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# Early loading (4 weeks) of dental implants Impladent in maxilla and mandible - monitoring of the healing process using resonance frequency analysis

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*Quintessenz Vol.14, No. 9, 2005*

*The aim of the study was to assess the impact of a reduced (4-week long) healing period following the application of an implant - Impladent STI BIO with a bioactive surface - in the maxilla and mandible with a statistical evaluation of the success rate. The statistical analysis included an evaluation of primary stability of implants and of the factors that influence primary stability, as well as concurrent monitoring of the time-dependent development of implant stability during the healing and fully-functional periods using resonance frequency analysis.*

## Introduction

There are certain conditions that enable the early, or even immediate, loading of implants as an alternative to the more 'classical' two-phase implantation process<sup>1,2,3,4,5</sup>. The classical implantation process involves a healing period of no-direct-loading, lasting six months for implants inserted into the maxilla and three months for mandible implants, using a titanium screw implant with a machined surface<sup>6</sup>. This ensures the needed immobility of the implant at the beginning of the healing period: necessary for the development of secondary stability of the implant, which results in the long-life of the fully-loaded implant<sup>7</sup>. A shorter healing period, or its complete elimination, brings with it new demands on both the primary and secondary stability of the implant. Primary implant stability is mainly dependent on the mechanical characteristics of the bone (its local quality and quantity), the type of implant used (its geometry, diameter, length and surface) and the method of insertion. Secondary stability represents an enhancement of stability as a result of new bone formation and its 'remodelling' at the contact surface of bone/implant and within the implant's surroundings. The use of a shorter healing period has to be compensated by an early and sufficiently fast increase in secondary stability that can withstand the expected demands of implant loading. Exceeding the limits of implant immobility might result in unwanted fibrous encapsulation of the implant and its subsequent failure<sup>8,9,10,11</sup>.

In order to achieve faster healing, the macro-morphology of the titanium surfaces of implants may be modified by sand-blasting, or the micro-roughness modified using acid-etching or anodic oxidation in mineral acids. Currently, a new generation of implant surfaces is appearing (e.g. STI-Bio, Osseospeed), initiated through the development of some chemical modification of the surface in order to obtain a specific surface reactivity - called *bioactivity*. This bioactivity of the surface stimulates the formation of calcium phosphates on the implant's surface immediately after implantation, i.e. at a time when the synthesis of bone minerals by osteogenic cells is not yet possible. Bioactive surfaces are characterized by their perfect hydrophilic character (wetting properties), high surface area and high levels of hydration<sup>13,28</sup>.

Implants STI-BIO with their bioactive surface initiate osseointegration faster and thus hasten the needed development of an implant's secondary stability<sup>12,13,14</sup>. The shorter healing period of Impladent implants achieved through their bioactive surface (STI BIO) – six weeks for a mandibular implant and twelve weeks for the maxillary implant – has already been documented by a clinical study<sup>15</sup>. The present study evaluates the possibility of a further reduction of the healing period to four weeks in both the maxilla and mandible, using Impladent BIO-surface implants. Resonance frequency analysis (RFA) was used to assess primary implant stability and the factors that influence it, and also to check the development of implant stability during the periods of healing and full-use.

The aim of this paper is to provide a description of the treatment protocol and an evaluation some two and half years after its first use.

## Material and methods

Between October and December 2004, altogether 90 implants of Impladent STI BIO (LASAK, Praha, Czech Republic) were implanted (Fig.1). This involved 34 patients, 22 men and 12 women, aged between 26-71 years (the average age was 51.5 years). None of the patients were diagnosed with any medical contraindication for implantation. Out of the total number of 90, 53 (58.9%) implants were implanted in the maxilla and 37 (41.1%) in the mandible. Indications are summarised in Table 1. A two-stage procedure was used in all cases. One week after implantation healing cylinders were introduced, and four weeks (at the latest) after implantation the implants were loaded using provisional restoration fixed to temporary abutments (Fig. 2). Thirteen weeks after implantation, at the latest, the provisional restoration was replaced by the final supraconstruction (Table 2). Bone quality, classified as D1, D2, D3 or D4 according to Lekholm-Zarb<sup>16</sup>, was assessed during the bone bed preparation using resistance as a subjective measure<sup>16a</sup>. The primary stability of implants and was evaluated in two ways: by measuring the insertion torque and with the use of resonance frequency analysis (RFA) by Osstell (Integration Diagnostics AB, Göteborg, Sweden). Insertion torque was measured using a ratchet torque-control adapter (Lasak) at the final position of the implant in the bone bed (ITf). With resonance frequency analysis, the range of the dynamic resonance frequency of the whole complex - transducer/implant/bone - (3,500 Hz – 8,500 Hz) is divided into 100 'intervals' and expressed as ISQ (Implant Stability

