Original article

Implant Stability Quotient (ISQ) vs direct in vitro measurement of primary stability (micromotion): effect of bone density and insertion torque

Paolo Trisi PhD[1,2],Teocrito Carlesi DDS[1],
Marco ColagiovanniDDS[3] , Giorgio Perfetti MD, DDS[3]

Objectives: Measuring peak insertion torque in relation to different bone densities, the present study seeks to determine whether micromotion at the bone-implant interface is related to the ISQ values.

Materials and methods: A total of 30 Tixos Implants (Leader SRL, Cinisello B., Milan, Italy) were used. Implants were placed in fresh bovine bone samples representing three density categories: hard, normal and soft (H-N-S). Customized electronic equipment connected to a PC was used to register the peak and insertion torque data. A loading device, consisting of a digital force gauge and a digital micrometer was used to measure the micromovements of the implant during the application of 25 N lateral forces. Resonance Frequency Analysis was calculated using the "Osstell ISQ", the latest version of the Osstell instruments, and the values were recorded in ISQ units. The data were analyzed for statistical significance by Spearman's rank correlation coefficient tests.

Results: Correlation coefficient showed a high dependency between the observed micromovement and ISQ values (ρ=-0.72 r^2=0.52 P=< 0.0001). This correlation was found in all the types of bone, in the Hard bone ρ=-0.89 r^2=0.80 P=0.0002, in the Normal bone ρ=-0.91 r^2=0.82 P=0.0007 and in the Soft bone ρ=-0.73 r^2=0.53 P=0.016 where the correlation was less powerful. The statistical analysis showed significant correlation between ISQ and torque-in (ρ=0.38 r^2=0.14 P=0.0394) and between Torque-in values and micromotion (ρ= -0.49 r^2=0.24 P=< 0.0059).

Conclusions: Results showed a high dependence between the observed micromotion and the ISQ values, indicating that micromotion decreased with increasing ISQ values. Contrarily, increasing the peak insertion torque increased the ISQ values.

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Key Words: bone density, dental implant, immediate loading, insertion torque, micromotion, primary stability, ISQ.

[1] Bio.C.R.A.,Scientific Director of the Biomaterial Clinical and histological Research Association, Pescara, Italy;
[2] Laboratory of Biomaterials and Biomechanics, Galeazzi Orthopaedic Institute, University of Milano, Italy;
[3] Department of Oral Surgery, University of Chieti-Pescara, Italy;

Corresponding author:
*Teocrito Carlesi DDS;
Biomaterial Clinical and histological Research Association,
Via Silvio Pellico 68, 65132 Pescara, Italy.
Tel:+39 085 28432; Fax: +39 085 28427; e-mail: t.carlesi@email.it

INTRODUCTION

Over the past few decades, implant rehabilitation has attracted increasing attention in dentistry as a result of improved success rates reported in the literature. More recently, the possibility of immediate functional loading of implants has been explored with particular success for the anterior mandible and with lesser success for the upper jaw and posterior mandible[1]. The cause of failure in these cases has not been attributed to immediate loading itself, but rather to the micromotion at the interface induced by the immediate loading, which, in turn, could ultimately be responsible for the failure of osseointegration of immediately loaded implants[2]. These same mechanisms are thought to be responsible for the failures of fracture healing according to the strain theory[3].

Implant stability depends on the direct mechanical connection between its surface and the surrounding bone and can be divided into primary and secondary stability. Classically, the clinical parameter relative to micromotion is 'primary stability,' which has been defined as "a sufficiently strong initial bone–implant fixation"[4]. Primary stability is achieved when the implant is positioned into the host bone site such that it is well seated. The success of this adaptation,

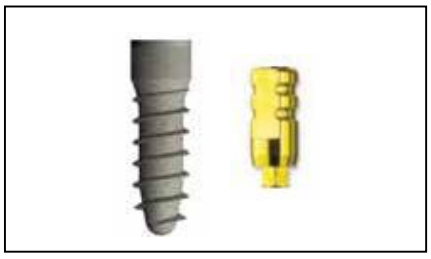

Figure 1. Implant with a mount-transfer used for the micromotion analysis.

