard loading protocols.1 The posterior maxilla, however, remains a challenging region, due to frequently reduced residual alveolar ridge dimensions and predominant bone types 3 or 4. This may result in lower primary stability, possible micromotion, and an increased chance of fibrous encapsulation of the implant with resultant failure, especially if implants are immediately loaded.2 A prerequisite for implant success is stability at the time of insertion (primary or mechanical stability) and successful osseointegration at time of loading the implant (secondary or biological stability).3 Primary stability of dental implants has been shown to be mechanical in nature, whereas secondary stability occurs through the process of healing and remodelling of bone.4 Assessment of implant stability may be done in various ways, but resonance frequency analysis (RFA) has been shown to be the most accurate.5 RFA was introduced in the 1990s and since then it has become the most widely accepted and used technique.6

Attempts to enhance primary stability by modification of macro- and micro-implant design have been introduced through the years. Hybrid self-tapping implants were introduced by Straumann primarily for use in an immediate implantation protocol. This type of macro-design induces controlled compressive forces in the cortical bone after installation, combining the characteristics of a tapered implant with those of a cylindrical shape. Self-tapping threads further enhance primary stability by increasing the surface area of the implant. This engages the surrounding bone to a greater extent. Five-year follow-up results of immediate loaded implants showed successful use of hybrid self-tapping implants in the posterior mandible.7 A recent study showed that this

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type of implant may achieve sufficient primary stability and subsequent successful osseointegration even in type 4 bone.8

Implant micro-design improvement, such as chemical surface modification with sandblasting and acid etching, also has been introduced to reduce the osseointegration time and enhance bone-to-implant contact. Research has shown that surface modification may lead to successful loading in as little as 3 weeks after placement.9–11

There is a need for more evidence about the outcome of immediately loaded implants in the posterior region of the maxilla as this is a frequent request from patients. This prospective split-mouth randomized controlled clinical study investigated the stability of immediately and early loaded hybrid self-tapping implants with a chemically modified surface.

The hypothesis was that implants with modified macro- and micro-design can achieve sufficient primary stability in type 3 and 4 bone and maintain secondary stability in an immediate loading protocol. The main objectives were to monitor and compare stability changes of immediate and early loaded implants and to analyze how primary stability may affect post-healing stability.

**MATERIALS AND METHODS**

**Patients**

The present study was carried out in accordance with the Declaration of Helsinki and approved by the Ethics committee of the School of Dental Medicine, University of Belgrade, Serbia. Eight patients were included in the study and signed informed consent. Patients, with bilateral posterior edentulism in the maxilla, requesting fixed reconstructions, were included in this study. All patients met the following inclusion criteria:

1. Edentulism class IV in the maxilla (Kennedy classification) with enough bone for the placement of 3 implants posterior to the canine;
2. Healed extraction sites of at least 4 months;
3. No known systemic diseases;
4. Bilateral identical opposing dentition (natural or prosthetic reconstruction) in the mandible.

Exclusion criteria:

1. Systemic conditions that could compromise successful implant therapy;
2. Any pathology in the site of the planned implant;
3. Any previous bone buildup in the site of the planned implant;
4. Oral parafunctions (bruxism);
5. Heavy smokers (≥10 cigarettes/d).

The 2 sides of the maxilla were randomly allocated to either immediate loading (IL) as a test group or early loading (EL) as a control group.

**Pretreatment, surgical procedures, and postoperative treatment**

Between October 2009 and February 2012, 8 patients were treated with 48 implants. All procedures were performed in the Oral Surgery Clinic, University of Belgrade. Initially, a full and comprehensive history was recorded and meticulous clinical and radiographic examinations done. Surgical and prosthetic guides were fabricated preoperatively, according to the diagnostic wax-ups. Scaling and root planing was done where indicated and patients were instructed in plaque control measures.

