# A Comparative Study of Crestal Bone Loss and Implant Stability between Osteotome and Conventional Implant Insertion Techniques: A Randomized Controlled Clinical Trial Study

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#### ABSTRACT

*Purpose:* The aim of this prospective randomized controlled clinical study was to assess the crestal bone loss and the implant stability in implants that were placed by the osteotome technique compared with the conventional drilling technique.

*Materials and Methods:* Forty-six screw type Straumann SLA® oral implants (Straumann AG, Waldenburg, Switzerland) were inserted in the anterior segment of maxilla of 30 patients. The implant site was prepared randomly using either osteotome technique (test group) or the conventional drilling technique (control group). Radio frequency analysis (RFA) values at implant placement and after 3 months were recorded. The crestal bone loss was measured using digital subtraction radiography technique after 3, 6, and 12 months.

*Results:* RFA demonstrated a statistically significant higher primary stability for implants in the osteotome group than that of the conventional group (p = .026) at the time of implant insertion. However, there was no statistically significant difference between both groups 3 months after the surgery (p = .06). At month 3, the osteotome group caused significantly more crestal bone loss than the conventional group (p = .04). At months 6 and 12, both groups had comparable bone levels (p = .29).

*Conclusion:* Osteotome technique yielded higher primary stability than conventional drilling technique. However, this technique was not superior to conventional technique after 3 months.

KEY WORDS: drilling technique, implant stability, marginal bone loss, osteotome technique, RFA

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## INTRODUCTION

Nowadays, dental implants are widely used for replacing missing teeth. Although success and survival of dental implants are considered high,<sup>1</sup> there are still cases of failure. The success of dental implants depends on several factors including bone quality, bone quantity, and degree of surgical trauma.<sup>2,3</sup> The bone quality in the maxilla is less favorable than in the mandible and it generally is classified as type III or IV.<sup>3</sup> In addition, the cortical bone is thin or completely absent and spiny ridge areas are common in maxilla.<sup>4</sup> Inadequate quantity and low

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quality of bone is a challenge in achieving primary stability, which could be important for successful osseointegration.<sup>5</sup> Attempts to improve primary stability have led to changes in implant design and modification of implant placement protocol. Drilling technique as a conventional method for dental implant placement has several drawbacks, such as heat generation, which is a major problem in osseointegration, and also sacrificing bone, which worsens the situation in low-density bone. Accordingly, several studies were conducted to introduce alternative methods that could improve primary implant stability that appears to be an important aspect for osseointegration.<sup>6-8</sup> Osteotome technique is one of the alternatives, which was introduced by Summer for implant placement in low-density bone, particularly in the maxilla. This technique aims to maintain the existing bone by compressing trabecular bone laterally and apically with minimal trauma, which leads to improved bone density.8 Probable increase in primary stability might be expected through the osteotome technique, which theoretically is believed to improve final healing. The osteotome technique also helps to improve the esthetic result by recontouring the alveolar ridge in the labial aspect especially in the maxillary incisor region.<sup>9-11</sup> On the other hand, although alveolar ridge expansion is achieved by the osteotome technique, the pressure exerted on the crestal cortical bone could theoretically cause peri-implant marginal bone loss.<sup>12,13</sup>

Primary and secondary implant stability and periimplant bone loss are decisive factors for evaluation of implant success.<sup>14–18</sup> Implant stability can be measured by resonance frequency analysis (RFA), which is a noninvasive and reproducible method. This technique is based on measuring the resonance frequency of a small transducer to an implant and presents data as numeric value termed "implant stability quotient (ISQ)."<sup>19–29</sup> Peri-implant bone loss can be determined by subtractive digital radiography, which overcomes some limitations of conventional radiographs such as the methodological difficulties in obtaining standardized and reproducible radiographs, inaccessibility of the labial, lingual or palatal aspects, and also eccentric beam guiding.<sup>12,30</sup>

