Stability changes of implants placed with high insertion torque: a prospective clinical trial.

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Abstract

Purpose: To evaluate the changes in implant stability during a 12-week healing period, as assessed by the resonance frequency analysis (RFA), when implants are placed with high insertion torque.

Materials and Methods: From October 2019 to April 2020, 56 implants were included in the study. All implants were placed in healed ridges. Care was taken to properly undersize the osteotomy to obtain a high insertion torque. Using the RFA method, measurements of implant stability quotient (ISQ) were made at implant placement and after 3, 6, 9 and 12 weeks during the non-submerged healing period. Four measurements for each implant at each time interval were recorded, 2 in the bucco-lingual direction and 2 in the mesio-distal direction.
Results: Average insertion torque for the 56 implants was 72.41±8.89 Ncm. The average ISQ values were 74.72±4.08, 73.19±4.91, 73.51±4.86, 74.55±4.97, and 75.43±5.14 at 0, 3, 6, 9 and 12 weeks respectively. The slight average decrease of 1.53 ISQ units at 3 weeks was statistically significant (-p-value=0.036). A significant gradual increase occurred between the 3rd and the 12th week (-p-value =0.017). No difference was found between baseline and 12 weeks (-p-value= 0.361). Not all implants lost ISQ units at 3 weeks. While 36 implants lost an average of 4.64 ISQ units (-p-value <0.0001) at 3 weeks, 20 implants gained an average of 4.07 units at the same time interval (-p-value <0.0001).
Conclusions: Implant stability was relatively

maintained at high ISQ levels throughout the 12 weeks period. This study suggests that high peri-implant bone strain achieved during a high insertion torque implant placement is not deleterious to implant stability, but on the contrary it keeps the implant continuously stable throughout the healing period.

Keywords: insertion torque, implant stability, resonance-frequency analysis

INTRODUCTION

As described by Albrektsson in 1981, primary implant stability is one of the prerequisites to achieve osseointegration[1]. And more recently, with the immediate and early loading protocols, primary implant stability is considered to be one of the most important factors in achieving predictable outcomes[2,3]. The implant's macrodesign, the bone quality and the drilling procedure seem to influence the primary implant stability [4,5]. Underpreparation of the implant osteotomy and the use of self-tapping implants make it possible to increase the moment of force needed to screw the implant into position[6]. This moment of force is referred to as insertion torque. Trisi et al.[7] have demonstrated that increasing insertion torque reduces implant micromotion and hence improves primary stability. However, high insertion torque produces compression on the peri-implant bone. This had been claimed to induce ischemia and localized bone necrosis at the implant-bone interface which may lead to bone resorption and possibly to implant failure[8]. Classically, to achieve good primary stability without creating excessive compression on the peri-implant bone, it has been suggested that implants' insertion torque should be between 30 and 45 Ncm. Recently, some clinical papers reported positive results with the high insertion torque implant placement under various loading conditions. Calandriello et al. have inserted their implants with an insertion torque reaching 72 Ncm with an overall survival rate of 98% for a multiple unit immediate loading protocol[9]. Khayat et al. have reached 176 Ncm (average 110.6 Ncm) with a 100% survival rate for a delayed loading protocol[6]. Grandi et al. have reached 80 Ncm (average 70.6 Ncm) with a 97.2 % survival rate for a single unit immediate loading protocol[8]. In an animal study, Trisi et al.[11] reported that high implant insertion torque (up to 150 Ncm, average 110 Ncm) in dense cortical bone, in an unloaded healing environment, did not induce bone necrosis or implant failure but increased the primary stability of the implants.

Resonance frequency analysis (RFA) is another method to assess primary implant stability[12]. Its main advantage is being noninvasive and its ability to assess implant stability changes throughout the healing period. The commercially available equipment converts the resonance frequency values into implant stability quotients (ISQs), which can be directly compared. This ISQ value varies on a 1–100 scale and, classically, it has been found to vary between 40 and 80; the higher the ISQ value is, the higher is the implant stability. Typically, after implant placement, stability as assessed by RFA is believed to drop. The timing of this drop in stability can start as early as the first week and can last up to 6 weeks. This drop in stability is believed to be associated with the bone remodeling phase that includes an osteoclastic activity. The implant stability starts rising afterwards to reach a plateau at the 7th to 16th week [13-18]. This pattern of stability changes have been typically described on implants inserted with a final seating torque not exceeding the conventionally set limit of 45 Ncm. To date, no study has been published to describe implant stability changes, as assessed by the RFA, of implants placed with high insertion torque.