Surgical procedures were performed with local anaesthesia (Ubistesin, 3M Espe AG, Seefeld, Germany) under aseptic conditions in an outpatient environment. A midcrest incision, with buccal releasing incisions, was performed in both areas. After flap elevation, osteotomies were prepared using surgical stents and in accordance with the recommended protocol. Each patient received 6 implants in total (split-mouth design) in the first and second premolar and first molar sites (Figure 1). All implants were of identical diameter and length (Straumann TE, Ø4.1; length 8 mm; SLActive, Straumann AG, Basel, Switzerland). Tension-free flap adaptation allowing for transmucosal healing was obtained in both sides, and the flaps were sutured with 4–0 monofilament sutures (Resorba Medical GmbH, Nuremberg, Germany). Impressions were taken using custom trays, with sterile impression material (Elite implant, Zhermack SpA, Italy).

Patients received antimicrobial therapy (amoxicillin, 1000 mg, 2 times a day), and analgesics (ibuprofen, 400 mg, 3 times a day) for 4 to 5 days. Postoperative oedema was controlled through 2 intramuscular injections of corticosteroids (dexamethasone, 4 mg, 1 hour pre- and 8 hours postoperatively). Patients were placed on a soft diet for 4 weeks postoperatively. A 0.2% chlorhexidine digluconate rinse was prescribed twice a day (Curasept 220, Curaprox, Switzerland). Sutures were removed after 7 to 10 days.

**Prosthetic procedures**

The implants of the test group were restored by screw-retained provisional acrylic fixed dental prostheses (FDPs) within 24 hours after surgery. In the control group, healing abutments were removed from the implants after 3 weeks, and identical provisional FDPs were placed. After 1 year, provisional prostheses were replaced by permanent FDPs. All prostheses were checked for adequate occlusal contacts and physiological lateral and protrusive movement.
Resonance frequency analysis

RFA measurements (Osstell Mentor; Integration Diagnostics AB, Sävedalen, Sweden) were taken to determine the implant stability in both groups. Measurements were taken immediately after implant insertion and again after 1, 2, 3, 4, 5, 6, 12, 26, and 52 weeks. A magnetic peg (Smartpeg; Integration Diagnostics AB, Sävedalen, Sweden) was attached to each implant, and RFA measurements were done according to manufacturer’s protocol. Measurements were taken from 2 different directions (buccal and palatal) and in case of different readings, mean values were calculated. The provisional prosthesis was removed to allow access to each implant.

Statistical analysis

Statistical analysis was carried out with SPSS 20.0 (SPSS Inc, Chicago, Ill). Demographic data were analysed by descriptive statistical method. The patient was chosen as a statistical unit of observation. The average stability values of 3 installed implants on the same side of maxilla were calculated and used in further analysis. Changes in implant stability within groups during the observation time period were tested for significance by Friedman’s two-way ANOVA, followed by Wilcoxon signed-rank post hoc test, with Holm–Bonferroni correction. Comparison of implant stability changes over the observation time period between investigated groups was performed by Wilcoxon signed-rank test. The critical P value of statistical significance was set to .05.

RESULTS

A total of 8 eligible adult patients (5 men; 3 women; average age at time of surgery: 54.38 ± 8.59 years; range: 38–64 years) received 48 implants. One implant inserted in a position of first premolar (IL group) was removed after 3 weeks due to instability, despite that this implant achieved good primary stability (72 ISQ). This resulted in a survival rate of 95.83% during the observational period for the IL group, compared with 100% for the EL group.