Figure 2. Digital torque wrench.

however, depends on several factors, including the density and dimension of the host bone, the implant geometry and the surgical technique used. Secondary stability is attained when new bone forms at the implant interface. Given the importance of implant stability, it appears obvious that every implantologist's normal instrumentation should include a tool to measure the stability of the implant.

Recently, new methods were developed to non-destructively measure the implant stability, there are literature reports on percussion tests, radiographs (BMD), cutting resistance, torque-in, impact hammer method (Periotest) and even resonance frequency analysis (RFA).[5] Among these, the RFA is the most used in experimental studies, as well as in clinical practice, but many aspects still need to be clarified.

Resonance Frequency Analysis developed by Meredith et al. [6] uses specified resonance characteristics of acoustically excited implants and utilises a small L-shaped transducer which is screwed onto an implant fixture or abutment. The transducer comprises 2 piezoceramic elements, one of which vibrates by a sinusoidal signal (5 to 15 kHz). The other serves as a receptor for the signal. Resonance peaks from the received signal indicate the first flexural (bending) resonance frequency of the measured object. The specific value that indicates the implant stability of a given situation is called the resonance frequency.[6,7] In vitro and in vivo studies have suggested that this resonance peak may be used to assess implant stability in a quantitative manner.[8,9]

In the first European Osseointegration Association Consensus Conference held in 2006 [10], some authors sustained that a single measure using RFA does not define the characteristics of the bone-implant interface and does not offer any reliable quantitative evaluation of the degree of osseointegration. Not only that, but the RFA would not have any prognostic validity on the development of the instability. These authors assert that the validity and reliability of RFA, from a clinical point of view, still remain to be demonstrated, for every implant system, such as the ISQ values which indicate the stability or the risk of loss of stability of the precise implant system.

Research evidences suggest that elevated values of ISQ in a specific implant indicates that the implant is stable, and if ISQ values remain high the stability is maintained; while low values of ISQ, or a lowering of the values with time would indicate risk of instability of the implant.[11] However, there are still many aspects that need clarification.

Although these instruments are widely used and appear in the scientific literature, the ISQ values were never directly compared to implant micromotion.[12]

In the present study, the micromovement of implants inserted in freshly slaughtered bovine bone samples of different densities was measured using a previously published experimental model[13] and compared to the ISQ values to evaluate its statistical relationship.

Figure 3. Osstell ISQ Instrument.

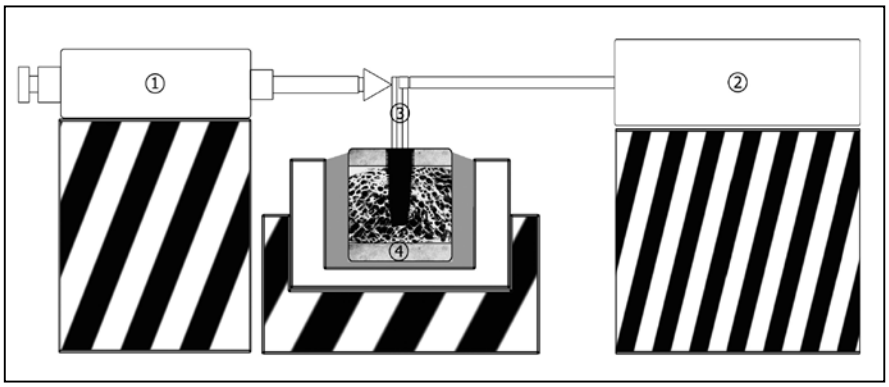

Figure. 4. Schematic drawing of the micromotion-testing tool. The bone specimen is located in the middle with the implant in place. On the right side, the digital force gauge is powered on the implant long abutment, and on the left side, the micrometer reveals the movement of the implant.