The purpose of the present clinical study was to evaluate the changes in implant stability up to 12 weeks after implant placement, as assessed by the RFA, when implants are

placed with high insertion torque.

MATERIALS AND METHODS

The study sample was selected from consecutive patients who required implant rehabilitation in healed bone sites, treated in two private practices (RS and TG) between October 2019 to April 2020. The study was performed according to the last Helsinki Declaration for research involving human subjects. At the first visit, all patients were informed about both the study and of any possible alternative treatment. Written informed consent was obtained for each patient.

Patient selection

All patients were subjected to a preliminary evaluation of their medical and dental status. The inclusion criteria were: (1) at least 18 years of age; (2) sufficient amount of bone volume for placement of implants of at least 8 mm in length and 3.7 mm in diameter. Bone dimensions were measured on preoperative computed tomography scans; (3) healed bone sites, i.e. at least 6 months post-extraction; and (4) adequate oral hygiene, i.e. Plaque Index [19] ≤ 2.

Exclusion criteria were: (1) systemic disease that could compromise osseointegration; (2) irradiation in the head and neck area; (3) treated or under treatment with intravenous amino-bisphosphonates; (4) uncontrolled diabetes; (5) substance abuse; and (6) heavy smoking (>10 cigarettes daily).

Implant placement

The patient was anesthetized by local infiltration with 4% articaine combined to 1:100,000 epinephrine (Septanest®, Septodont, France). A midcrestal incision was performed, followed by elevation of a mucoperiosteal flap. The osteotomy was prepared and the implant was placed at the crestal level. Care was taken to properly undersize the osteotomy to be able to achieve high insertion torque values. During implant surgery, bone type was categorized following the classification of Lekholm & Zarb[20]. Tapered self-tapping implants were used (JDEvolution plus®, JDentalCare, Modena, Italy). Final insertion torque was measured with a calibrated torque wrench (JDTorque®, JDentalCare) allowing torque measurement within a range of 15-80 Ncm, with 5% precision. During the protocol formulation phase it was decided that implants with an insertion torque less than 45 Ncm will be excluded from the study. Care was taken not exceed the 80 Ncm insertion torque at final seating by repeated unscrewing and rescrewing of the implant when needed. After implant placement, a healing abutment was placed and the soft tissues were sutured with 4–0 vicryl sutures (Ethicon, Inc., Somerville, NJ, USA). All patients were instructed to use 0.2% chlorhexidine mouthrinse twice daily, commencing the day following the intervention and thereafter for a two-week period. Anti-microbial prophylaxis was obtained with the use of 1g of amoxicillin (Amoxil, Glaxosmithkline plc, UK) twice daily for 6 days, starting 1 h before surgery. The implant was allowed a non-submerged healing period of 3 months. Three qualified surgeons inserted all the implants.

Measurements

The primary outcome variable of the study was the ISQ value recorded at implant placement (baseline), at 3, 6, 9 and 12 weeks after implant placement. Measurements were performed using the Osstell Beacon instrument (W&H, Austria). At each time point, the healing abutment was removed and the smart peg type 32 (article no. 100440) was hand-screwed into the implant body as recommended by the manufacturer. Four measurements for each implant at each time interval were recorded, 2 in the bucco-lingual direction and 2 in the mesio-distal direction. For each implant, the same smart peg was

used throughout the study. Mean value were calculated for each implant and used for statistical analyses.