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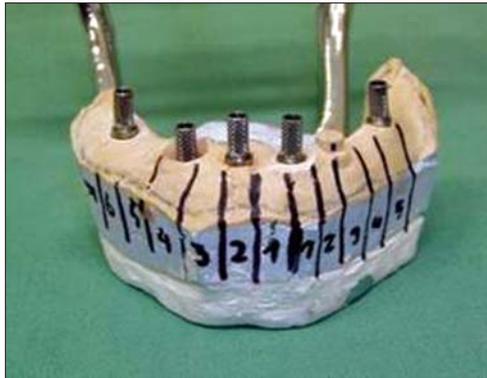
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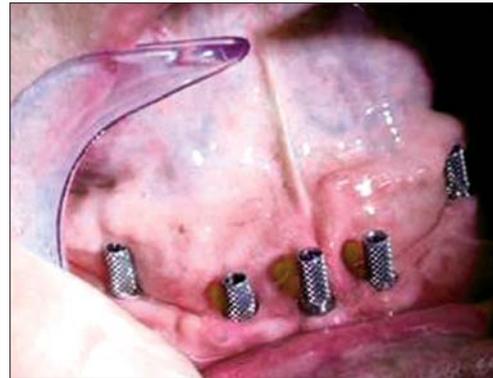


Fig. 1: Implants Impladent STI BIO - 3.7 and 5 mm in diameter

Quotient) from 0 to 100. Implant stability values, ISQ(t), were always measured by RFA at weeks one, four and thirteen after implantation (time t being measured in weeks). Change in implant stability after t weeks of healing, DISQ(t), was expressed as the difference between the stability in a given week of healing [ISQ(t)] and primary implant stability (ISQp). The success rate was assessed following Albrektsson<sup>17</sup>. Implants considered as successful were every loaded implant that: was clinically not moving; did not cause any chronic discomfort (pain or other); showed no observation of repeated infections or radioluscent bone in the implant surroundings; and did not show progressive marginal bone loss. For the



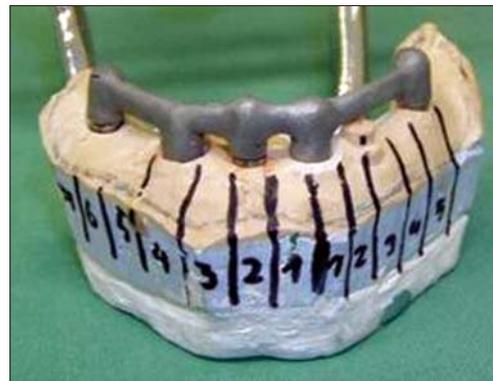
a)



b)



c)



d)



e)



f)

Fig. 2: Making temporary prosthesis (c,d) from acrylate on temporary abutments Impladent (a,b) and final prosthesis with a screw-retained metal-ceramic bridge (e,f). The implant in localization 33 showing a remarkable reduction in stability during the first week after implantation (d(ISQ(1))=-11) was not loaded by a temporary prosthesis (c,d) and was later explanted. When healed, reimplantation in the same localization was done and the implant was loaded with final prosthesis (e,f).

evaluation of success, life-table analysis was used. Data obtained on implant stability underwent statistical analysis (mean value and standard error). Differences of experimental data were tested using a twin-tailed Student's t-test (Type 2), being statistically significant if  $p < 0.05$ .

