

Is There a Need for Standardization of Tightening Force Used to Connect the Transducer for Resonance Frequency Analysis in Determining Implant Stability?

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Purpose: The purpose of this *in vitro* study was to determine the minimum placement torque required to attach the transducer (measuring peg) to the implant to provide an accurate assessment of implant stability using resonance frequency analysis. **Materials and Methods:** One hundred 4 × 11-mm screw-shaped titanium implants were inserted into a uniform polyurethane block with similar density to bone in a standardized surgical protocol. The implants were distributed into 10 groups, with 10 implants each (G1 to G10). In G1, the transducer was manually attached by a female operator and in G2 by a male operator using the manual connector provided by the manufacturer. For the remaining groups (G3 to G10), the transducers were placed using a connector adapted to a digital torque wrench with different torque settings: 3 Ncm (G3), 4 Ncm (G4), 5 Ncm (G5), 6 Ncm (G6), 10 Ncm (G7), 13 Ncm (G8), 17 Ncm (G9), and 20 Ncm (G10). Stability was measured for all groups using the Osstell equipment (Diagnosis of Integration) and the implant stability quotient (ISQ) annotated for statistical comparison between the groups. **Results:** The mean ± standard deviation ISQ values for groups G1 to G10 were 9.50 ± 5.54, 19.05 ± 2.67, 29.25 ± 4.22, 26.55 ± 5.37, 40.90 ± 0.99, 69.60 ± 2.41, 71.30 ± 0.82, 71.20 ± 1.32, 72.40 ± 0.97, and 70.90 ± 0.88, respectively. Statistical comparisons determined that the amplitudes of the confidence intervals, relative to the standard deviations, were lowest for groups G5, G7, G8, G9, and G10. For the means, the lowest amplitudes of the confidence intervals were observed in G6, G7, G8, G9, and G10. When checking the conjugated confidence intervals (mean and standard deviation), the results were homogenous for G7, G8, G9, and G10. When the torque of 20 Ncm was reached, the connection between the transducer and the implant failed. **Conclusion:** In this *in vitro* model experiment, transducer torques between 10 and 17 Ncm appear to be adequate for accurate measurement of implant stability, allowing more precise comparisons without damaging the prosthetic connection in the implant. *INT J ORAL MAXILLOFAC IMPLANTS* 2019;34:886–890. doi: 10.11607/jomi.7361

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Measuring dental implant stability is a useful and objective way to establish implant placement protocols as well as implant loading protocols for each clinical case.^{1,2} There are several methods for measuring implant stability, though the most applicable is resonance frequency analysis (RFA).³ The device measures implant stability via magnetic waves, using a transducer connected to the implant and a magnetic tip, giving an implant stability quotient (ISQ) value.

When assessing implant stability, a quantitative method such as RFA may provide valuable information that could contribute to the long-term success of the treatment. RFA allows stability measurements on a numerical scale ranging from 0 to 100, and such measurements can be obtained after implant placement (initial stability) or at any time during healing,

providing important information regarding the status of the bone-implant interface or osseointegration. According to Nedir et al (2004),⁴ RFA may assist in the decision-making process regarding the best moment for placement of the coronal restorations during the healing period. Failed implants commonly present with low stability measurements at the earliest stages of healing^{5,6} and also show a steady decrease in stability until failure occurs. Such information could be useful to avoid implant failure by removing or delaying occlusal loading.⁶

Unlike other methods such as radiography, percussion, and insertion torque values, stability analysis by RFA is not regarded as empirical. RFA is also noninvasive and does not compromise the implant at any phase of the treatment, unlike other methods such as reverse torque and histologic/histomorphometric analysis. In theory, a device that could measure implant stability noninvasively would be the Periotest; however, it was developed to evaluate mobility of natural teeth, which are not in direct contact with bone and, therefore, allow for a much wider range of movement than osseointegrated implants. In addition, the Periotest is very technique-sensitive, since it is subject to many variables.⁷ Nkenke et al (2003)⁸ found a higher association between RFA and bone contact by histomorphometric analysis than the Periotest.