Peri-implant marginal bone level changes were evaluated on intraoral radiographs taken with the paralleling technique at implant placement, and at 12 months after implant placement. The measurements of bone level changes were made by an independent outcome assessor. Radiographs were scanned, digitized in JPG format, converted to TIFF format with a 600 dpi resolution and stored in a personal computer. Peri-implant marginal bone levels were measured using Image J 1.42 software (National Institute of Mental Health, Maryland, USA). The software was calibrated for every image using the known implant length. Measurements of the mesial and distal crestal bone levels adjacent to each implant were made to the nearest 0.01 mm and averaged at patient level and then group level. The measurements were taken parallel to the implant axis. Reference points for the linear measurements were the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact.

Statistical analysis

Statistical analysis was performed using the statistical package StatView (version 5.01.98, SAS Institute Inc, Cary, NC, USA). The level of significance was set at 5%. Repeated measure analysis of variance followed by Bonferroni multiple comparisons tests were conducted to explore significant changes in mean ISQ over time. The paired-samples t test was used to evaluate the bone level changes.

RESULTS

A total of 56 implants inserted in 54 patients were included in the study. Patients had a mean age of 52.8±8.3 (39.3 % male). 6 patients had medication controlled hypertension and 2 patients had controlled diabetes. 11 patients were smokers (less than 10 cigarettes per day). Post-surgical healing was uneventful. Pain and discomfort were within the limit of a flapped implant surgery. No dropout occurred and the data of all patients were included in the statistical analysis. Bone quality, implant position and dimensions (diameter and length) as well as insertion torque values are listed in Table 1. Average insertion torque for the 56 implants was 72.41±8.89 Ncm. After a healing period of 3 months, all implants were stable and were successfully loaded.

The average ISQ values were 74.72±4.08, 73.19±4.91, 73.51±4.86, 74.55±4.97 and 75.43±5.14 at 0, 3, 6, 9 and 12 weeks respectively (Figure 1). The mean ISQ decreased 1.53 units at 3 weeks, and the decrease was statistically significant (-p-value=0.036). A significant gradual increase occurred between the 3rd and the 12th week (-p-value = 0.017). No difference was found between baseline and 12 weeks (-p-value= 0.361).

Because there were some implants exhibiting a decrease in stability at 3 weeks and some others exhibiting an increase at 3 weeks, the study population was divided in 2 groups (Table 2) and a post-hoc analysis was performed. One group was labeled the "decrease at 3 weeks group", and the other the "increase at 3 weeks group".

Behavior of the "Decrease at 3 weeks group"

36 implants out of 56 (64.3%) constituted the "Decrease at 3 weeks group". Their mean insertion torque was 70.83 ± 9.2 Ncm. The mean ISQ decreased significantly after 3 weeks of 4.64 units (-p-value <0.0001), followed by a significant increase at week 9 (-p-value = 0.003). No significant difference was found between baseline and 12 weeks (-p-value= 0.189) (Figure 2).

Notably, 34 out of the 36 implants that constituted the "Decrease at 3 weeks" group were placed in type II and type III bone, only 2 were in type I bone.

Behavior of the "Increase at 3 weeks group"

20 implants out of 56 (35.7%) were "early risers". Their ISQ increased at 3 weeks. Their mean insertion torque was 75.25 ± 7.7 Ncm.

The mean ISQ increased significantly of 4.07 units after 3 weeks of implant placement (-p-value <0.0001). No difference was found between 3, 6, 9 and 12 weeks (-p-value=0.534) (Figure 3).
Notably, 5 out of the 20 implants that constituted the "Increase at 3 weeks" group were placed in type I bone.
Measurements from postoperative radiographs were analyzed in order to assess crestal bone level changes. The average value at baseline was -0.002 mm, which means that the implants were positioned at crestal level or slightly apical to it. After 12 months, an average of 0.41 mm (CI 95% 0.522; 0.263) of peri-implant bone was lost. The crestal bone level change between baseline and 12 months was statistically significant.

