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A comparative *in vitro* evaluation of two different magnetic devices detecting the stability of osseo-integrated implants

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Background and Objective: It is unknown whether the resonance frequency analysis (RFA) measurements made by two different magnetic resonance frequency analysers are comparable. This *in vitro* study was designed to compare the RFA measurements made by the two magnetic resonance frequency analysers and to evaluate the intra- and interobserver reliability of the magnetic devices.

Material and Methods: Thirty-two implants were placed in four cow ribs. The RFA value of each implant was measured by five different examiners. The measurements were repeated five times, in both the buccal and mesial directions, for each implant at 2 h intervals, and the averages of registered implant stability quotient (ISQ) units were recorded as the buccal ISQ value and the mesial ISQ value for every implant.

Results: No statistically significant differences ($p > 0.05$) were observed between the RFA measurements made by the two magnetic devices. The intra-observer reliability of both devices was excellent, whereas the interobserver reliability of the devices was poor.

Conclusion: The results of the RFA measurements of both tested devices overlap. Although both devices show excellent intra-observer reliability, there are variations between the measurements of different examiners.

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Treatment of missing teeth with osseo-integrated implants is a highly accepted procedure, and its success is well documented in the literature (1,2). A dental implant can be defined as successful when it integrates into the surrounding tissues. This integration is termed osseo-integration, which was originally defined by Brånemark *et al*. in 1985 as 'direct structural and functional connection between ordered, living bone and the surface of a load-carrying implant' (3). More recently, osseo-integration has been defined as 'a process whereby clinically asymptomatic rigid fixation of alloplastic materials is achieved and maintained in the bone during functional loading' (4). In other words, an implant is regarded as osseo-integrated when there is no progressive relative movement between the implant and the bone, which means that the implant is stabilized. Therefore, implant stability both immediately following surgery (primary stability) and during the healing process (secondary stability) is a prerequisite for the long-term clinical success of osseo-integrated implants (5–7). Primary stability that is achieved

during the surgery depends on factors related to the bone (quality and quantity), the surgical technique used and the implant design (8,9). Limiting micromovements to certain levels during surgery by obtaining primary stability prevents the formation of a connective tissue layer between the implant and the bone, thus ensuring bone healing, especially when the peri-implant bone interface is subjected to mechano-biological stimulation by immediate and early loading protocols (10,11). Additionally, in the early or immediate loading protocols, the type and magnitude of loading may influence the ongoing healing process and, in some cases, this may lead to demineralization of the bone–implant interface, loss of stability and eventual implant failure (12). In this manner, it should be emphasized that numerical information about the amount of stability of an implant is vital for determination of the timing of loading (7,8,12,13).

The method used for measuring implant stability is expected to be accurate, repeatable and reliable (14). Various measurement techniques have been proposed for measuring dental implant stability (15,16). Among these, resonance frequency analysis (RFA) is a recent and widely accepted method, which has been reported to be reliable, easily predictable and objective (5,7,8) Since RFA was initially described by Meredith *et al*. (5), it has been possible to monitor implant stability at various time points during the treatment with RFA and determine whether implants are sufficiently stable to be loaded and receive the final restoration (12). Furthermore, it has been shown that implants showing unusual decreases in resonance frequency values during the healing period should alert the clinicians to propose a tighter follow-up schedule for these implants and to take additional precautions, such as unloading until implant stability is regained or checking for trauma or infection (6,17,18).

Three commercial devices have been developed for measuring RFA. The first one is the Osstell™ device. It is electronic and uses a direct cable connection between the L-shaped transducer and the resonance frequency analyser. The transducer has a vertical beam with two attached piezo-ceramic elements and is fastened by a screw to the implant or to the abutment. The piezo-ceramic element transmits a sinusoidal signal over the range of 5–15 kHz in steps of 25 Hz. The other piezo-ceramic element analyses the response of the transducer to the vibration. Resonance frequency is calculated from the peak amplitude of the signal (19). The resonance frequency values were initially presented in hertz, but the values were later transformed to implant stability quotient (ISQ) units, which are presently used to describe implant stability with the RFA technique (12). The ISQ values range from 1 to 100, where 100 signifies the highest degree of stability (12).

The Osstell™ device has been shown to be effective in detecting implant stability, distinguishing implants placed in different qualities of bone and evaluating the prognosis of implants with different geometric or surface characteristics. However, this device was hard to use, especially when mounting onto the implants, and was designed for only a few implant systems (19). Furthermore, the use of the Ostell™ can impair sterility and is difficult to handle during surgery. For these reasons, a new commercially available device was developed with a magnetic mechanism for detecting implant stability (18,20). An aluminum magnetic peg ('Smartpeg'; Integration Diagnostic AB, Göteborg, Sweden) calibrated for each implant company, is screwed into the implants using a plastic screwdriver, and the measurements are performed by using the Osstell™ *mentor* instrument (18). The Osstell™ *mentor* utilizes electromagnetic pulses across a frequency range and analyses the response of the Smartpeg. The peg is excited, starts to vibrate, and the magnet induces electric voltage within the probe coil. The electric voltage is sampled by Osstell™ *mentor*, and the resonance frequency is expressed electromagnetically as ISQ (20,21).