The osteotome technique has been well established in the clinical practice.<sup>10,11</sup> However, until recently, only few studies have been carried out to evaluate the efficacy of the osteotome technique. Cehreli and colleagues showed that conventional techniques resulted in higher implant primary stability than the osteotome technique.<sup>16</sup> In addition, Büchter and colleagues reported that the osteotome technique caused negative effects on bone-implant contact (BiC) ratio in the early phase of osseointegration.<sup>17</sup> Nevertheless, Nkenke and colleagues demonstrated that the osteotome technique intensified BiC ratio in the early phase after implant placement and resulted in an improved osseointegration of dental implants in trabecular bone.<sup>7</sup> Therefore, the available data are contrasting and do not present an obvious answer on the efficacy of the osteotome technique. Moreover, these studies are not clinical studies and the results could not be extrapolated to the actual human clinical situation. Shalabi and colleagues conducted a metaanalysis to review limited clinical studies that had used the osteotome technique for implant placement. They reported that there was no randomized controlled trial available in the literature on the osteotome technique.<sup>31</sup> Accordingly, the aim of this prospective randomized controlled clinical study was to compare implant stability and crestal bone loss around implants inserted by the osteotome technique and conventional drilling technique. The null hypothesis was that there would be no difference in implant stability and bone loss between two surgical techniques. The implant stability was assessed using RFA and crestal bone loss measured radiographically by digital subtraction radiography technique.

# MATERIALS AND METHODS

## Calculation of Sample Size

A power calculation was performed to determine the sample size. The implant was considered as the statistical unit. It was calculated that 23 implants per group would provide 80% power to recognize a significant difference of 1.5 mm between test and control, using crestal bone loss as the primary outcome variable. Therefore, a sample size of 23 test and 23 control implants were recruited.

## **Patient Selection**

Thirty consecutively recruited patients (18 women and 12 men), ranging from 21 to 61 (mean 40.5 years) who were in need of 46 fixed implant-supported crowns in the anterior segment of the maxilla (Table 1) were included in this study. They were recruited from the pool of the Department of Implantology, Faculty of Dentistry, Tehran University of Medical Sciences, Iran. Patients were excluded if they had any medical condition contraindicating elective oral surgery interventions.

TABLE 1 Distribution of Teeth per Experimental Group							
Tooth Number	#6	#7	#8	#9	#10	#11	
Osteotome technique	3	4	4	6	3	3	
Conventional technique	3	4	4	1	5	5	
Total	6	8	8	7	8	8	

Patients with signs of parafunctional habits, untreated periodontal disease, smokes cigarettes (more than 10 cigarettes/day), have type I and type IV bone, and are pregnant or lactating were also excluded from the study. Furthermore, all participants had to meet the following inclusion criteria: good oral hygiene, bone division A (abundant bone; width and height more than 6 and 12 mm, respectively),<sup>32</sup> and mutually protected occlusion.

After explaining the study clearly, all participants gave their informed consent. The study was performed according to the principles outlined in the Declaration of Helsinki on experimentation involving human subjects. The university's Clinical Research Ethics Board approved the research protocol, including recruitment procedures, exclusion/inclusion criteria, and the informed consent.

### Study Design

The study was conducted as a randomized controlled clinical trial using a double-blind design to prospectively assess crestal bone loss and implant stability in implants were placed by osteotome technique (test group) or conventional drilling technique (control group). Subjects were allocated to the test or to the control group according to the predefined computer-generated randomization table. Clinical evaluation of implant stability was performed using RFA. Crestal bone loss was measured radiographically using digital subtraction radiography technique (Figure 1). All patients were treated by the same qualified surgeon. Patients did not receive detailed information about the surgical technique that was used. Prosthetics procedure was performed by an experienced prosthodontist who was not informed about the surgical procedure. Clinical evaluations and radiographic

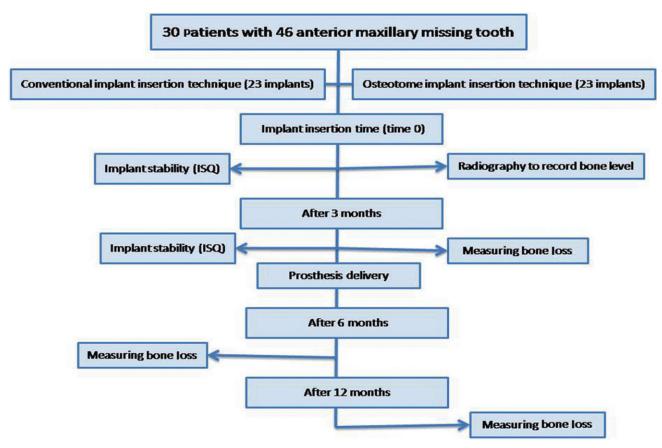


Figure 1 Flowchart-study design with groups/procedure. ISQ = implant stability quotient.

analysis were performed by an oral and maxillofacial radiologist who was not aware of the type of surgical technique that was used.