Tab. 1: Indication

	Loss of one tooth	Shortened dental arch	Large gap	Edentulous jaws
Maxilla	10	4	4	5
Mandible	4	6	2	4
Total	14	10	6	9

Tab. 2: Supraconstruction

	Individual crown	Fixed bridge	Hybrid prosth
Maxilla	10	11	-
Mandible	4	11	3
Total	14	22	3

Tab. 3: Dimensions of implants used

diameter/length [mm]	8 mm	10 mm	12 mm	14 mm
5.0 mm	2	9	17	2
3.7 mm	-	6	25	29

Tab. 4: Implant frequency per bone quality

Bone quality	Maxilla	Mandible
D1	9	13
D2	41	36
D3	3	4
D4	0	0

## Results

### Primary stability

Mean primary stability (ISQp) of all introduced implants was  $60.2 \pm 7.7$  ( $n=90$ ). Altogether six parameters that could influence primary stability were considered: implant localization (maxilla and mandible), bone quality, diameter and length of implant, and the means of implant insertion. The primary stability of mandible implants was statistically somewhat higher  $63.6 \pm 7.8$  ( $n=37$ ) in comparison to maxilla implants  $57.8 \pm 6.6$  ( $n=53$ ), ( $p=0.0003$ ). In the mandible,

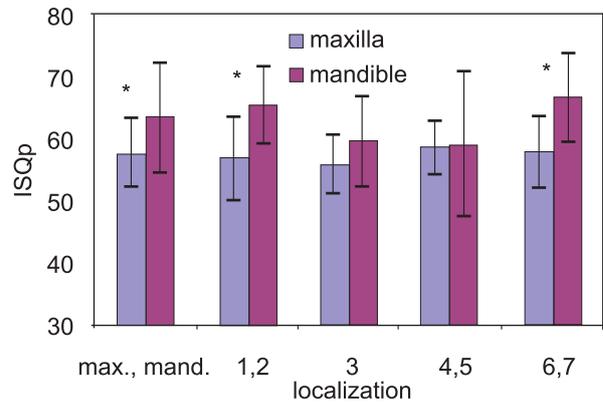


Fig. 3: Primary implant stability ISQp according to the localization in maxilla and mandible (\* )  $p < 0.05$

primary stability (ISQp) was higher for all teeth positions compared to those in the maxilla. For the position 3 (canine) and 4, 5 (premolars), however, the difference was not statistically significant (Fig. 3).

The data obtained on stability were further analyzed to assess the implant's impact on the bone. With decreasing bone quality (D1"D2"D3), the decrease in primary stability of implants was statistically significant (Fig. 4). In turn, bone quality had an impact on the insertion torque, which at its final position may indicate the primary stability of the implant<sup>18</sup>. Mean values of final insertion torques of the implant groups, divided according to bone quality, became lower with lowering bone quality (Fig. 5) in a similar way to that of ISQp (Fig. 4). Analysing the data for individual implants ( $n=90$ ) showed that the final insertion torque ( $IT_f$ ) and primary stability (ISQp) were directly related:  $[IT_f] = 0.5 Ncm$ ,  $[ISQp] = -6.3$ ; though the correlation coefficient was low ( $R^2=0.1892$ ).

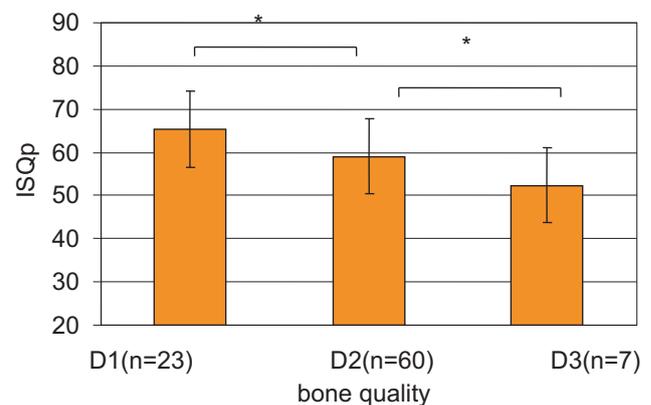


Fig. 4: Mean values of primary implant stability according to bone quality - categories D1, D2 and D3 after Lekholm-Zarb (\* )  $p < 0.05$

The diameter of the implant was found to be an important parameter having an influence on primary stability of the implant. Implants with a diameter of 5.0 mm showed a higher primary stability of  $62.4 \pm 7.8$  ( $n=30$ ) compared to implants with a diameter of 3.7 mm with  $59.0 \pm 7.4$  ( $n=60$ ), the difference being statistically significant ( $p=0.0485$ ). There was no significant correlation of primary stability of the implant and implant length. The measured differences of

implant stability for various implant lengths were not statistically significant.