<table>
<thead>
<tr>
<th>Time</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>73.87</td>
<td>6.50</td>
<td>75</td>
<td>66.3</td>
<td>85.0</td>
<td>68.34–79.31</td>
</tr>
<tr>
<td>1st week</td>
<td>72.22</td>
<td>5.11</td>
<td>74</td>
<td>65.3</td>
<td>77.0</td>
<td>68.38–75.78</td>
</tr>
<tr>
<td>2nd week</td>
<td>72.08</td>
<td>4.42</td>
<td>75</td>
<td>65.0</td>
<td>76.0</td>
<td>68.39–75.78</td>
</tr>
<tr>
<td>3rd week</td>
<td>72.04</td>
<td>4.57</td>
<td>73</td>
<td>63.3</td>
<td>76.6</td>
<td>68.21–75.86</td>
</tr>
<tr>
<td>4th week</td>
<td>72.02</td>
<td>5.19</td>
<td>72</td>
<td>63.7</td>
<td>76.4</td>
<td>67.68–76.36</td>
</tr>
<tr>
<td>5th week</td>
<td>73.64</td>
<td>5.26</td>
<td>74</td>
<td>63.7</td>
<td>80.3</td>
<td>69.24–78.04</td>
</tr>
<tr>
<td>6th week</td>
<td>75.27</td>
<td>5.34</td>
<td>76</td>
<td>65.3</td>
<td>82.7</td>
<td>70.80–79.74</td>
</tr>
<tr>
<td>12th week</td>
<td>77.35</td>
<td>4.87</td>
<td>78</td>
<td>69.3</td>
<td>83.0</td>
<td>73.28–81.43</td>
</tr>
<tr>
<td>26th week</td>
<td>79.29</td>
<td>5.64</td>
<td>80</td>
<td>69.7</td>
<td>87.7</td>
<td>74.58–84.00</td>
</tr>
<tr>
<td>52nd week</td>
<td>79.79</td>
<td>5.29</td>
<td>81</td>
<td>71.0</td>
<td>87.7</td>
<td>75.37–84.21</td>
</tr>
</tbody>
</table>

*IL indicates immediately loaded implants; ISQ, implant stability quotient; SD, standard deviation; CI, confidence interval.

Implant stability in IL group

At the time of implant insertion, the mean ISQ value was 73.87 ± 6.5, which indicated high primary implant stability for the IL group (Table 1). Subsequently, a decrease of stability was observed after the first week, which continued until the end of the fourth week. Implant stability values from the fifth to the 26th week showed a significant gradual increase for the consecutive time points, with no significant differences between the 26th and 52nd weeks. A significant increase in stability was observed at the 26th and 52nd weeks, compared with baseline values (Figure 1).

Implant stability in EL group

In the EL group, the mean baseline ISQ value was 71.91 ± 6.52, demonstrating high primary stability (Table 2). Initial decrease in stability was observed from the first to the third week, with no significance in comparison with the baseline. Afterward, steady increase in stability was observed from the fourth week, with significance at the sixth, 12th, 26th, and 52nd weeks, respectively, compared with baseline. A significant gradual increase was observed among consecutive time points from the fourth to 26th weeks. Implant stability did not differ significantly between the 26th and 52nd weeks (Figure 2).

Comparisons of implant stability between the groups

When implant stability values were compared between investigated groups a significantly greater increase in implant stability was observed in EL group at the fourth, fifth, sixth, 12th, 26th, and 52nd weeks, respectively, in comparison with IL group (Figure 3).

DISCUSSION

In the available literature, very few randomized controlled trials could be found that evaluated immediately loaded implants with chemical surface modification. The aim of the present study was to evaluate stability changes of hybrid self-tapping implants with chemical surface modification, inserted in the posterior maxilla and loaded immediately. The intentions were...
to decrease, as much as possible, the risk of bias and establish a standardized investigation protocol. All implants were of the same diameter, length, and macro- and micro-design, and were inserted bilaterally under the same conditions during 1 procedure (split-mouth design). The small sample size in this study (8 patients; 48 implants) was due to the very strict inclusion criteria. It turned out that a small number of patients met those criteria.

It is well known that mechanical and biologic aspects of implant stability vary during implant healing. At the time of surgical implant placement, the stability is mechanical only. During the healing period, mechanical stability decreases, whereas biologic stability increases.\(^1\)\(^3\) According to previous research, overall implant stability should increase during the healing process.\(^1\)\(^4\),\(^1\)\(^5\) One study showed marked increase in secondary stability for implants with low initial primary stability (ISQ \(< 68\)), whereas implants with high initial primary stability (ISQ \(> 72\)) lost some stability over time.\(^1\)\(^6\) Balshi et al found similar evidence in their assessment of immediately loaded implants in the maxilla and mandible.\(^1\)\(^7\) Hence, it can be concluded that the most important factor in overall implant stability is primary stability.\(^1\)\(^3\) Implants in the present study achieved high primary stability values and yet, after initial decrease in both groups, an increase was observed over time contrary to the aforementioned studies.