According to Sennerby and Meredith (1998),⁹ it is extremely important to determine implant stability to decide on immediate or early loading strategies. A commercially available electronic device based on RFA, known as Osstell, has been widely used for this purpose, both clinically and in research. However, the literature addressing the use of such device does not mention what the transducer placement torque should be for standardizing the measurements. By contrast, many researchers and clinicians have been connecting the transducers manually, ie, unaided by torque measuring equipment. This may have a negative impact on the accuracy of the measurement, thus introducing an important element of bias on an individual operator basis. This may explain the significant number of conflicting results found in the literature regarding *in vivo* studies.^{4,6,10-17}

As there is significant controversy between *in vivo* studies, an *in vitro* study was designed to allow greater control of the aforementioned variables. With this in mind, the objective of this study was to determine the minimum transducer placement torque to the implant that would provide an accurate reading of implant stability and thereby suggest a torque protocol for the transducer to increase the accuracy of such an approach for clinical and research use.

MATERIALS AND METHODS

One hundred screw-shaped implants, measuring 4 × 11 mm, from IntraOss, were placed in a synthetic bone block with 20 PCF-CP (Nacional Ossos), simulating real bone in terms of density (0.32 to 0.35 g/cm³). This model has a technical certificate following the American Society for Testing and Materials (ASTM) international standards. Preparation of the test specimen was performed respecting the distance between the osteotomy sites, namely, 9.1 mm longitudinally and 8.82 mm transversely. These distances provided the equidistant arrangement of 100 sites (Fig 1). The preparation of the implant-receiving bed followed the alveolar preparation dimensions recommended by the implant manufacturer, ie, 3.3 mm diameter × 12 mm deep to place an implant of 4.0 mm diameter × 11 mm deep. In order to standardize the preparation and implant angulation, a 3.3-mm-diameter and 12-mm-long helical drill was used for all osteotomies in a Romi motor, model D560, with the assistance of a lathe to standardize the process.

The implants were distributed into 10 groups (n = 10 per group):

- G1: Transducers were manually placed by a female operator.
- G2: Transducers were manually placed by a male operator.
- G3: Standardized torque (digital torque wrench) at 3 Ncm
- G4: Standardized torque (digital torque wrench) at 4 Ncm
- G5: Standardized torque (digital torque wrench) at 5 Ncm
- G6: Standardized torque (digital torque wrench) at 6 Ncm
- G7: Standardized torque (digital torque wrench) at 10 Ncm
- G8: Standardized torque (digital torque wrench) at 13 Ncm
- G9: Standardized torque (digital torque wrench) at 17 Ncm
- G10: Standardized torque (digital torque wrench) at 20 Ncm

In groups G1 and G2, the transducers were placed manually (finger grip torque), in a gentle manner, using Osstell's carrier to connect the transducer into the implant. In groups G3 to G10, the transducers were placed with the help of a carrier customized by the authors to fit both the "smartpegs" and a digital torque wrench (Instrutherm), so that the measurement of the tightening force in Ncm was achieved accurately (Fig 2). The error limit of the digital torque wrench is



Fig 1 Implant distribution on the specimen.



Fig 2 Digital torque wrench display showing the torque used in G7.

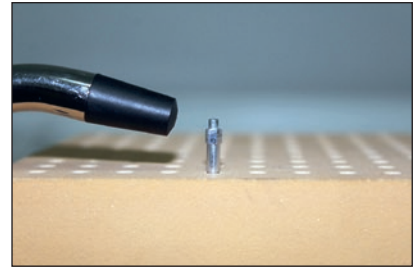


Fig 3 Transducer placed and Osstell equipment being used to verify implant stability.

Table 1 Descriptive Statistics of Analyzed Groups (Measurements in ISQ)

Group	Mean	SD (\pm)	Median	Min	Max	n
G1	9.50	5.54	10.25	1.00	17.00	10
G2	19.05	2.67	20.00	14.00	22.00	10
G3	29.25	4.22	31.00	22.00	35.00	10
G4	26.55	5.37	28.00	17.00	33.00	10
G5	40.90	0.99	41.00	40.00	43.00	10
G6	69.60	2.41	70.00	63.00	71.00	10
G7	71.30	0.82	71.50	70.00	72.00	10
G8	71.20	1.32	71.00	70.00	73.00	10
G9	72.40	0.97	73.00	70.00	73.00	10
G10	70.90	0.88	71.00	70.00	73.00	10

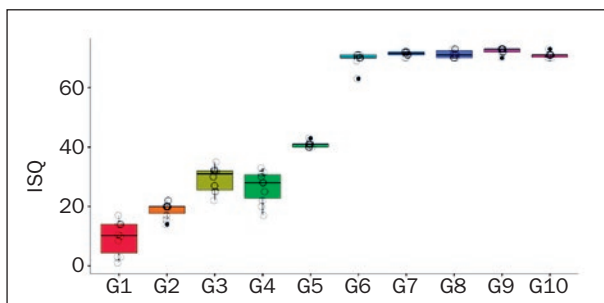


Fig 4 Boxplot of ISQ values across the groups.