Another studied factor that has an influence on primary implant stability was the selected surgery procedure. Groups of implants with high (ISQp>60), medium (ISQp=50-60) and low (ISQ < 50) primary stability were assessed. Within the group ISQp>60, a statistically-significant higher mean primary stability (ISQp) was found in implants where the bone bed had been prepared using a threadformer rather than the drill alone. Within the group with lower primary stability (ISQp=50-60 and ISQ<50), higher ISQp was observed in self-tapping implants but this was not statistically significant (Fig. 6).

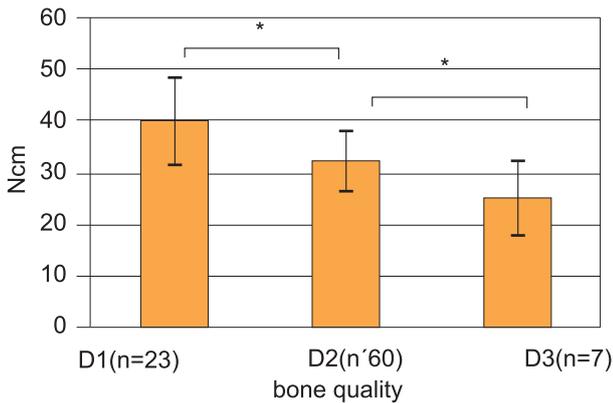


Fig. 5: Mean values of implant insertion torque according to bone quality - categories D1, D2 and D3 after Lekholm-Zarb (\*) p<0.05

### Loaded implant stability 13 weeks after implantation

The mean value of stability of loaded implants 13 weeks after implantation (ISQ<sub>13</sub>) was 59.1±5.2 (n=88). For the mandible the value of ISQ<sub>13</sub> reached 62.8±5.3 (n=36) and for the maxilla ISQ<sub>13</sub> 56.4±3.7 (n=52). Bone quality did not influence implant stability measured 13 weeks after implantation. Mean values of implant stability ISQ<sub>13</sub> did not show any statistically significant differences between implant groups of varying bone quality (Fig. 7). In contrast, the impact of implant diameter was statistically significant. Implants of 5.0 mm in diameter showed higher stability ISQ<sub>13</sub> 61.6±6.3 (n=30) than implants of 3.7 mm in diameter (ISQ<sub>13</sub> = 57.4±4.2; n=58).

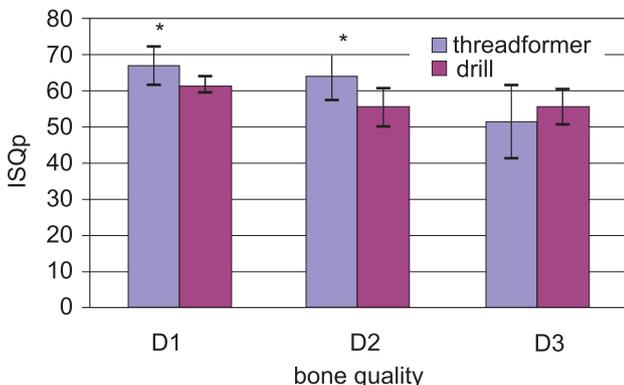


Fig. 6: Mean values ISQp of implants inserted into bone bed prepared by threadformer or drill, for implants of ISQp >60, 50-60 and <50 (\*) p<0.05

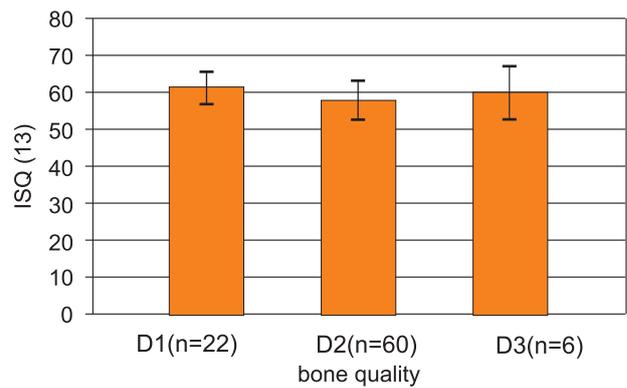


Fig. 7: Mean values of implant stability 13 weeks after implantation ISQ<sub>13</sub>, for implant group categories D1, D2 and D3 after Lekholm-Zarb