This improved magnetic technology presents more reproducible and representative results, is clinically much easier to handle and can be sterilized (19,22).

In a recent *in vitro* study, it was reported that the newer wireless electromagnetic resonance frequency analyser was a suitable, sensitive and reliable device to measure implant stability. It was expressed that it could detect circular, vertical peri-implant bone loss around implants in 1 mm increments (22). The standardization of the device positioning has been reported to be an important aspect to consider during implant stability measurements (23). It was shown that device positioning had no effect on the reproducibility of the ISQ values obtained with Osstell™ *mentor*, which can be regarded as an another advantage over the Ostell™ (21,24).

In a clinical trial, Valderrama *et al*. (20) demonstrated that the Osstell™ and the Osstell™ *mentor* were capable of showing similar implant stability changes. However, the ISQ values measured by the Osstell™ *mentor* were 8–12 units higher than those of the Osstell™ device (20). It was concluded that the measurements obtained with these two devices cannot be compared directly (20). In the light of the above-mentioned studies, it can be confidently expressed that the Osstell™ *mentor* represents an improved device for determining ISQ values.

More recently, Osstell™ ISQ was introduced, which uses the same magnetic technology as Osstell™ *mentor*. Osstell™ ISQ is the latest implant stability meter from the Osstell™ Company. In their manual, the Osstell™ Company suggests that Osstell™ ISQ is less sensitive to electromagnetic noise, more efficient and user friendly, and can obtain faster measurements.

Numerous *in vitro* and clinical studies have been performed using the original Osstell™ device. However, studies with the RFA devices using magnetic technology are scarce. Moreover, it is unknown whether the RFA measurements made by the two magnetic resonance frequency analysers are similar and can be directly compared. Hence, this *in vitro* study was conducted to compare the RFA measurements made by the two magnetic resonance frequency analysers and to evaluate the intra- and interobserver reliability of both magnetic devices.

Material and methods

In vitro specimen preparation

Four fresh cow ribs belonging to the same animal, obtained from a butcher's shop, were selected for the experimental procedures. The ribs served as a model of human edentulous jawbone owing to the macroscopic composition of cortical and medullar bone. The ribs had a minor portion of cortical bone and a greater proportion of medullary bone (14), being similar to a type 3 quality bone according to the classification of Lekholm and Zarb (24,25).

Eight implants were inserted into each rib, with a safe distance from each other (a total of 32 implants; Fig. 1). The implants were all 4.5 mm wide and 11 mm long and belonged to the same manufacturer (Osseospeed; Astra Tech, Mölndal, Sweden). The implant beds were prepared following the standard drilling protocol recommended by the manufacturer (Fig. 2).

Measurements

The RFA measurements were carried out by five prosthodontists, blinded to the study protocol, using the two magnetic resonance frequency analysers. A magnetic peg calibrated for Astra Tech implants was inserted by means of a plastic screwdriver (Smartpeg type 7; Integration Diagnostics, Savedalen, Sweden) and hand-tightened by each examiner on each implant (Fig. 3). Every examiner made the measurements with the Osstell™ *mentor* (OM1; Osstell Mentor; Integration Diagnostics) and the Osstell™ ISQ (OM2; Osstell™ ISQ; Integration Diagnostics). The probes of the analysers were held 1 mm from the peg at a 90° angle (Fig. 2). After a few seconds, the RFA value was registered as ISQ on the digital screen of the instrument. For detecting intra-observer reliability, the measurements were repeated five times (25), in both the frontal and the lateral directions for each implant at 2 h intervals. The averages of registered ISQs were recorded as buccal ISQ value for the frontal and mesial ISQ for the lateral measurements for each implant.

Fig. 1. View of the eight implants after insertion into one of the cow ribs.

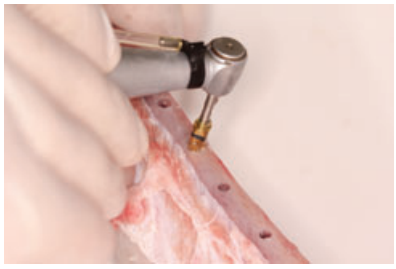

Fig. 2. Implant bed preparation following the standard drilling protocol of the manufacturer.