MATERIALS AND METHODS

The test was performed on 2cm X 2cm samples of fresh humid bovine bone representative of the following quality categories: Hard, Normal and Soft (H-N-S). The bone qualities were selected according to (1) drilling resistance[14] and (2) a preliminary histological analysis of the bone structure. Hard bone is dense with a completely compact structure. Normal bone is average hard bone with a 2–3mm cortical layer and a normal cancellous structure inside. Soft bone has low drilling resistance and a 1mm cortical layer with a low-density cancellous structure. Tixos implants (Leader SRL, Cinisello B.mo, Milan, Italy) 3.3mm in diameter and 11.5 mm in length were specifically utilized for this study. Each implant was fitted with a mount-transfer of 11mm in length to allow for the application of the lateral load. (Fig.1) The implants were placed according to the manufacturer's instructions using the appropriate burs. A customized digitally controlled hand wrench was used to measure the peak insertion torque. In addition, electronic equipment consisting of a digital handoperated torque wrench (Fig.2), equipped with a calibrated strain gauge and connected to a PC reading the peak insertion torque value every 0.5 ms, was customized for this study. To obtain the peak insertion torque, the signal was subsequently evaluated by the MECODAREC software (ATech s.r.l., Bergamo, Italy). After implant placement, the smart peg type 32 was screwed onto the implant (Integration Diagnostics AB, Göteborg, Sweden) and ISQ was measured using the new "Osstell ISQ" device. (Fig. 3)

After ISQ was measured, the bone blocks were fixed on a customized loading device for evaluation of micromovement (Fig. 4). This device consists of a digital force gauge [Akku Force Cadet (range of 0–90N and accuracy of 0.5%), Ametek, Largo, FL, USA] and, on the opposite side, a digital micrometer (Mitutoyo Digimatic Micrometer, Kawasaki, Japan) that detects the micromovements of the implant under lateral load application, as previously published [13]. Horizontal forces of 25 N/mm were tested on each implant, and the lateral movement of the mounting-device was measured by the digital micrometer 10 mm above the crest. On each implant, the load application was repeated five times for 2 s, simulating the occlusal load in a patient's mouth. The average value of these five measurements was calculated for each implant. A total of 30 implants were tested in groups of 10 implants, in each bone quality including hard, normal and soft as defined above. The linear Pearson coefficient of correlation (ρ) was applied to test the relationship between the micromotion vs. ISQ values and between the torque-in vs. micromotion.

To the normality test which evaluates the deviation from the Gaussian distribution, was applied the D'Agostino and Pearson test. The one-way non-para-

	N° Sample	Torque In (N Cm)	ISQ (V-D)	Microm (µm)
Bone type H	H 1	150	68	130
	H2	120	75	56
	H3	113	77,5	44
	H4	58	77,5	42
	H5	46	77,5	67
	H6	110	78	39
	H7	137	72	70
	H8	100	73,5	58
	H9	50	70	88
	H10	89	76,5	47
	H11	128	75	55
Mean ± SD		100.09 ± 35.53	74.59 ± 3.37	63.27 ± 26.36

Table 1. The values of Torque-in (N cm), values of RFA (ISQ) and micromotion (µm) of implants loaded with 25N lateral force for each implant at the time of the placement in relation to the Hard bone.

	N° Sample	Torque In (N Cm)	ISQ (V-D)	Microm (µm)
Bone type N	M1	50	72	120
	M2	64	73	100
	M3	10	67,5	384
	M4	20	69	250
	M5	140	76	77
	M6	113	76,5	88
	M7	76	73,5	100
	M8	125	76	83
	M9	68	75,5	92
Mean ± SD		74.00 ± 45.00	73.22 ± 3.23	143.77 ± 104.48

Table 2. The values of Torque-in (N cm), values of RFA (ISQ) and micromotion (µm) of implants loaded with 25N lateral force for each implant at the time of the placement in relation to the Normal bone.

	N° Sample	Torque In (N Cm)	ISQ (V-D)	Microm (µm)
Bone type S	S1	36	68,5	130
	S2	62	74	49
	S3	47	73,5	60
	S4	46	73	80
	S5	27	71	148
	S6	32	71,5	146
	S7	40	73	95
	S8	46	74	83
	S9	38	74,5	96
	S10	46	75	80
Mean ± SD		42.00 ± 9.74	72.8 ± 1.96	96.70 ± 34.22

Table 3. The values of Torque-in (N cm), values of RFA (ISQ) and micromotion (µm) of implants loaded with 25N lateral force for each implant at the time of the placement in relation to the soft bone.

metric Kruskal-Wallis test was used to verify if there were difference in the mean of the different bone densities groups, in term of ISQ values, torque-in values and micromotion and the Dunn's Multiple Comparison Test was used to verify the different between each group.

