Implant Stability Changes during Early Phase of Healing: A Prospective Cohort Study

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Abstract:
Objective: To assess the stability changes as a reflection of early healing around roughened-surface implants in human by resonance frequency analysis (RFA).

Materials and Methods: One hundred and fifty one ITI SLA implants were placed in either maxilla or mandible of 68 patients. Bone type was classified into 4 groups according to Lekholm and Zarb index. RFA was used for direct implant stability measurement on the day of implant placement, and at 14, 30 and 60 days after placement. Student t-test and ANOVA served for statistical analysis.

Results: No early failure occurred. The highest and lowest primary stability was measured in type 1 and type 4 bone, respectively. Implant stability increased over time in types 3 and 4 bone but continuously decreased in type 1 bone during the first 60 days of healing. In type 2 a small decrease in stability was observed until 30 days, and after that the stability increased. The difference between implant stability in type 2 and type 4 bone at each time point was highly significant (P<0.001). Implant stability did not change significantly during the 60-day period in type 2 bone (P>0.05). The effect of implant length and diameter on stability at different times was tested with mixed model ANOVA, and no significant difference among groups was observed (P>0.05)

Conclusion: The present study demonstrated that the pattern of stability changes was different among various bone types. With regard to primary stability and pattern of stability changes in types 2 and 3 bone, immediate and early loading protocols can be recommended in these two bone types, respectively.

Key Words: Dental Implants; Data Interpretation, Statistical; Bone Density

INTRODUCTION
Bone-anchored endosseous implants are being used progressively more in craniofacial, dental, and orthopedic surgery. Clinicians have reported success rates as high as 90% [1]. However, this rate is noticeably reduced when implants are placed in bone of poor quality, or where tissues have been compromised [1], for example, following radiotherapy. There is some evidence suggesting that the early failure of implants placement may be due to excessive mechanical stress and poor primary stability at the time of placement [2,3]. Currently considerable interest exists in improving the quality and rate of bone formation around implants through coating the surface, or modifying the
surface topography or geometry of the implant. In other words, in addition to various host site conditions, different implant geometries and surfaces may affect the interface development and its characteristics [4]. Brunski [5] has suggested only four basic mechanisms by which implants may be anchored to bone: macro and micromechanical interlocking; bioactive substrate; soft tissue attachment; and osseointegration.

Primary stability occurs at the time of implant placement and is believed to be related to the level of primary bone contact, while secondary stability is the result of the formation of secondary bone contact of woven, and following that, lamellar bone. Thus, as primary bone contact decreases, secondary bone contact increases [6]. Primary and secondary stability in healed bone has classically been assessed clinically via tapping the implant in a lateral direction with two opposing mirror handles [7,8]. Although this is a widely practiced clinical technique, there is little evidence suggesting it being valid, depicting the need for a quantitative method to measure implant stability [8]. Tapping an implant with a metallic instrument aims to determine the resonance and damping of the implant from the audible ringing produced [7,8]. However, such a test is relatively insensitive to changes in implant stability for two main reasons: first, the ear is inadequately sensitive to distinguish the resonance frequency, damping, and amplitude of the tone produced, and second, tapping the implant and the abutment is a simplification of what is essentially a multifaceted system [1]. A simple tap with a mirror handle will not transfer sufficient energy to the implant to allow precise measurements.

Radiographic methods are probably the most commonly used clinical technique for the evaluation of osseointegration and the assessment of abutment fit. The objective of radiographs is to detect peri-implant radiolucencies and to accurately evaluate marginal bone height. Generally, this is performed using implant threads as an internal dimensional reference [9]. However, the use of radiographs, being two-dimensional and difficult to standardize is criticized. Sundén et al [10] concluded that, despite the rather good diagnostic accuracy of the technique, the likelihood of predicting clinical implant instability from radiographic examination was low in populations with a low prevalence of implant instability.

A quantitative method describing the stability of an object in a solid medium is via vibration analysis. Vibration analysis of an implant following measurement of an implant’s vibratory oscillation can be divided into two categories: transient excitation and continuous excitation. Manual percussion is a form of transient vibration analysis [11]. Periotest (SiemensAG, Bensheim, Germany) is another one [12]. However, when the periotest is applied to the implant, the values obtained stand for only a narrow range over the scale of the instrument, thus, indicating a lack of sensitivity in the measurement of implant stability [13].