Immediate or early loaded implants may present with a different stability curve due to functional loading during the healing period.\(^1\)\(^8\) Where a rapid decrease in mechanical stability is found, in the presence of a slow increase in secondary stability, a transient decrease in overall stability may be seen. This phenomenon has been termed a dip/drop or gap in stability,\(^1\)\(^9\),\(^2\)\(^0\) and may have a major role in failure of immediate or early loaded implants. More precisely, if the implant stability drops below a certain level during the healing period, the loaded implant may become mobile and eventually fail.\(^1\)\(^6\) Some studies have identified this dip in

**Table 2**

Descriptive statistics of implant stability in EL group*

<table>
<thead>
<tr>
<th>Time</th>
<th>ISQ Descriptive Statistics</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Baseline</td>
<td>71.91</td>
<td>6.52</td>
</tr>
<tr>
<td>1st week</td>
<td>71.29</td>
<td>6.55</td>
</tr>
<tr>
<td>2nd week</td>
<td>70.88</td>
<td>6.74</td>
</tr>
<tr>
<td>3rd week</td>
<td>71.50</td>
<td>6.66</td>
</tr>
<tr>
<td>4th week</td>
<td>72.79</td>
<td>6.18</td>
</tr>
<tr>
<td>5th week</td>
<td>73.64</td>
<td>6.26</td>
</tr>
<tr>
<td>6th week</td>
<td>75.66</td>
<td>6.40</td>
</tr>
<tr>
<td>12th week</td>
<td>77.35</td>
<td>6.61</td>
</tr>
<tr>
<td>26th week</td>
<td>79.58</td>
<td>6.62</td>
</tr>
<tr>
<td>52nd week</td>
<td>80.33</td>
<td>5.52</td>
</tr>
</tbody>
</table>

*EL indicates early-loaded implants; ISQ, implant stability quotient; SD, standard deviation; CI, confidence interval.

**Figure 2.** Implant stability changes (ISQ) in IL group during 52 weeks observation period. Line represents mean; error bars represent standard deviation. Crosses indicate a statistically significant difference in comparison with primary stability values (*\(P = .017\), **\(P = .012\)). Asterisks indicate a statistically significant difference between 2 consecutive weeks (*\(P = .011\), **\(P = .012\), ***\(P = .034\), ****\(P = .012\)).

**Figure 3.** Implant stability changes (ISQ) in EL group during 52 weeks observation period. Line represents mean; error bars represent standard deviation. Crosses indicate a statistically significant difference in comparison with primary stability values (*\(P = .018\), **\(P = .012\), ***\(P = .011\), ****\(P = .012\)). Asterisks indicate a statistically significant difference between 2 consecutive weeks (*\(P = .012\), **\(P = .012\), ***\(P = .012\), ****\(P = .011\), *****\(P = .018\).
surprisingly high values of primary stability (73.87 ± 6.5 ISQ IL group; 71.91 ± 6.52 EL group). This might be due to the hybrid macro-design of the implants used in this study, which combines advantages of conical and cylindrical shaped implants.

In the present study, only one implant in the IL group failed, resulting in survival rates of 95.83% and 100% for IL and EL groups respectively. Decrease in stability of the failing implant started after the first week, from an initial 72 ISQ to 55 ISQ prior to its removal in week 3. No explanation for this failure could be found.

In conclusion, hybrid self-tapping dental implants with a chemically modified surface showed sufficient primary implant stability in the posterior maxilla, with very high overall success rates. Statistical significant differences were found in implant stability during healing between the IL and EL groups, yet minimal alterations in stability were observed. The dip in stability was evident in both groups, but the subsequent increase in stability was seen earlier in the EL group than in the IL group.

**ABBREVIATIONS**

EL: early loading  
FDP: fixed dental prostheses  
IL: immediate loading  
RFA: resonance frequency analysis

**ACKNOWLEDGMENTS**

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