RESULTS

11 implants were placed in the group of Hard bone, 9 implants in Normal bone and 10 implants in Soft bone. All data are reported in Tables 1-2-3. The D'Agostino and Pearson normality test showed the data were normally distributed. The linear Pearson Coefficient of correlation between all micromotion data and the relative ISQ values was ρ=-0.72 and r^2=0.52, with a P=< 0.0001, statistically highly significant. (Fig. 5). When the correlation was plotted for each different type of bone, again these variables were significantly correlated.

The correlation in Hard bone between micromotion and ISQ was highly significant (*ρ=-0.89, r^2=0.80, P=0.0002)* (Fig. 6). In Normal bone the correlation was highly significant too (ρ=-0.91, r^2=0.82, P=0.0007) (Fig. 7), as well as in Soft bone (ρ=-0.73, r^2=0.53, P=0.016) (Fig.8).

Looking at the data, it was possible to note that the distribution in the Soft bone group was more scattered with more outliers, while in the Medium and Hard bone the data distribution was more linear with few outliers.

When correlating the insertion torque to the ISQ values, the linear Pearson Coefficient of correlation showed a less strong correlation (ρ=0.38, r^2=0.14,

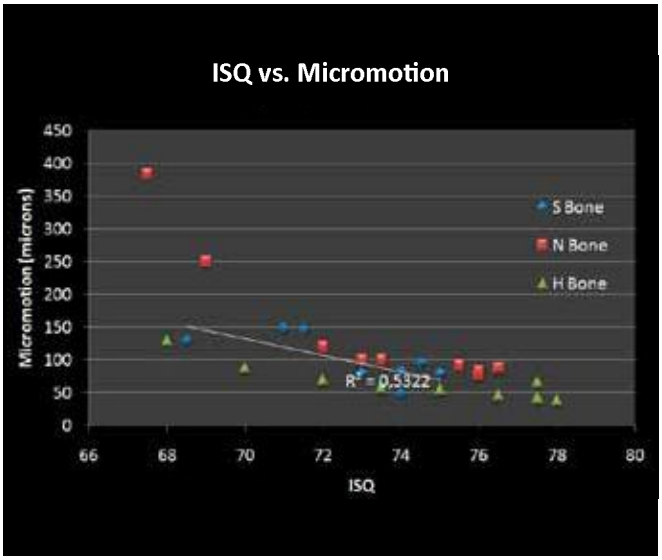

Figure 5. Regression analysis and Spearman's rank correlation coefficient shows a correlation between the micromotion values and the ISQ values indicating that micromotion decreased with increasing ISQ values The linear Pearson Coefficient of correlation (ρ) and (r^2) values for the all values of Torque-In and ISQ was ρ=-0.72 r^2=0.52 P=< 0.0001

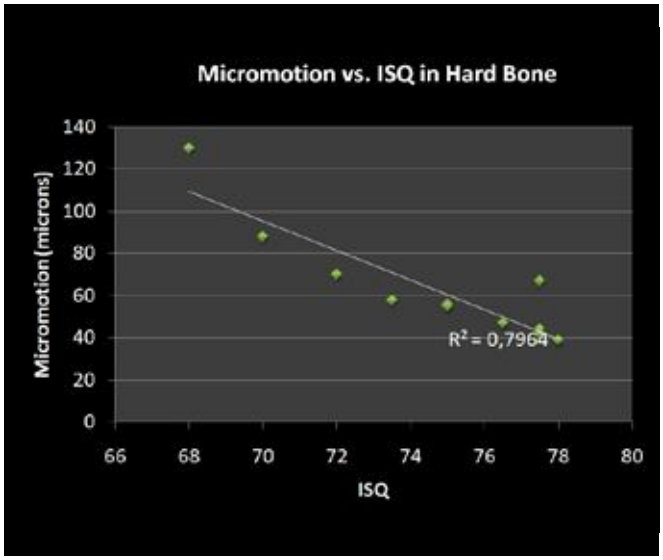

Figure 6. In the Hard bone, regression analysis and Spearman's rank correlation coefficient shows a high dependence between all values of the micromotion and the ISQ values, indicating that micromotion decreased with increasing ISQ values *ρ=-0.89 r^2=0.80 P=0.0002;* the variables are correlated and test is statistically significant.