± 2.20651 Ncm, which was attested by the calibration company Ceime. For groups G3 to G10, transducers were torqued by the same researcher (D.B.S.). A total of 20 transducers were used, so after using the transducers for five implants, the transducers were discarded. Therefore, two transducers were used per group, one for the first five implants and a second one for the following five implants.

The Osstell Mentor (AB Integration Diagnostics) was used to measure resonance frequency, and the ISQ was annotated to permit statistical comparisons between the groups (Fig 3). The angulation of the machine to the transducer was the same for each test. The distance from the machine to the transducer was also

the same for each test. For the statistical analysis, the confidence interval adopted was 95% and was calculated using the Bootstrap technique.

RESULTS

The results of the measurements are shown in Table 1.

Regarding the standard deviations obtained from the readings across the groups, a significant drop in standard deviation was observed for groups G5, G7, G8, G9, and G10. The amplitude of the confidence intervals was significantly lower for groups G5, G7, G8, G9, and G10 in comparison to the other groups (G1 to G4 and G6).

Concerning the means, the amplitude of the confidence intervals was lower and more homogenous for groups G5, G7, G8, G9, and G10, when compared with the remaining groups (G1 to G4 and G6) (Fig 4).

In the G10 group (20-Ncm torque), the connection between the transducer and the implant stripped. This occurred in all 10 implants from G10, but no other specimen from any of the remaining groups.

DISCUSSION

Successful osseointegration has a high correlation to implant stability; thus, accurate techniques for measuring implant stability are extremely important both clinically and for research purposes. Although RFA analysis currently represents the most suitable method for assessing implant stability, much controversy is observed in the literature regarding its use. There are opposing findings for RFA correlations, namely, (1) male/female (Boronat López et al, 2008¹⁴ versus Zix et al, 2005¹³), (2) implant diameter (Bischof et al, 2004¹² versus Horwitz et al, 2003¹¹), (3) implant failure (Glausser et al, 2004⁶ versus Nedir et al, 2004⁴), (4) insertion torque (Akça et al, 2010¹⁵ versus Friberg et al, 1999¹⁰), and (5) implant length (Barikani et al, 2013¹⁶ versus Kheur et al, 2016¹⁷). Such conflicting results may be a consequence of a lack of standardization of variables

between studies. Variables such as the use of different implant systems, different implant designs, and a number of different conditions between studies (eg, immediate implant placement, implant placement in healed sites, differences in the location of implants, etc) may lead to conflicting reported results in the scientific literature. These variables make the comparison between the previously cited studies difficult. Another variable that may result in different stability readings is the torque applied to the transducer connected into the implant. The force used to connect the transducer to the implant is not standardized among the studies reviewed in the literature. In this context, the objective of this *in vitro* study was to determine the minimum transducer connection torque that would permit accurate assessment of implant stability, thereby suggesting a torque guideline to be used in future studies.

The authors of the present study performed an *in vitro* study in order to ensure control of variables. A recent publication also used a similar bone block model (Jorba-García et al, 2019).¹⁸ Instead of selecting animal bone for implant placement,^{19–21} a synthetic material was used with density compatible with that of real bone and with minimal bone density variation (0.32 to 0.35 g/cm³), thus reducing the inherent element of bias relating to density variability found in animal bone.^{22–24} However, despite the advantages of using this *in vitro* design, it is important to state that it cannot truly represent what is found in humans due to important differences between vital bone and a plastic model (eg, blood supply, collagen content of bone, elasticity of bone, etc). Moreover, it is known that all torque wrenches have an error limit, and the digital torque wrench used in this study has an error limit of ± 2.20651 Ncm. Therefore, this *in vitro* study permitted a high level of standardization between groups, which would not be possible in a clinical study. However, the limitation with the use of this plastic model is that translation of the results into a live clinical setting is difficult.