### Development of implant stability during the periods of healing and functional loading

Primary stability of implants had an essential impact on the development of secondary stability during the healing and loading periods. Figure 8 shows the development of implant stability for high (ISQp>60), medium (ISQp=50-60) and low (ISQp<50) primary stability, the mean values being ISQp 66.3±3.8 (n=45), 56.7±2.0 (n=34) and 45.8±3.9 (n=11), respectively; differences of mean ISQp values are statistically significant (p<0.05). In the group ISQp> 60, implant stability initially declined but after the first week remained stable. The group of implants with medium ISQp did not show any statistically significant changes either during the healing period or within the thirteen weeks of functional loading. The group of implants with low primary stability showed an increasing enhancement of stability since the first week of the healing period and through the period of functional loading studied.

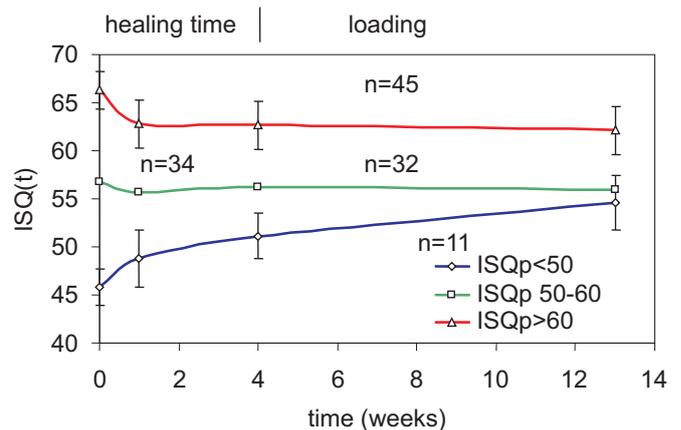


Fig. 8: Time dependence of stability ISQ(t) for implant categories (ISQp >60, 50-60 and <50) during the healing period (0-4 weeks) and functional loading (4-13 weeks)

### Implant failure

Within the study group, two implants were lost during the healing period. The first case was a 63-year-old man, with an implant 3.7 mm in diameter and 12 mm in length, inserted in tooth location 33, of bone quality D1; during the healing period, the implant stability ISQp value of 55 had markedly decreased 44 by week 4, [dISQ (0-4) = -11]. The second case

was a 63-year-old woman, with an implant of equal dimensions (3.7/12mm), implanted in location 25, and bone quality D3; the implant stability ISQp of 55 showed no significant change during the healing period,  $DISQ(0-4) = 1$ . All other implants complied with the success criteria even after nine weeks of functional loading. The healing phase success rate (with a four-week-long healing period) reached 97.8% (97.3% and 98.1% in mandible and maxilla, respectively). The success rate of the nine-week functional loading was 100% (Table 5).

Tab. 5: Life-table analysis

Time period	Number of implants	Number of implant loss	Lost from evidence	Success rate (%)	Cummulative success rate (%)
Healing period (0-4 weeks)	90	2	0	97,8	97,8
Functional loading (4-13 weeks)	88	0	0	100	97,8

Tab. 6: Success rate of STI BIO implants for experimental and control set

Time period	Success rate per interval % (n- number of implants)		Statistical significance of difference between sets compared
	Experimental set – present study	Control set <sup>(15)</sup>	
Healing phase	97.8 (n=90)	99,1(n=582)	p=0.3998 NS
Mandible	97.3(n=37)	98,8(n=1013)	p=0.2678 NS
Maxilla	98.1(n=53)	98,4(n=431)	p=0.8877 NS
Functional loading	100 (n=88)	99,5(n=771)	p=0.5012 NS

NS –statistically insignificant difference

## Discussion

A healing period reduced to four weeks offers less time for osseointegration of an implant prior to its loading, which increases the risk of micromovements of the implant in the bone bed that can result in fibrous membrane formation when loaded <sup>8,9</sup>. In this case, a higher frequency of implant loss can be expected. The effect, therefore, of a reduced healing period was evaluated against a control group of implants STI BIO where a longer healing period (twelve weeks for maxilla and six weeks for mandible) was used and the results evaluated after twelve months of functional loading <sup>15</sup> (Table 6).