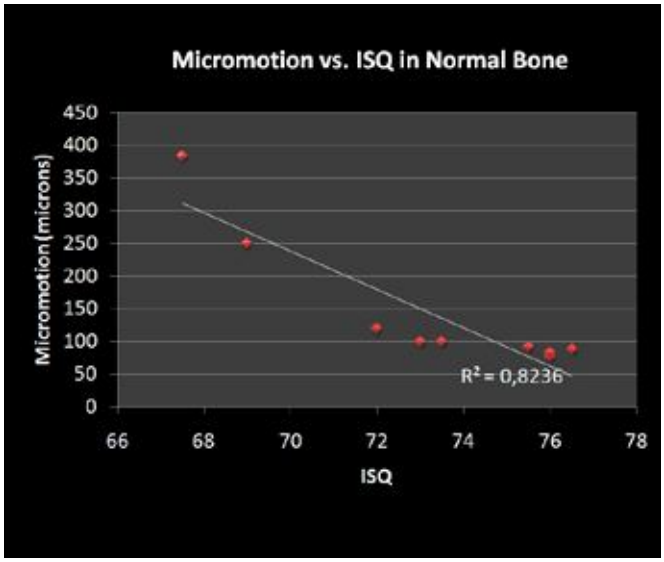

Figure 7. In the Hard bone, regression analysis and Spearman's rank correlation coefficient shows a high dependence between all values of the micromotion and the ISQ values, indicating that micromotion decreased with increasing ISQ values *ρ=-0.91 r^2=0.82 P=0.0007;* the variables are correlated and test is statistically significant.

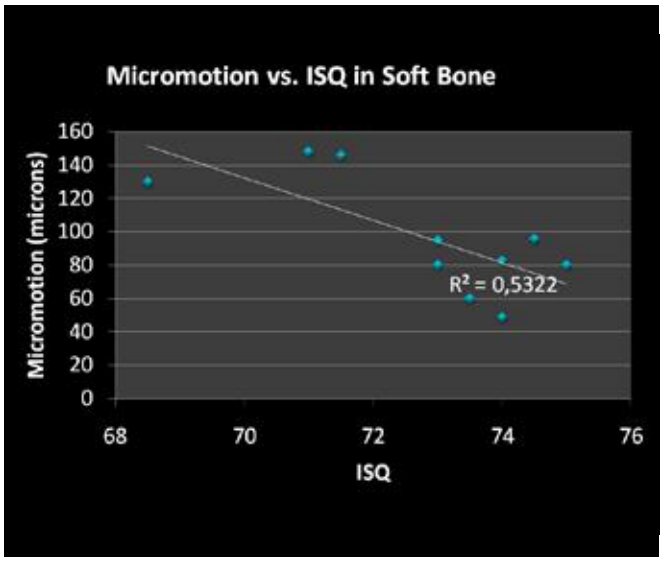

Figure 8. In the soft bone, regression analysis and Spearman's rank correlation coefficient shows a high dependence between all values of the micromotion and the ISQ values, indicating that micromotion decreased with increasing ISQ values *ρ=-0.73 r^2=0.53 P=0.016;* the variables are correlated and test is statistically significant.

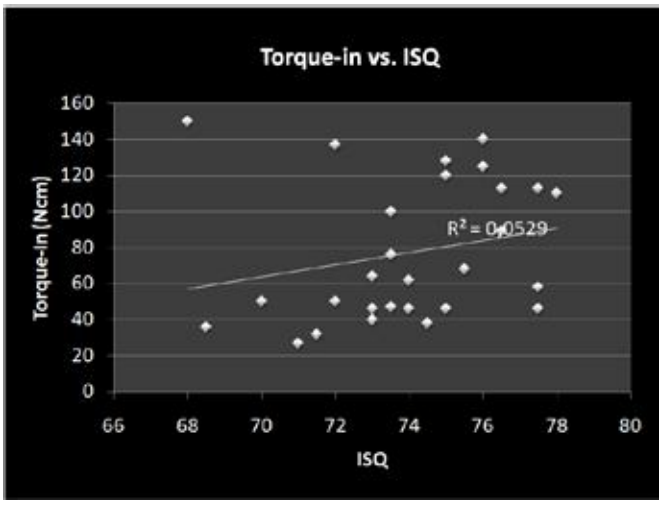

Figure 9. Regression analysis and Spearman's rank correlation coefficient showed a correlation between the torque-in values and the ISQ values indicating that torque-in increases with increasing ISQ values. The linear Pearson Coefficient of correlation (ρ) and (r^2) values for all the values of Torque-In and ISQ was ρ=0.38 r^2=0.14 P=0.0394.