# **Surgical Procedure**

Forty-six screw type Straumann SLA<sup>®</sup> oral implants (Straumann AG, Waldenburg, Switzerland) with the length of 10 or 12 mm and a diameter of 4.1 mm were used.

A full thickness flap was elevated after achieving local anesthesia (Lidocaine, Daropakhsh, Tehran, Iran). Then, prior to implant bed preparation, the bone width was clinically measured at the surgical site. Patients with the bone width lower than 6 mm were excluded from the study.

For the control group, implant bed sites were prepared with pilot and spiral drills to a final diameter of 3.3 mm, according to the protocol recommended by the manufacturer. For the test group, after preparing a pilot hole with a 2.2-mm diameter drill, the procedure was continued with a series of consecutive osteotomes (Straumann AG) to a final diameter of 3.5 mm, according to manufacturer's instructions. Each osteotome remained in the socket for 1 minute before using the next instrument. For increasing the primary stability of implants, no tapping was performed previous to implant placement. All implants were placed in the sites using a nonsubmerged technique and in a one-stage procedure. They were between adjacent roots, though some patients received two implants (one in each quadrant).

# Postsurgical Instructions

To reduce postsurgical swelling, all patients were instructed to sporadically use an ice bag for the first 2 hours after the operation. Patients received 1 g of amoxicillin (Farabi Pharmaceutical Co., Isfahan, Iran) 1 hour before the surgery and 7 days postsurgically (500 mg/8 hours). In addition, nonsteroidal analgesics were given postoperatively. Patients were instructed to rinse two times per day with 0.12% chlorhexidine digluconate (Shahre Daroo Lab, Tehran, Iran). They were instructed to use modified oral hygiene protocol, according to Heitz and colleagues<sup>33</sup> in the treated area for the first 4 weeks after the surgery. After 4 weeks, patients were returned to the normal oral hygiene protocol.

# **Prosthetic Procedure**

After 3 months, the prosthetic abutments were fixed onto the implants with 35 N/cm torque, according to manufacturer's recommendation. All implants resisted the applied torque and the classical prosthetic steps were conducted and metal-ceramic prosthesis were prepared and cemented within 3–4 weeks on all implants. All prostheses were fixed prosthesis option 1 (FP1) or fixed prosthesis option 2 (FP2) according to Misch classification.<sup>34</sup>

# RFA

The ISQ of each implant was measured clinically using RFA (Osstell<sup>TM</sup>, Integration Diagnostics, Sävedalen, Sweden). RFA was carried out at the time of implant placement and 3 months after surgery. It was recorded three times for each implant at every interval. The system frequency response was measured by attaching transducer to the implant in buccolingual direction. The excitation sign was given over a range of frequencies (typically 5–15 KHz with peak amplitude of 1 V) and the first flexural resonance was measured.

# Radiographic Analysis

Crestal bone loss was measured using digital subtraction radiography technique. For this purpose, Patients in both the test and the control groups received periapical radiographs at implant insertion session and also at 3, 6, and 12 months after surgery, employing the digital radiography system using long cone paralleling technique and using an individualized positioning device as described in detail by Cune and colleagues.<sup>35</sup> The measuring reference was the implant shoulder and the vertical distance to the first BiC was measured. Bone loss was then the difference expressed as  $\Delta$  BiC of the time intervals. This difference was measured mesially and distally, three times per implant with 0.1-mm accuracy. All measurements were performed by a blind oral and maxillofacial radiologist.

# Statistical Analysis

The normal distribution of the data was tested (Kolmogorov–Smirnov test) and statistical analysis for determination of differences in marginal bone levels, which measured 3, 6, and 12 months after implant insertion, were performed by Wilcoxon Signed Ranks test. Comparisons of ISQ values between both techniques

TABLE 2 Mean Marginal Bone Loss Measured in Millimeter 3, 6, and12 months after Implant Insertion							
	Bone Loss (Mean $\pm$ SD)						
Treatment Groups	3 Months	6 Months	12 Months				
Conventional technique	$0.41\pm0.23$	$0.23\pm0.23$	$0.34\pm0.21$				
Osteotome technique	$0.61 \pm 0.21$	$0.18\pm0.20$	$0.41\pm0.22$				
Statistical significance between groups	<i>p</i> = .04	<i>p</i> = .21	<i>p</i> = .29				

were performed using paired *t*-tests, and a significance level of  $\alpha = 0.05$  was used for all comparisons.