Statistical analyses

For statistical analysis of the results, the NCSS 2007 and PASS 2008 statistical software packages (NCSS, Kaysville, UT, USA) were used. Kolmogorov–Smirnov test was used for detecting the appropriateness of the parameters to normal distribution. Student's paired *t*-test was used for the comparison of parameters with normal distributions. The intra-observer and interobserver reliability were estimated by the intraclass correlation coefficient (ICC). Analysis of variance (ANOVA) was used for detecting the significance between the examiners' measurements, and *post hoc* testing was performed using Bonferroni's correction for multiple comparisons. Friedman's test was used for analysing the significance between each examiner's measurements. The results were assessed at 95% confidence interval, at a significance level of 0.05.

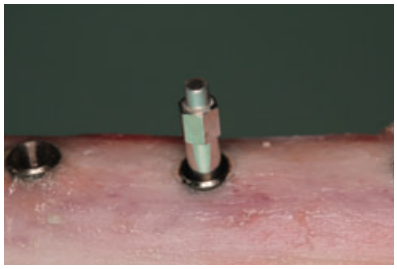

Fig. 3. View of the Smartpeg after hand-tightening with the plastic driver.

Results

The relationship between ISQ values obtained from OM1 and OM2 are shown in Table 1. No significant differences were observed between the two measurements made by each examiner ($p > 0.05$); indeed, excellent ICC values were detected according to the recommendations of Schuck (26; range 0.73–0.99; see Table 1).

The ICC values for the intra-observer reliability were 0.95 for examiner 1, 0.97 for examiner 2, 0.91 for examiner 3, 0.91 for examiner 4 and 0.94 for examiner 5 for the buccal ISQs of OM1. For the mesial ISQs, the ICC values were 0.95, 0.98, 0.98, 0.98 and 0.97, respectively. For the buccal ISQs of OM2, the ICC values were 0.92 for examiner 1, 0.98 for examiner 2, 0.94 for examiner 3, 0.93 for examiner 4 and 0.92 for examiner 5; and for the mesial ISQs of OM2, the ICC values were 0.93, 0.97, 0.98, 0.96 and 0.98, respectively. All the ICC values were evaluated as excellent according to the recommendations of Schuck (26).

Significant differences were detected between the examiners' measurements ($p = 0.029$ for OM1 and $p = 0.049$ for OM2). The ICC values for the interobserver reliability were 0.32 for the buccal and 0.35 for the mesial RFA measurements of OM1, and 0.219 for the buccal and 0.313 for the mesial RFA measurements of OM2, which were all evaluated as poor according to the recommendations of Schuck (26).

Discussion

Implant stability is a chief consideration for successful osseo-integration and is of principal importance for implant survival and success (14,17,18,20). Recent *in vivo* and *in vitro* evidence has supported the use of RFA for detecting implant stability. With the introduction of noninvasive and easy-to-perform

Table 1. The relationship between the ISQ values obtained from OM1 and OM2

Examiner and site	OM1 (mean ± SD)	OM2 (mean ± SD)	*p*-Value	ICC (95% confidence interval)
E1				
Buccal ISQ	80.87 ± 3.04	80.87 ± 3.04	0.999	1.000 (1.000–1.000)
Mesial ISQ	87.25 ± 1.83	87.25 ± 1.67	0.997	0.907 (0.608–0.981)
E2				
Buccal ISQ	74.62 ± 5.53	74.87 ± 5.43	0.170	0.996 (0.982–0.999)
Mesial ISQ	85.75 ± 1.28	85.37 ± 0.91	0.080	0.892 (0.557–0.977)
E3				
Buccal ISQ	83.75 ± 2.55	85.37 ± 3.81	0.142	0.734 (0.551–0.914)
Mesial ISQ	87.75 ± 1.49	87.63 ± 1.50	0.351	0.972 (0.868–0.994)
E4				
Buccal ISQ	79.12 ± 5.77	79.00 ± 5.88	0.351	0.998 (0.991–1.000)
Mesial ISQ	86.87 ± 1.35	86.87 ± 1.35	0.999	1.000 (1.000–1.000)
E5				
Buccal ISQ	84.25 ± 2.18	84.50 ± 2.33	0.626	0.811 (0.315–0.959)
Mesial ISQ	86.75 ± 3.10	86.87 ± 3.22	0.598	0.980 (0.902–0.996)

p-Values are from Students' paired *t*-test. Abbreviations: CI, confidence interval; E, examiner; ICC, intraclass correlation coefficient; ISQ, implant stability quotient.

RFA devices to dental practice for detecting the stability of implants, it is now possible to monitor healing and to predict unexpected changes around implants that may result in implant failures and thus foresee the timing of loading and take precautions to improve the bone to implant contact (18,20). Numerous *in vitro*, animal and clinical studies have been presented by using the original RFA device, for which RFA recordings were shown to correlate with insertion torque and histological evidence of bone to implant contact (16,20,27,28). With the evolution of technology, two different wireless magnetic RFA devices were recently developed by the same manufacturer. However, there is a lack of studies evaluating these new magnetic RFA devices. It is unknown whether the RFA measurements made by these two devices are similar. Moreover, no articles have been published evaluating the intra- and interobserver reliability of the magnetic RFA devices. Therefore, the present study was designed to compare these magnetic RFA devices and to evaluate the intra- and interobserver reliability.