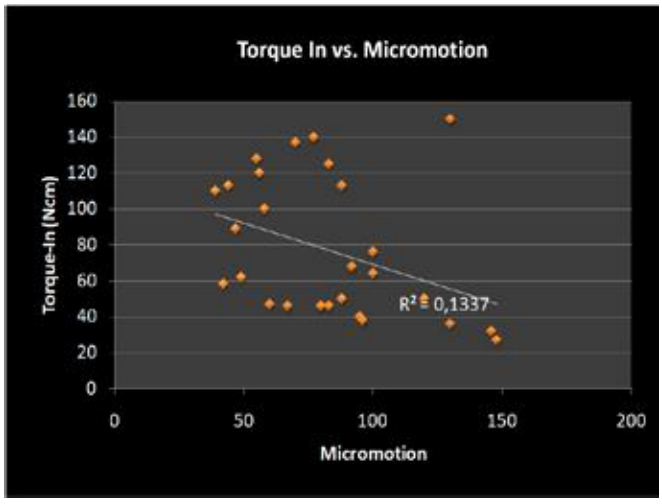

Figure 10. Regression analysis and Spearman's rank correlation coefficient showed a high dependence between the torque-in values and the micromotion values indicating that torque-in increases with decreasing micromotion values. The linear Pearson Coefficient of correlation (ρ) and (r^2) values for all the values of Torque-In and micromotion (Test-3) was ρ= -0.49 r^2=0.24 P=< 0.0059.

P=0.0394), even if it was statistically significant (Fig.9). When correlating the insertion torque to the micromotion, the linear Pearson Coefficient of correlation showed also a good correlation (ρ= -0.49, r^2=0.24, *P*=< 0.0059) (Fig.10).

The Anova test demonstrated that the ISQ data from the different bone density groups were not statistically significant (fig.11), but the micromotion and torque-in values between the different groups were statistically different (p<0.001).

DISCUSSION

It was suggested that the success of immediate loading on implants is not related to either immediate or delayed loading[15,16], but a critical micromotion threshold could be responsible for the peri-implant bone loss. For this reason, recently, primary stability has gained more and more interest in the scientific and clinical world of dental implantology. Primary stability is nothing more than the absence of micromotion immediately after implant placement. Unfortunately, nowadays there is no instrument which can directly measure the amount of micromotion in the mouth of the patients.

The RFA (resonance frequency analysis) is not a direct measure of the primary stability, but it measures the stiffness of the structure connected to the instrument. Despite the fact that RFA is today the most used method to measure primary stability in experimental studies, as well as in clinical practice, it has never been tested in direct relation to micromotion. To our knowledge the present study is the first that compares the ISQ value to the implant micromotion, which is the only direct measurement of the primary stability.

The results of the present study indicate that the ISQ value is related to the amount of implant micromotion with a statistically significant correlation.

When combining the samples from all the bone density groups together, the r^2 measured 0.52, meaning that 52% of the variance in the ISQ values could be explained by variations in the micromotion.

When the same analysis was plotted for the Hard and Normal Bone groups separately, this r^2 value raised up to 80% (H group r^2=0.80 and in N group r^2= 0.82), while in the Soft bone group this chance was much lower (53%, r^2=0.53). This means that the "Osstell ISQ" is more suitable for analyzing the primary stability in Hard and Medium bone than in Soft bone. In addition, when comparing ISQ from the different groups of bone density, the average values were not statistically different,

while the mean values of micromotion and insertion torque were statistically different between these groups. Looking at figure 5 it is possible to observe how, in many cases, the same ISQ values correspond to different amount of micromotion (Fig. 5).

One possible explanation of these results, is the fact that when loading an implant which is not integrated, as in the present case, it is possible that in our model, there is not only a shift between the implant and the bone itself, but also an elastic movement of the bone itself. This elasticity is different between different bone density and this could explain the different sensitivity of the ISQ between the different bone densities.