#### RESULTS

A total of 184 radiographs were made to determine the peri-implant alveolar bone levels of 46 implants inserted by the osteotome and conventional techniques in 1 year. Two patients dropped out as they were not available for the follow-ups and were replaced with two other patients. All implants sites healed uneventfully. No complication was reported during the healing phase. The mean and standard deviation of peri-implant bone levels of each group were calculated for each evaluation point (Table 2). A comparison of the treatment groups with Wilcoxon Signed Ranks test revealed that only at month 3, the osteotome group caused more crestal bone loss  $(0.61 \ [0.21])$  than conventional  $(0.41 \ [0.23])$  group (p = .04). At month 6, both osteotome  $(0.19 \ [0.20])$  and

conventional (0.23 [0.23]) groups had closely similar bone levels (p = .21). Also, at the end of the study, month 12, both groups had comparable bone levels (p = .29) (Table 2). The results also showed that majority of the implants exhibited crestal bone loss within the 0–1.3-mm range in both groups after 12 months of function.

The RFA measurements showed an ISQ of 70.9 as a mean value for the test group, indicating the higher primary stability for osteotome technique than conventional procedure of implant placement, which showed ISQ of 64.70 as a mean value on the day of surgery (Figure 2). Therefore, RFA demonstrated a statistical significant higher primary stability for implants in osteotome group than that of conventional group (p = .026). The ISQ values of both groups increased during the 3 months. However, there was no statistically significant difference between both groups 3 months after the surgery (p = .06) (Figure 2).

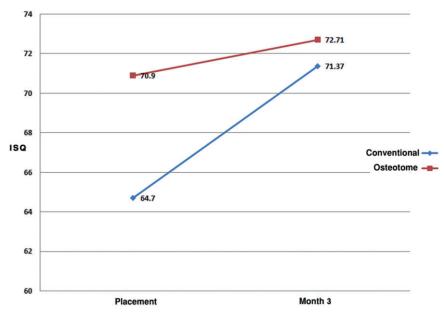


Figure 2 ISQ in two groups at the time of implant placement and after 3 months. ISQ = implant stability quotient.

## DISCUSSION

There are limited clinical studies that used the osteotome technique for implant placement. This study aimed to compare implant stability and crestal bone loss around implants placed by the osteotome technique and the conventional drilling technique. The results of this study demonstrated that ISQ values were significantly higher for the implants inserted by the osteotome technique immediately after surgery procedure. This might be explained by the findings of Fanuscu's study, which showed increase in the trabecular numbers, in the bone volume, and decrease in the trabecular separation of bone around implants placed using the osteotome technique.<sup>36</sup> In addition, Büchter and colleagues histologically observed a higher density of peri-implant bone for the osteotome technique.<sup>17</sup> Therefore, these changes in the trabecular bone volume and bone density could affect the ISQ values at the time of implant insertion.<sup>20</sup> It has been shown that there is a correlation between ISQ measurements and bone quality classification proposed by Lekholm and Zarb.<sup>21</sup> Because the main focus of the present study was to compare the two surgical techniques to eliminate the possible effects of variation in bone quality, patients with bone type I and IV were excluded from the study. Patients with bone types II and III were not separated from each other because it was not always possible to differentiate between these two bone types during surgery, and also, it has been reported that there was no significant difference in ISQ measurements between these bone types.<sup>21</sup>

In the present study, RFA measurements showed an average primary stability of about 64.7 ISQ, ranging from 43 to 71 for conventional drilling technique and 70.9 ISQ, ranging from 47 to 74 for osteotome technique. Because it has been reported that an implant that expresses an ISQ value of more than 47 could be considered a stable implant,<sup>22</sup> these ISQ values indicate that both procedures provided good primary implant stability. The result of the present study are in line with Nedir's findings, which showed initial ISQ values of Strumann implants between 40-77 for conventional drilling technique. Bischof and colleagues also evaluated implant stability of Strumann implants. They reported the mean ISQ values of 55 and 59.8 for maxilla and mandible, respectively.<sup>21</sup> The higher primary stability of implants placed in the present study compared with Bichrof study could be explained by using undersize drilling in the current study.<sup>16,17</sup> Karl and colleagues also reported that Strumann implants inserted in the anterior maxilla with the conventional drilling technique had the least ISQ value (69.41) compared with other regions of maxilla and mandible. In addition, they reported the ISQ range of 39–89, with the highest mean for posterior mandible (75.98). They found the mean ISQ of 68.89 for posterior maxilla and 61.87 for anterior mandible.<sup>23</sup>