Dynamic vibration analysis of implant stability uses a continual excitation of the implant. The pulsed oscillation waveform was developed by Kaneko [14] to measure mechanical vibration features of the bone-implant interface in vitro. In this technique, a high-energy pulse is repeatedly applied to the implant with piezoelectric elements containing probes, and the resonance frequency (RF) is measured. Meredith et al [1,15] have reported the use of a transducer directly attached to an implant body or to the abutment. Resonance frequency analysis (RFA) offers a clinical, noninvasive measure of stability and the presumed osseointegration of implants. Initial in vitro studies confirmed the ability of the device to evaluate changes in interfacial stiffness [8]. Clinically, RF values have been allied with changes in implant stability during osseous healing, to osseointegrate, and the supracrestal dimensions of the levels of bone-implant contact [16-18].
More recently, the commercial instrument was modified, now being wireless and using an aluminum peg (smart peg; Integration Diagnostic AB, Sweden) attached to the implant. It utilizes electromagnetic pulses across a frequency range and then analyzes the response of the smart peg. The peg is excited and the RF is uttered electromagnetically as Implant Stability Quotient (ISQ) units. The result is two-dimensional through a planar measurement instead of the linear one used with the previous device. Osstell™ mentor (integration Diagnostics AB, Sweden, 2004) the current RFA device is a simplified and more user-friendly version of the original transducer based Osstell™ device (integration Diagnostics AB, Sweden). This improved technology presents more reproducible and representative results around 360º of the implant, via a mathematical algorithm.

The ISQ value essentially correlates with the lateral stiffness of the interface between the implant and the surrounding bone. Although the values cannot directly link to actual cellular activities, they provide us with a repeatable assessment of the condition of the bone-implant interface [15,16,19]. Thus, they can be used to monitor and control the biologic conditions of the bone-implant interface.

The objective of the present clinical study was to investigate stability changes of ITI SLA (sandblasted, large-grit, and acid etched) solid-screw implants (Straumann AG, Basel, Switzerland) by RFA during early healing stage before abutment placement, in humans.

**MATERIALS AND METHODS**

This clinical trial was designed as a prospective study to measure implant stability with an RF analyzer (Osstell™ mentor; integration Diagnostics AB, Sweden) at the time of implant placement and at 14, 30, and 60 days post placement. The samples consisted of 68 patients (30 male, 38 female), 18-70 years of age, treated with 151 ITI SLA implants in Tehran University of Medical Sciences. Eligible samples were selected based on inclusion/exclusion criteria (Table 1).

The implant lengths used in this study were 10 mm (n=75) and 12 mm (n=76) with different diameters: Narrow Neck with 3.3 mm wide (n=17), Regular Neck with 4.1 mm wide (n=95) and Wide Neck with 4.8 mm wide (n=39). Seventy implants (46%) were placed in the maxilla and 81 implants (54%) were placed in the mandible. Thirty two percent of implants were placed in premolar sites, 51% in molar sites, and 17% in canine sites.

The effect of implant length, diameter and location, as well as patient bone type, age, and gender on implant stability expressed as ISQ units was evaluated. The data were analyzed using descriptive statistics, student t-test, and ANOVA, by SPSS software.

**Clinical Protocol**

After the inform consents were obtained, all the implants (70 in the maxilla and 81 in the mandible) were placed using a non-submerged technique according to the manufacturer’s instructions. Bone quality categorized as type 1, 2, 3, or 4 at the time of surgery based on Lek-
holm and Zarb index [20], with respect to tactile sense of the surgeon. Immediately after the implant placement, the proper smart peg (type 17 or 4) (Integration Diagnostics AB, Sweden) was screwed onto the fixture and the implant stability was measured by the RF analyzer and expressed in terms of ISQ units on a scale from 1 to 100 (Fig 1). An increase in ISQ values means progress in implant stability, whereas decreased values means vice versa. Readings were performed three times each and the mean amount was jot down. All measurements were performed by a single operator and to lessen observer bias, the previous recordings on the implant were not accessed earlier than RFA measurement.

RESULTS
The distribution of implant according to bone type was as follows: 3.31% (n=5) in type 1 bone, 72.84% (n=110) in type 2 bone, 17.88% (n=27) in type 3 and 5.96% (n=9) in type 4 bones. None of the implants failed. ISQ values showed a high level of repeatability, with an accuracy of ± 2 units.

Regarding implant length, the greatest difference was observed at 14 days, when 12 mm long implants presented non-significantly higher stability than 10 mm long ones (P>0.05). Concerning implant diameter, the greatest difference was seen at 30 days between 4.8 mm and 4.1 mm wide implants (P>0.05) and also between 4.1 mm (RB) and 3.3 mm wide implants (NB) (P>0.05). Although implants with 4.8 mm diameters had higher stability than 3.3 mm and 4.1 mm wide ones, there was no significant difference in ISQ values with regard to different implant diameters (P>0.05). Regarding bone quality, the lowest stability mean at 60 days was observed in type 1, at 30 days in type 2, and at the base line in types 3 and 4 bones. Type 4 bones demonstrated the lowest stability at the time (Fig 2). Implants placed in bone types 3 and 4 presented an increase in stability from baseline to
the 60th day; while implants in type 1 bone showed a decrease in stability in the same period. In type 2 bone, a non-significant decrease in stability from baseline to 30th days was observed, as well as increase from 30th days to 60th days (P>0.05). Generally, little change of stability was noticed in types 1 and 2 (Fig 2 and 3). According to ISQ values; no significant difference existed between genders (P>0.05).