Another option could be the hypothesis that the RFA is more sensitive to the amount of cortical bone anchorage than of the trabecular bone, as suggested by other studies.[17-20]

In a study by Trisi et al. a correlation was found between the values of ISQ and the number of threads in contact with the compact bone, both on the crest and along the whole bone-implant interface; in some samples compact bone was found on the apex or along the lateral surface.[17] Similar results were found in a experimental study in cadaver jaws[18] in which the histomorphometric analysis was performed at the time of implant placement. The authors found that the BMD values, TBPf (trabecular bone pattern factor), BV/TV (density of trabecular bone) were not related to ISQ; while the BIC measured on the lingual aspect of the implants was positively correlated with ISQ values, and the correlation increased only when implants were in contact with the cortical bone. A similar positive correlation (the height of the cortical passage implants vs ISQ) was found by Miyamoto et al.[19], who measured digitally (Computed Tomography) the thickness of the cortical bone at the implant sites (mesial and distal). In another human study a micro-CT was used for measurements of the BVD (bone volume density) and BCT (bone trabecular connectivity) of the implant site before the insertion of the implant, no significant correlation was found with values of ISQ.[20]

The results of the present study support the hypotheses that RFA is more sensitive to the rigidity of the bone-implant complex within the compact bone than in cancellous bone.

Measuring the primary stability of an implant being subject to immediate load is of utmost important since it has been shown that micromotion in the healing phase may be detrimental to the interfacial bone.

In the past, it was generally agreed that implant interface failure was a consequence of bone resorption due to excessive load.[3] In contrast to this hypothesis, a series of experiments have been conducted where both the displacement and the load were controlled, and it was clear that the resorption was induced by instability, even when only small loads were applied.[3,21,22] These experiments showed that, in cortical bone, a displacement of only a few micrometers at the bone interface can induce resorption of the bone surface. This resorption process increases the distance between the mobile surfaces, thus placing deformation or 'strain' on regenerating tissues.[3,22] The basic working hypothesis of this 'strain' theory[3] is that, when bone segments are tightly compressed, leaving only a small gap

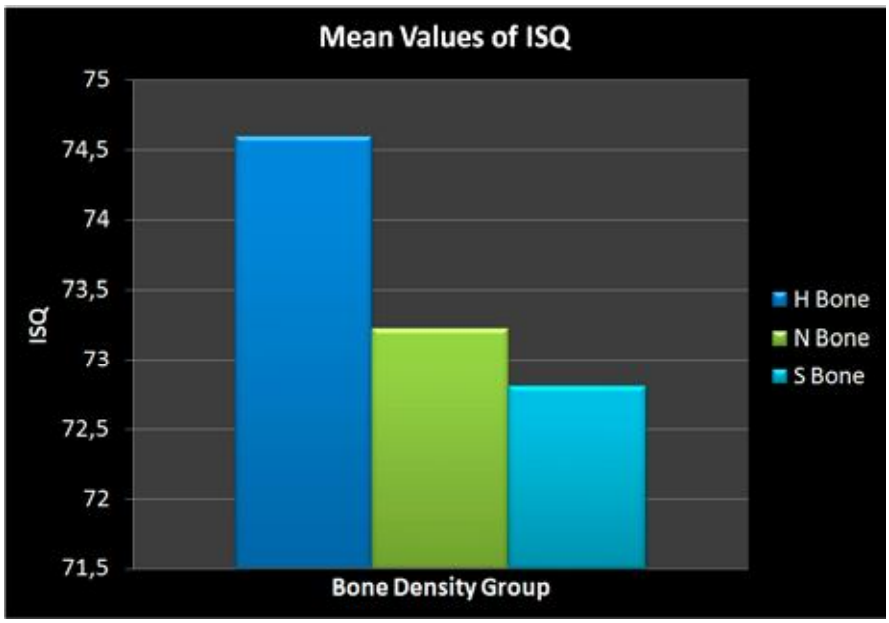

Figure 11. The Anova test demonstrated that the ISQ data from the different bone density groups were not statistically significant (fig.11), but the micromotion and torque-in values between the different groups were statistically different ($p<0.001$)

between them, then almost no movement should be allowed at their interface. Otherwise, even movements in the micrometer range could induce a stretch, or a strain, that could destroy the new cells and vessels forming in the gap. In such a case, osteoclasts enter the gap and begin to reabsorb bone in order to increase the space over the critical threshold of strain of the regenerated tissue.