DISCUSSION

The purpose of this clinical study was to assess implant stability changes after high insertion torque implant placement over a 12-week healing period. We investigated the general pattern for stability changes of implants placed with high insertion torque and if bone compression caused by the high torque implant placement was deleterious to implant stability in the healing period.
Different methods have been used to monitor changes in implant stability. Removal torque and histological evaluation provide reliable data on the strength of the interface and the quality of implant anchorage in peri-implant bone [21]. But these methods being destructive are only applicable in an experimental environment. In this study the resonance frequency analysis method was used. RFA has been advocated to provide an objective measurement of implant primary stability and to monitor implant stability over the healing period and in the long term in a non-destructive manner[22].
In our study, the mean ISQ of implants placed with high insertion torque decreased 1.53 ISQ units between baseline and 3 weeks. The drop in implant stability in the early weeks of healing is commonly reported in the literature and is believed to be associated with the predominantly resorptive activity of the early bone remodeling phase[13-18]. Even though this average decrease of 1.53 ISQ units was statistically significant, it is considered to be relatively small in comparison to what is reported in the literature. Han et al. (2010)[17], for example, have reported a loss at 3 weeks of 2.7 and 4.3 ISQ units for SLA and SLActive Straumann implants respectively. Oates et al. (2007)[18] had the lowest dip at 4 weeks with a drop of 3.4 and 1.9 ISQ units for SLA and SLActive Straumann implants respectively. Barewal et al. (2003)[13] have reported a drop at 3 weeks of 1% in type I bone, 4.1% in types II and III and 8.6% in type IV. In comparison, the percentage ISQ loss at 3 weeks in our study was 2% for the types I, II and III combined, noting that only 7 out 56 implants were placed in type I bone. Comparing our results with the previously mentioned literature, we can assume that the small decrease that was observed in our study at the third week reflects the fact that the high initial implant stability was relatively maintained and that the surrounding bone did not seem to be negatively affected by the compression caused by the high insertion torque implant placement.
Although the general pattern is a slight decrease in stability at the third week, more than one third of the implant population showed an increase in stability at the third week. Actually 20 implants were "early risers" and showed an average increase at the third week of 4.07 ISQ units. The average insertion torque for the "early risers" was 75.25± 7.7 Ncm, whereas the average insertion torque for the 36 implants that experienced a drop in stability at the third week was 70.83± 9.22 Ncm. The difference between them was not statistically significant (-p-value = 0.062).
The decrease in stability at the third week is commonly reported in the literature[13-18],

however, the increase in stability at the third week, as noted in our study, is not. This increase in stability at the third week is difficult to explain because this period is dominated by an osteoclastic resorptive activity. The possible explanation is that the strong mechanical fixation that was achieved at baseline was not affected by the areas in the peri-implant bone exhibiting resorption and possibly, as explained by Trisi et al. [11], because the osteoclastic activity at this stage does not affect the bone-to-implant interface but it rather affects the more distant peri-implant bone. Trisi et al.[11] also suggested that the microcracks caused by the high insertion torque placement accelerate bone remodeling, causing earlier bone apposition on the implant surface. Interesting to note also, is the fact that 5 out of 20 implants (25%) that constituted the "early risers" group were placed in type I bone, whereas 2 out of the 36 implants (5.5%) that constituted the "decrease at 3 weeks" group were in type I bone. This distribution let us suppose that bone density could be a factor among others governing the pattern of stability changes, but the sample was too small for conclusive evidence.

After the third week, the average ISQ value increased gradually to score 71.49± 4.69 at 6 weeks, 73.36± 5.31 at 9 weeks and 74.78± 5.80 at 12 weeks. This increase in stability is in accordance with the reported literature and corresponds to the bone apposition period[13-18].

A limitation of the present investigation is the small sample size. Randomized clinical trials with larger sample sizes and longer follow-ups are needed. Another limitation could be the potential role of the implant design that was not investigated. In this study a tapered self-tapping implant with aggressive thread design was used, and the findings cannot be generalized on all implant macrogeometries. According to Sennerby and Meredith [23], macrogeometry and implant design affect implant primary stability, and it is possible that other more heterogeneous implant designs, cylindrical or with marked steps and edges along the implant surface may result in greater bone remodeling when using high insertion torque because of stress concentration. In our study sample a marginal bone loss of 0.41 mm was recorded at 1 year which is in agreement with a pervious report using implants with the same geometry and placed with high insertion torque[24].