The secondary stability mostly depends on bone remodeling and adaptation at the bone-implant interface.<sup>18</sup> After a 3-month healing period, the mean ISQ values were increased for both groups. This finding is in line with several studies that have evaluated implants stability of Straumann implants.<sup>22,24-26</sup> Changes in ISQ values indicate changes in bone-implant interface during the process of osseointegration.<sup>37</sup> It has been shown that the mean ISQ values slightly decreased during the early weeks of healing because of loss of mechanical stability, and then started to increase considerably with time because of replacement of initially formed bone by matured lamellar bone.<sup>22,24-26</sup> Oates and colleagues showed that a shift from decreasing to increasing stability with Strumann implants occurred 4 weeks after implants insertion using conventional drilling surgical technique.<sup>27</sup> Because the stability measurement of this study was later than 4 weeks (month 3), this decrease could not be recorded.

Implant surface characteristics is another factor that could affect the secondary stability.<sup>18</sup> Therefore, the shifting pattern could be different in various implant systems. Friberg and colleagues evaluated implant stability of machined surface implants and they found that implant stability decrease rather than increase during 15 weeks of healing period.<sup>28</sup> In addition, Turkyilmaz and colleagues monitored stability changes of oxidizedsurface implants over a period of 12 months. They showed that the ISQ values decreases during the first 3 months following surgery and then increases from the third- to the 12th-month measurements.<sup>29</sup> These evidences imply the importance of implant surface characteristics along with surgical techniques.

In the present study, the stability increase of the osteotome group was not as much as the conventional group. After 3 months, there was no significant difference in ISQ values between the two techniques. A reason for this finding could be the excessive loads exerted on the bone by the osteotome insertion technique. It has shown that loads of more than 20 MPa, which might be anticipated during use of osteotomes, could displace bone marrow spaces and consequently disturb the blood supply. Therefore, the bone needs more time to form new spaces for angiogenesis.<sup>7,17</sup> Furthermore, it is showed that excessive loading results in degradation of the physical integrity of collagen fibers and also micro damage of trabecular bone.<sup>17,38</sup> It has been indicated that bone remodeling needs 3 months or more to repair micro damaged bone.13 Therefore, inadequate bone regeneration could cause impaired implant stability 3 months after the surgery in the osteotome group. Moreover, the results of the present study is in accordance with the study conducted Nedir and colleagues, which showed that implants with low ISQ values yielded a more noticeable increase in ISQ values during the healing period than implants with high initial ISQ values.22

The results of the present study showed a significantly higher bone loss for implants that were inserted by the osteotome technique compared with the conventional technique after 3 months. It might be explained by the fact that bone micro damages are a direct stimulus for the activation of osteoclasts.<sup>39</sup> In addition, it is assumed that the osteotome technique puts pressure on the crestal cortical bone layer, which leads to a significant peri-implant bone loss.<sup>12</sup> After 6- and 12-month follow-ups, 0.79 and 1.2 mm mean marginal bone loss was observed respectively for the implants placed by the osteotome technique. These results are in accordance with the radiographic finding of Strietzel and colleagues who observed the mean bone loss of 0.8 mm for the osteotome technique after 6 months.<sup>12</sup> In the current study, there was no significant difference in the marginal bone loss between the two groups after 6 and 12 months of follow-ups. Logically, it could be related to the completeness of bone regeneration after 6 months. As is stated before, bone modeling needs 3 months or more to repair micro damages. Probably after 6 months, this process would have been completed. Thus, although there were differences between these two techniques at month 3, after 1 year it was not clinically relevant.

Because the magnitude of load is a critical factor in the prognosis of osteotome technique, further investigation could be performed to develop a mechanism for measuring the extent of load while using osteotome. In addition, future studies are needed to compare the prognosis of osteotome technique in various bone types.

## CONCLUSIONS

Within the limitations of the present study, it was concluded that comparing these implant insertion techniques after implant loading had comparable bone levels. Moreover, the osteotome technique yielded higher primary stability than the conventional drilling technique, though it was not superior to the conventional technique after 3 months.

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