A similar mechanism can be hypothesized to be involved in the failure of immediately loaded implants. Previous animal studies reported a micromotion above the range fo 50-100 micrometers could induce bone resorption at the interface, thus producing fibrosis and ultimately failures of immediately loaded endosseous implants. [16,23,24]

Human studies assert a correlation between the values of RFA (ISQ) measured at the time of implant placement and the values of insertion torque[25-27]. In other studies, this correlation was confirmed for Hounsfield values of the implant site calculated using TC[28-29].

Currently, 2 RFA machines are in clinical use: the Osstell[tm] device (Integration Diagnostics AB, Göteborg, Sweden) and Implomates (Bio Tech One,Taipei,Taiwan). Osstell combines the transducer, computerized analysis and the excitation source into one machine closely resembling the model used by Meredith. In the early studies, the Hertz signal was used as a measurement unit. [6-9,30] Later, Osstell created the implant stability quotient (ISQ) as a measurement unit in place of Hertz. Resonance frequency values ranging from 3500 to 8500 Hz are translated into an ISQ of 0 to 100, where a high value indicates greater stability, whereas a low value implies instability. The manufacturer's guidelines suggest that a successful implant typically has an ISQ greater than 65. An ISQ < 50 may indicate potential failure or increased risk of failure.[31]

Only very wide ranges are hypothesized since there are many variables that come into play. Literature data help identify the numerous factors that can influence such measurements, as for example, the characteristics of the bone tissue (density and quality), mono and bicortical anchoring of the implant,[32] the inclination of the transducer,[33] the effective length of the implant above the bone crest, the diameter of the implant, the micro and macro geometry of the implant [34].

The results of the present study showed that the ISQ values is statistically related to the micromotion and to the insertion torque values, indicating that ISQ increases with decreasing micromotion values and with increasing torque-in values. There are, however, literature reports that demonstrate a lack of correlation between the Torque-In test and ISQ values measured at implant insertion on cadavers[18,35] in humans[27,36,37] and in dogs[38]. In the first study[27] the cutting-torque at the crest (first third of implant insertion) was related to the ISQ, while the overall insertion torque values was not related to the ISQ.

The peak insertion torque measures the maximum torque of insertion obtained during implant placement until it is totally lodged in its site. Such a procedure may be influenced by the preparation of host bone sites, the bone density and the type of implant (self-tapping or not, cone-shaped or cylindrical, surface roughness). Trisi et al. found that high insertion torque values correspond to a high degree of primary stability of an implant, and increasing the peak insertion torque reduces the level of implant micromotion.[13] In addition, micromotion in soft bone was found to be consistently high and in the soft bone it was not possible to achieve more than 35 N/cm of peak insertion torque, when placing standard cylindrical screw type implants with a blasted surface. As well, in the present study the correlation between torque-in values and the implant micromobility values was also demonstrated, but as opposed to the Trisi et al. study[13] it was possible to attain peak insertion torque values in soft bone, up to 62 Ncm. This could be explained by the fact that the implant surface used in the present study is a laser-microfused titanium powder one with a much higher surface roughness able to increase the grip during implant insertion.

It was also shown that insertion torque values are correlated to bone mineral density (BMD) of the receiving bone site, obtained by measuring TC or micro TC[39-41], or by the sensitivity of the operator during the preparation of the surgical site[14]. Such measurements have therefore been considered valid instruments for the determination of the quality of the implant site, and can foresee good primary stability of the implant.

It must be pointed out that in the present study the ISQ was measured using the latest version of the machine, i.e. the new "Ostell ISQ" instrument, which is claimed to be less sensitive to

electromagnetic noise. This fact should be considered when evaluating the results of the present study in comparison to previously published papers.

In conclusion, the present study shows an inverse correlation between the ISQ and micromotion, demonstrating that it is able to understand if an implant is more stable than another. Nevertheless similar values of ISQ were found for quite different micromotions and for this reason the ISQ value cannot be taken as an absolute substitute of the micromobility of an implant.

It must be underlined that the present is an in vitro study and the results cannot be directly transferred to clinical applications. Specific clinical follow-up studies are necessary to confirm the hypotheses that a certain amount of micromotion could be responsible for implant failures under immediate loading conditions.

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