The statistical evaluation of success rate of the experimental and control implant sets did not show any significant difference during the healing phase or the nine-week loading phase tested. We can say, therefore, that the reduced healing period does not increase the risk of implant loss compared to the original twelve-week healing period for the maxilla and six-week period for the mandible.

Resonance frequency analysis allows for an objective assessment of the implant stability with sufficient exactness and reproducibility of results ( $\pm 0.5$  ISQ units). The method, however, does cover an aggregate of implant stability, based on the dynamic resonance frequency of the whole complex: transducer/implant/bone, including the stiffness of their connections. The higher the frequency, the higher is the stiffness of the measured complex. When interpreting data, it has to be borne in mind that the value of ISQ combines a number of factors.

Amongst the six parameters assessed, the highest impact on implant stability was found to be the location in maxilla or mandible, bone quality, the method of implant insertion and implant diameter. The higher primary stability found for the mandible ensures implant immobility and a higher success rate when compared with the maxilla <sup>19</sup>. The main difference can be attributed to bone density and to some extent also tooth location <sup>20</sup>. The use of a threadformer to prepare the bone bed is characterized by its greater exactness and is less traumatic,

enabling a higher implant stability to be achieved and is in accordance with the Implants protocol. Some authors recommend the use of implants of larger diameter to deal with compromised clinical situations, with the expectation of enhancing the implant's primary stability <sup>21,22</sup>. Our results, that show a significantly higher primary stability for implants of 5 mm in diameter compared to those of 3.7 mm, confirm the above clinical assumption.

The development of implant stability with time during the first week after implantation is characterised either by a decrease or increase in stability, depending on the primary implant stability (Fig. 8). During the first of week after implantation, the stability decreases in cases where the primary stability was high ( $ISQ > 60$ ), being characterized by high insertion torque and high frequencies of dense bone. In this case, osseointegration can be seen as compensation for low mechanical fixation caused by relaxation processes and biological changes accompanying the early healing stage. The resulting stability (measured by RFA) after the first, fourth and thirteenth week following implantation was not decreasing further as the decrease in primary stability was fully compensated by increasing secondary stability due to the fast interaction between the implant's bioactive surface and the bone <sup>23</sup>. This situation makes it suitable for early implant loading and is typical for bone of high density (Fig. 10). The rate at which a stable boundary between the implant and the bone bed is formed, besides the primary stability, is given by the osseointegrative characteristics of the implant surface. When bio-inert surfaces (such as titanium with a machined surface) are used, secondary stability starts to grow later and thus, also, compensation of any marked decrease in primary stability occurs later. As an example can be given the loss of primary stability measured by a reverse torque method on machined surfaces of titanium implants when used in rats, where a decreasing reverse torque (reducing from 24 Ncm to 19 Ncm) was measured still four weeks following implantation <sup>24</sup> and clinical measurements using RFA which indicated decreasing implant stability for twenty weeks with

machined titanium surfaces and for eight weeks with the oxidized surface TiUnite<sup>25</sup>. A sand-blasted and acid-treated implant surface (SLA) tested on sheep using the reverse-torque method showed a decrease in stability from 100 Ncm to 88 Ncm after two weeks of implantation<sup>26</sup> and statistical tests on RFA data revealed decreasing stability up until the sixth week for implants of primary stability higher than 60 ISQ<sup>27</sup>. Implants of low primary stability, ISQp<50, showed increasing stability from the first week of the healing period (Fig. 8). These implants have a lower insertion torque (Fig. 9) and higher frequency of soft, spongy bone.

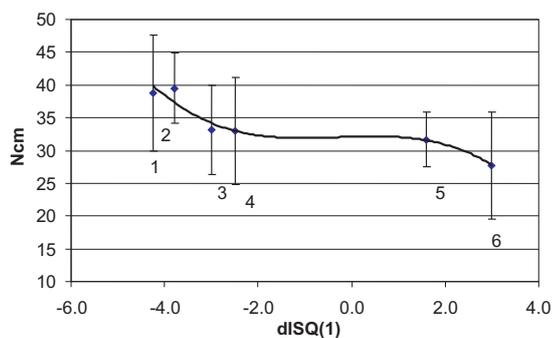


Fig. 9: Relationship of the implant insertion torque and the change in implant stability in the first week after implantation dISQ(1) for implant groups ISQp (1) >70, (2) 66-69, (3) 61-65, (4) 56-60, (5) 51-55 and (6) <50