According to the data obtained from the study by Glauser et al (2004),⁶ implants that failed in their study showed low stability (measured in ISQ) after 1 month of placement. Implants with ISQ values greater than 69 showed a 100% success rate, while baseline values of less than 39 had a 100% failure rate. Initial ISQ scores between 48 and 59 had a failure rate of 19%. When comparing these results with that of the present research, it could be speculated that a large part of the implants from groups G1, G2, G3, G4, and G5 (with ISQ values of 9.50 ± 5.54 , 19.05 ± 2.67 , 29.25 ± 4.22 , 26.55 ± 5.37 , and 40.90 ± 0.99 , respectively) would have a very poor outcome, while the majority of the implants from groups G6, G7, G8, G9, and G10 (with ISQ values of 69.60 ± 2.41 , 71.30 ± 0.82 , 71.20 ± 1.32 , 72.40 ± 0.97 , and 70.90 ± 0.88 , respectively) would be

more likely to succeed. As the implants from all groups (G1 to G10) were placed using the same protocol and into the same standardized specimen, it is anticipated that they would have similar ISQ values and a low rate of standard deviation. However, this was not observed, due to the difference in torque values applied to the transducers, which was the only variable in this *in vitro* study. The mean ISQ value seemed to be more adequate in groups G6, G7, G8, G9, and G10. Concerning the standard deviation, according to Nedir et al (2004),⁴ an acceptable value that falls within the error of the machine would be ± 2 ISQ units, and when comparing these data with the results of the present study, it can be concluded that G7 to G10 provide readings with standard deviations that all fall within the error of the machine. The reason for a higher standard deviation in G6, when compared with G7 to G10, was the presence of one outlier (in the first implant of this group). A high standard deviation was also observed in groups G1 to G4, but with a significantly lower mean. This can be credited to the lack of adequate mechanical friction between the transducer and implant with such low connection torque. The present study showed that when the transducer is loosely connected, there is no accuracy with the ISQ measurement.

In G1 and G2, where transducers were placed without the assistance of the torque wrench, it is important to state that a light touch or force applied by hand was used by the researchers. However, it is not possible to record the force used with these two groups since no torque wrench was used. For this reason, the authors decided to perform this research. It is not possible to standardize or measure the force generated with hands or fingers. However, by using a torque wrench to connect the transducer to the implant, the torque used to tighten the transducer may be measured. The results of this study showed that a torque value between 10 and 17 Ncm seems to be adequate. Certainly, a lower torque was used in G1 and G2 (less than 10 Ncm), as light strength was used, but the main question is: How could someone, accurately, apply more than 10 Ncm but less than 17 Ncm without the assistance of a torque wrench? Therefore, a torque wrench, and a transducer carrier that allows its usage, should be used to torque the transducer if accuracy with ISQ measurement is desired. In the authors' opinion, this is especially true when clinical studies are performed.

Comparing the results obtained between the groups, when checking the conjugated confidence intervals (mean and standard deviation), it was observed that the results were most homogenous for G5, G7, G8, G9, and G10. This suggests that a transducer torque between 10 and 20 Ncm tends to generate homogenous results when other variables are controlled. Therefore, if different studies have reported conflicting results to the

extent that significant differences could be obtained in terms of ISQ values, direct comparisons between the studies should be avoided, since other variables may be interfering with the outcome. This would explain the apparent discrepancy in the results. The present study suggests that a difference as small as 2 Ncm in transducer placement torque may influence implant stability, as observed when comparing G4 and G6. By contrast, from a certain torque value upward, an increase in torque does not seem to result in significant change, which could be verified when comparing the results from G7, G8, G9, and G10. However, for G10, the connection between the transducer and the implant stripped in all the specimens, which was not found in any other group. One may therefore suggest that torque should be applied to the transducer in the order of 10 to 17 Ncm. In this way, the lowest accurate value could be achieved, and therefore, a torque of 10 Ncm should be considered as a standard for tightening the transducer into the implant. The authors of the present study suggest that both clinicians and researchers who are striving to ascertain suitable stability values from the outset using RFA should consider using a dedicated carrier to place the transducer, permitting the carrier to be attached to a precision torque wrench to achieve a final torque of 10 Ncm with the transducer.

CONCLUSIONS

In this *in vitro* model experiment, the following conclusion may be drawn: Transducer torque values between 10 and 17 Ncm proved adequate for accurate measurement of implant stability, allowing accurate comparisons and with no damage to the connection within the implant.

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