Implants placed in the mandible had relatively higher stability compared to those placed in the maxilla. Pattern of stability changes was also obviously different in two jaws (P<0.05) (Fig 4)

**DISCUSSION**

The overall objective of this study was to quantify the early stability pattern of roughened surface implants placed in various bone types. Most previous studies have recorded the RF values in Hertz [16,17,21]. However, the current understanding is that ISQ values will become the standard unit of stability reports in future articles [13]. Valderrama et al [22] showed that changes in implant measured with the magnetic device (Osstell™ mentor Integration Diagnostics AB, Sweden) correlated well with those of the electronic one (Osstell™ Integration Diagnostics AB, Sweden).

In most previous studies the stability of the implant was seen to be affected by healing time [12,16,17,19,23], which was also a finding in the present study. This study showed that from baseline to 60 days, stability pattern in type 1 and 2 was noticeably different from that in type 3 and 4 bone. Friberg et al [21] evaluated the stability of 75 mandibular Branemark implants in 15 edentulous patients through 15 weeks, and, contrary to our results, found it to decrease rather than increase. This incongruity may be attributable to the district surface state (machined VS SLA) and its subsequent reactions at the interface. Although no occlusal force was applied to the implants, the increase in stability after 30 days in type 2, 3 and 4 bone agrees with the concept of improved bone formation around the SLA surface and the likelihood of reduced clinical healing times prior to restoration [13,24].

According to the results, it seems that not only
the amount and location of cortical and cancellous bone around the implant may be an important factor in providing resistance to lateral mobility, but also surface characteristics (SLA) and/or implant geometry play important roles as well. When the stability of the implant in bone tissue is measured quantitatively, the stiffness of the tissue neighboring and surrounding the implant will affect the stability measurements [25]. In type 4 bone, for example, the overall stiffness of the bone will be less because of the thin cortical layer and the large trabecular core with low density. Therefore, the majority of the implant surface will be occupied by bone with a low stiffness; resulting in lower stability values. It was not surprising then that implants in type 1 bone showed highest ISQ values at base line, 14 and 30 days, as greater bone density contributes to higher levels of stability during the first month of early healing period.

It is considerable that in type 1 bone, ISQ values continued to show a slight decline after 30 days, being lower than type 2 bone ISQ values at day 60. The likelihood of overheating during drilling in dense bone, might due to marginal bone loss and increase the effective implant length [26] upshot less ISQ values. Less bone marrow and poor blood circulation could be other causes for longer resorptive phase in type 1 bone and declining the ISQ levels all through the 60 days of study [27]. The greatest increase in stability occurred after 30 days in types 2, 3 and 4 bones, and a slight change in mean ISQ values in type 1 bone was observed. The change in stability, seen in our study, might coincide with the physiologic changes reported by Roberts [28], speaking of a bridging callus bone developing from the endosteum and periosteum to the surface of a coated implant during the early modeling phase (0 to 6 weeks). The later stage of lamellar compaction within the loose stroma of the woven bone begins at 6 weeks and progresses until the 18th week. He assumed that the lamellar compaction would provide ample strength for loading of the implant. Relevantly of interest, is the remarkable 9.98% increase in stability for type 4 bone from 30 to 60 days (P<0.05). This finding confirms that bone density/quality is not static but is indeed dynamic, as it seems to change in relation to an implant surface with time [29].

With regard to stability, initially, primary stability occurs at the time of implant placement. This may be largely due to the press-fit of the slightly larger diameter of the implant (in the case of the ITI implant) against the cut native bone surface, referred to as primary bone contact [5]. One of the factors also thought to affect primary stability is the length of the implant. In this study, only two implant lengths were used: 10 and 12 mm. The implant length had no significant effect over time (P>0.05). Bischof et al [30] through a study with 106 ITI implants placed in both the mandibular and the maxillary bone concluded that positions and lengths of the implants did not affect the ISQ values. Farzad et al [31], Horwitz et al [32] and Balleri et al [33] reached the same conclusion in their studies. Also in a multicenter study evaluating the long-term success of 2,359 non-submerged ITI titanium plasma-