In the present study, the mean ISQ values obtained from the two devices showed no significant differences and an excellent correlation. Two previous studies comparing the Osstell™ and the Osstell™ *mentor* had found significantly higher ISQ values measured for the Osstell™ *mentor* device (20,22). These discrepancies were speculated to be related to design differences, in that the height of the piezo-electric stack of the original Osstell™ was considerably further from the alveolar crest than the subsequent magnetic Smartpeg (7), which was also measured as 2.8 mm above the bone level in a clinical study (20). In order to simulate the clinical situation and place the implants in a similar environment to the jaw bone, fresh cow ribs were used in our study (14). The ribs served as a model of human edentulous jaw bone because of their macroscopic composition of cortical and medullar bone.

The recording attachment supplied by the manufacturer of the RFA devices for the electronic and magnetic devices and their design and working basis are totally different (20,22), accounting for the difference in stability values recorded by Osstell™ and the Osstell™ *mentor*. However, exactly the same pegs and the same wireless magnetic technology are used by the Osstell™ *mentor* and Osstell™ ISQ devices. That may be the reason why no significant differences were found between the ISQ values obtained from the two devices in our study, and thus measurements made with Osstell™ *mentor* and Osstell™ ISQ may be able to be compared directly. Nevertheless, this important finding should be confirmed in clinical conditions in further studies.

Obtaining intra- and interobserver reliability of an RFA device is important for prospective research and for clinical treatment evaluating the stability of implants. The reliability of the measurements taken with the original Osstell™ RFA device was investigated by Brouwers *et al.* (29) in dry human mandibles, and the ICC value for the intra-observer reliability was established as 0.46, which could be evaluated as fair to good, while the ICC value for the interobserver reliability was 0.70, which was on the edge between fair to good and excellent. In our study, interobserver reliability was considered poor for both of the magnetic devices, which could be regarded as a disadvantage of the new devices compared with the electronic Ostell™. The transducers for the electronic device are screwed to the implants (20), whereas the Smartpegs for the magnetic devices are hand-tightened by using a plastic driver (18). In their manuals, the Osstell Company suggests that the Smartpegs should be tightened to 4–5 N cm, which is described as 'finger tight'. However, it is not possible to standardize the finger pressure of every clinician in the range of 4–5 N cm, which may account for the poor interobserver reliability of the magnetic RFA devices that we observed. This result emphasizes the importance of standardization of the clinical protocol, in which the measurements are performed by the same clinician each time. Moreover, the present study was an *in vitro* study, which does not necessarily simulate the *in vivo* environment. It was reported that when using Osstell™ *mentor* in clinical situations, the Osstell probe should maintain a distance of approximately 1–3 mm from the Smartpeg, at an angle of 90° and 3 mm coronal to the soft tissues, otherwise the measured value may be affected (21). These parameters may also account for variations in the interobserver reliability of the magnetic devices *in vivo*.

However, the ICC values for the intra-observer reliability, which were regarded as excellent in our study, indicate that if the RFA measurements are made with magnetic devices, it is only possible to monitor stability changes of an implant over time when

the measurements are performed by the same clinician. Our results suggest that measurements obtained by several clinicians may show variable results owing to different forces applied during Smartpeg tightening and positioning of the probe. In order to achieve an interobserver reliability in multiexaminer, multicentre or independent studies, tightening the Smartpegs should be standardized with objective methods, either by the manufacturer or by the examiners, to the range of 4–5 N cm, instead of leaving it to subjective finger pressure.

One major reason claimed for the introduction of a new magnetic RFA device was the improved measurement speed. However, the measurements obtained by the five different clinicians in our study did not reveal any differences between the two devices. Factors encountered in clinical situations, such as a wet environment due to saliva or blood, and limited access due to lips and cheeks or a surgical flap, might cause differences between the devices that were not observed in our *in vitro* study. It is also noticeable that even though these factors were not present in our *in vitro* study, the range of measurements showed greater interexaminer variability for the buccal recordings (using both of the devices) than for the mesial recordings. Due to less amount of bone on the buccal sides of the implants, the ISQ values could be affected more by the positioning of the probe by each examiner, which may be the reason for greater interexaminer variability for the buccal recordings.

Within the limitations of our study, it can be concluded that there is no difference between the RFA measurements of the two magnetic devices. The ISQ values of the two magnetic devices may be compared with each other or longitudinally over time using the same device, but only if the measurements are made by the same examiner.

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