Although all implants placed in this study were successfull, generalizing the recommendation for high torque implant placement should be considered with caution. Clinical experience and technical skills are required from the practitioner to be able to fully seat the implant in dense bone without risking bone fracture in thin crest.

Although the RFA method did not reveal any deleterious effect caused by bone compression generated by the high torque implant placement, and even though implants placed with high torque relatively maintained their stability throughout the 12-weeks healing period, long term prognosis is yet to be established. These preliminary results must be confirmed by larger and longer follow-ups, and the phenomenon of the "early risers" deserves a more in depth investigation. Further histological studies on biological reactions of bone under pressure generated by high insertion torque are needed.

CONCLUSION

Within the limitations of this study we can conclude that over a 12-week healing period, implants placed with high insertion torque were able to relatively maintain their stability. The bone compression generated by the high insertion torque did not seem to negatively affect the implant stability.

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TABLES AND FIGURES

Table 1 : Bone quality, position, final seating torque, and dimensions (diameter and length) recorded for the inserted implants (n=56).

	Frequency
Bone quality	
Type I	7
Type II	39
Type III	10
Position	
Maxilla	13
Mandible	43
Insertion Torque (Ncm)	
50	1
55	1
60	8
65	10
70	6
80	30
Diameter x Lenght (mm)	
3.7x10	5
3.7x11.5	3
3.7x13	2
4.3x10	22
4.3x11.5	4
4.3x13	9
4.3x8	6
5x10	1
5x11.5	3
5x8	1

Table 2: Stability changes of the “Decrease at 3 weeks group” and of the “Increase at 3 weeks group”

		Mean	Std. Deviation	N
"Decrease at 3 weeks" group	ISQ at Baseline	75.9653	2.99354	36
	ISQ at week 3	71.3264	4.14721	36
	ISQ at week 6	71.4931	4.68641	36
	ISQ at week 9	73.3681	5.31188	36
	ISQ at week 12	74.7847	5.79506	36
"Increase at 3 weeks" group	ISQ at Baseline	72.4875	4.84393	20
	ISQ at week 3	76.5500	4.43491	20
	ISQ at week 6	77.1375	2.49668	20
	ISQ at week 9	76.6875	3.49141	20
	ISQ at week 12	76.6000	3.52939	20

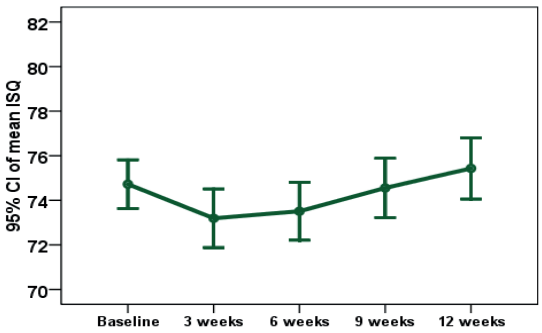

Figure 1 : Mean ISQ values recorded at each follow up interval

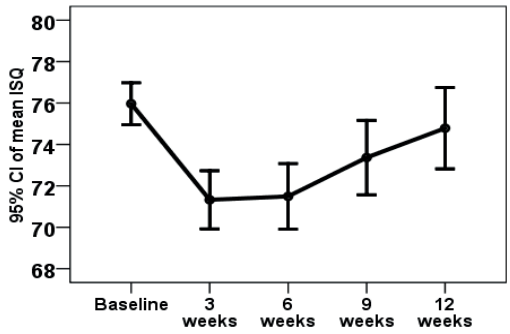

Figure 2 : Stability changes of the "Decrease at 3 weeks" group

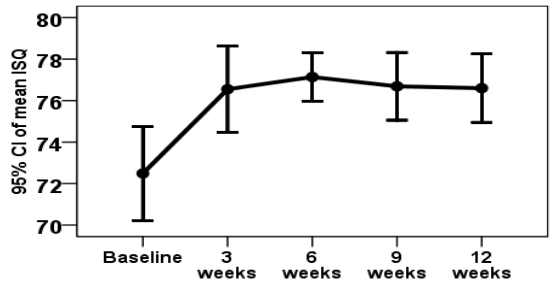

Figure 3 : Stability changes of the "Increase at 3 weeks" group