A less traumatic preparation of the bone bed (in spongy bone with abundant blood supply), along with the bioactive properties of the STI BIO implant surface, are the main stimulators of a remarkable increase in secondary stability during the healing period of unloaded implants. In this case, the increased rate in implant stability is considered to be a critical parameter which decides when the implant can be loaded. This is especially true for bones of a lower quality. In bones of D3 quality, already after four weeks implants reached 98.7% of their final stability as measured thirteen weeks following implantation (Fig. 10).

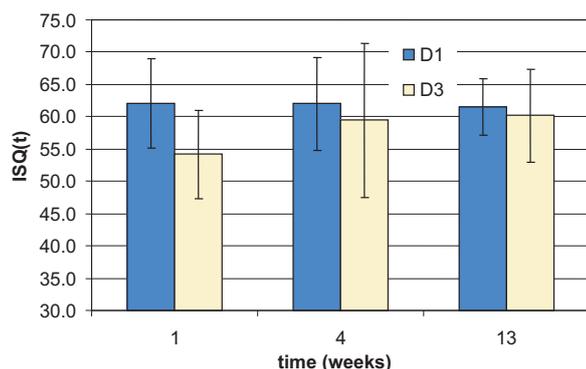


Fig. 10: Implant stability ISQ(t) after the first, fourth and thirteenth week of implantation for implants of bone qualities of D1 and D3

The value of primary stability of the implant, assessed by resonance frequency analysis does not unambiguously predetermine implantation success. The study presented did not find a difference in primary stability between implants that were lost during the healing phase and those that were successful and clinically stable when fully loaded thirteen weeks after implantation. However, a marked decrease in

stability often indicates unsuccessful implantation and calls for a specific treatment procedure (Fig. 11).

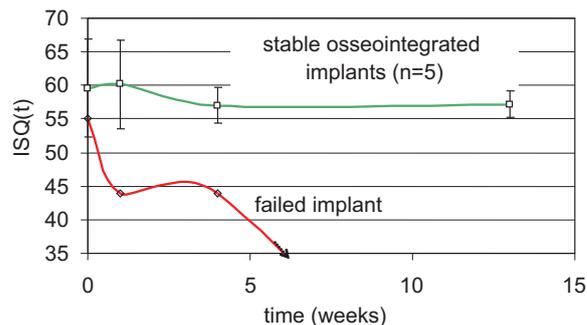


Fig. 11: Development of stability for a lost implant and for five clinically stable implants inserted in mandible (Fig. 2). Twenty percent of stability decline in week one after the implantation indicates unsuccessful implantation

## Conclusions

The statistical evaluation of data shows that, for Implants STI BIO implants, a healing period reduced to four weeks for both maxilla and mandible does not reduce the rate of the implants' healing success, nor does it increase the frequency of lost implants during the nine week period of full loading. The reduced healing period thus does not pose any enhanced risk on implantation and maintains the prediction of a similar success rate.

Primary implant stability is influenced by the implant localization, bone quality, selected insertion method, and implant diameter. Higher values of primary stability were found for mandibular implants ISQp 63.6±7.8 rather than maxillary implants ISQp 57.8±6.6. Bone quality mainly influences the primary stability of implants. ISQp within the higher D1 bone quality (65.3±8.8) was reduced by 10% within the group with D2 bone quality (59.1±6.2), and by 20% within the D3 bone quality group (52.4±8.8). Preparation of the bone bed in dense bone with the use of a threadformer, in accordance with the protocol for the Implants system, enabled a higher primary stability to be achieved. The implant diameter was found to have a significant impact on the implant's primary stability: implants with a diameter of 5.0 mm showed a higher primary stability 62.4±7.8 compared to implants with 3.7 mm in diameter, for which the primary stability was 59.0±7.4. The differences in stability for various implant lengths were not statistically significant.

The level of primary stability of the implant, assessed by resonance frequency analysis, does not determine unambiguously implantation success. It does, however, have an impact on stability development during the healing period and full loading.

## Acknowledgement

The study was funded by the grant MPO ČR FT-TA/087

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