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**Fig 4.** Implant Stability Quotient (ISQ) levels and pattern of implant stability changes according to jaw position.
sprayed implants, Buser et al [34] found no significant difference in the success rate of 10 and 12 mm implants over a period of 8 years. The present study examined the transition in levels of stability from the time of primary bone contact to the development of early secondary bone contact during the first 60 days of healing in each of the four bone types. During the early transition period between primary and secondary stability in contrary to types 3 and 4 bones, types 1 and 2 bone had no detectable difference at any time point up to 60 days. With the larger cortical bone volume and the dense spongy bone around these implants, lateral bending forces of the RFA would most likely be better resisted than in the case of implants in poorer quality bone. Studies have indicated that if stable fixation exists between the bone and the implant, even minute interfragmentary movements can be avoided and dynamic load bearing can be withstood [35]. In those implants showing high primary stability with little change over time, an immediate loading protocol can be indicated [13]. Immediate and early loading of implants placed in bone types 1 and 2 has been advocated in the literature, especially with roughened-surface implants [36,37]. An implant presenting an ISQ value of above 60 (with electronic device) has been recommended to be loaded directly after insertion [38]. Valderrama et al [22] demonstrated that the mean ISQ value obtained using the magnetic device is 8 to 12 units higher than the one obtained via the original device. With regard to ISQ values in type 4 bone (mean ISQ value at baseline=50.0, SD=8.64), as the primary stability was under acceptable range for immediate loading and the stability pattern significantly changed, immediate loading seems not to be recommendable. Regarding type 3 bone, although the mean ISQ values were closer to that in type 2 bone, it seemed difficult to advocate immediate loading protocol as primary stability levels were under the acceptable range (mean ISQ values at baseline=60.55, SD=8.5). However, due to the increase in ISQ values over time, turning to be favorable at the 60th day (mean ISQ values at day 60=67.51, SD=4.67), early loading protocols seemed proper to be advocated. In our study, implants placed in type 2 bone had high primary stability (mean ISQ value at baseline=70.14, SD=8.76) with no significant changes during baseline and day 30, although the ISQ values were found to be more at day 60 compared to days 0, 14, and 30 (mean ISQ value at day 60=71.82, SD=5.72). Thus, it appeared tempting to advocate the immediate loading protocol for implants placed in type 2 bone. According to the results, it is difficult to make a certain decision about the immediate loading protocol in type 1 bone because ISQ values slightly decreased over time and also the number of implants placed in type 1 bone were rather small (n=5). Nonetheless, ISQ values were in high limits (more than 65) at all times during the study with only a 2% change in mean ISQ value after 30 days. On the other hand, it is suggested that for implants with high primary ISQ values, lessening of implant stability during the first 3 months of healing should be supposed as a common incident that should not required amendment of routine follow-up [24]. As the ISQ values in type 1 bone were over 65 and little decline in high primary stability in 2 months of our study was observed, immediate loading protocols could be advocated in ITI SLA implants in type 1 bone. However, continuous declining of ISQ levels in type 1 bone and the least mean ISQ values in 60 days concerning other three earlier measurements favoring the early loading protocols, just to be in the safe side. Implant length did not affect implant stability according to ISQ measurements. maybe, once the bone-implant contact was established at the marginal level that is composed mainly of dense bone, and the implant is firm, a 2 mm distinction in length in apical section that natu-
rally serene of very cancellous bone, does not provide a significant progress in implant stability [22]. Implant diameter was observed not to be effective on ISQ levels. This finding was inconsistent with previous reports proposing the use of wider implants to increase primary stability due to creating a larger bone-implants contact with cortical bone [39-47]. Implants used in these studies mostly had different surfaces and this inconsistency might be attributed to the surface features of roughened-surface SLA implants offering a more osteoconductive surface than smooth-surface ones [13]. Moreover since ITI implants are parallel wall they cannot increase lateral compression effectively against surrounding native bone even with larger diameter. This would be important for earlier osseous healing and the development of secondary bone contact during the modeling and remodeling phases, shadowing the effect of implant diameter.

Stability levels were higher in the mandible, in harmony with previously reported higher survival rates of implants in mandible [46,47]. This is probably due to bone density [41-43] as denser mandibular bone favors towards more stability.

This study allowed the primary stability evaluation of different implant diameters and length in different bone types during the critical period of early healing and appears to have provided valuable insights concerning implant stability changes in ITI SLA implants throughout the critical early stage of healing. With the recent interest in immediate loading of single-unit restorations, other studies should be designed to investigate different loading protocols, effect of splinting vs. non-splinting and also examine occlusal factors as potential variables in the healing process.

CONCLUSION

The present study demonstrated that pattern of stability changes are different among different bone types. With regard to our findings, immediate and early loading protocols can be recommended in bone types 2 and 3, respectively that are the most published bone types on the literature.

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