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Effects of osseodensification on primary stability of cylindrical and conical implants - an *ex vivo* study

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Abstract: Primary stability is an important factor for dental implant success. In the past years, a new method for bone site preparation was introduced, named osseodensification (OD). OD produces a condensation of the trabecular portion of the bone, increasing bone-to-implant contact and primary stability. This study aims to compare the effect of OD in cylindrical and conical implants to conventional instrumentation. A total of 40 implants, divided in 4 groups, were placed in porcine tibia: cylindrical conventional (1a); cylindrical OD (1b); conical conventional (2a); and conical OD (2b). Each implant was measured for implant stability quotient (ISQ), insertion torque (IT) and removal torque (RT). Group 2b showed the higher values for each of the evaluated parameters; groups 1b and 2b showed better results than 1a and 2a, respectively. Regarding IT and RT, group 1b achieved higher values than group 2a, but not for ISQ. The inter-groups comparison showed significant difference between groups 1a vs 2a, 1a vs 2b and 1b vs 2b for ISQ, and 1a vs 1b and 1a vs 2b for RT analysis. OD resulted in improved ISQ, IT and RT of both cylindrical and conical implants. Conical implants groups showed higher ISQ, but cylindrical OD resulted in higher IT and RT, compared to conical conventional ones.

Keywords: dental implants; osseodensification; primary stability; macrogeometry

1. Introduction

Dental implants represent one of the greatest advances in oral rehabilitation. Initially indicated for specific patients, for lower full arch fixed rehabilitation, combined with upper arch denture, it underwent many improvements which led to broaden indications in cases of partial, upper total fixed or removable dentures, and single elements in situations where the aesthetic result is mandatory [1-3]. The treatment time also decreased, due to evolutions in implant macro- and microgeometry, surface treatment, types of implant/abutment connection [4-8]. Besides, the technique of bone instrumentation of the implant site is an important factor that has been intensively studied in order to improve the primary stability of dental implants, especially in areas with low density bone [9-11].

Primary stability of dental implants is an important factor to achieve clinical success, at least, in the early stages of bone healing. Some techniques are based on sub-instrumentation procedures, aiming to increase the initial bone-to-implant contact and bone density

around the implant, especially in areas of type IV bone (Misch classification) [12-15]. However, the sub-instrumentation technique is not always achieved and therefore, it might compromise the secondary implant stability [10,16,17].

Osseodensification (OD) is an osteotomy bed technique that preserves the bulk bone and increases bone density by compacting the bone from the instrumentation itself, causing expansion of the ridge and increasing its density [18]. The resulting bone quality around the implants can be improved, increasing primary stability torques even in unfavorable situations. Several *in vitro* [18,19], animal [20-23] and human studies [24,25] have been carried out, demonstrating the improvement of the previously mentioned biological factors in the peri-implant bone, which leads to a greater probability of treatment success [26]. Moreover, the total treatment time, compared to the traditional techniques, is reduced, leading to greater patient satisfaction. Osseodensification burs can be used in both conical and cylindrical macrogeometry implants, but, as conical ones have been predominant, the majority of the clinical studies evaluated dental implants with conical macrogeometry [21,23,24,26,27].

The aim of this *ex vivo* study is to compare the level of initial stability by assessing the implant stability quotient (ISQ), initial insertion torque (IT), and removal torque (RT) of dental implant with different macrogeometry, cylindrical and conical, inserted in fresh porcine bone tibia, comparing the conventional bone instrumentation and OD.

2. Materials and Methods

2.1. Sample Preparation

An experimental *ex vivo* study model was designed, using fresh commercially available porcine tibia cuts, belonging to animals of the same age and gender, after removal of all attached soft tissue and exposing a flat surface of medullar bone, similar to bone density III-IV, as described by Misch [28]. Since no animal sacrifice was carried out, there was no need for an Ethical Committee approval for this study. It was determined by ANOVA Post hoc analysis, that a sample size of 10 implants per group is necessary to provide a 90% power with an α of 0.05. The implants used are Tryon, 4.0x11.5mm (SIN, São Paulo, Brazil), double acid etched, of different macrogeometric format, conical (Tryon Sc) and cylindrical (Tryon St).

Four different groups with 10 implant sites each were selected based on the osteotomy technique:

Group 1a – Conventional instrumentation for 4.0 cylindrical implants (Tryon St, SIN Implants, São Paulo, Brazil), in type III-IV bone – FRLTD 2020, FHTD 2015, FPTD 2030, FHTD 3015;

Group 1b – OD instrumentation (Versah, Jackson MI, USA) for 4.0 cylindrical implants (Tryon St, SIN Implants, São Paulo, Brazil), in type III-IV bone – pilot (clockwise), VT 1828, VT 2838, VS 3238 (counter clockwise);

Group 2a – Conventional instrumentation for 4.0 conical implants (Tryon Sc, SIN Implants, São Paulo, Brazil), in type III-IV bone – FRLTD 2020, FHTD 2015, FPTD 2030, FTCD 35, FTCD 40;

Group 2b – OD instrumentation (Versah, Jackson MI, USA) for 4.0 conical implants (Tryon Sc, SIN Implants, São Paulo, Brazil), in type III-IV bone – pilot (clockwise), VT 1828, VT 2838 (counter clockwise).

The characteristics and design of Tryon St and Tryon Sc implants (SIN Implants, São Paulo, Brazil) are shown in Figure 1 a, b.

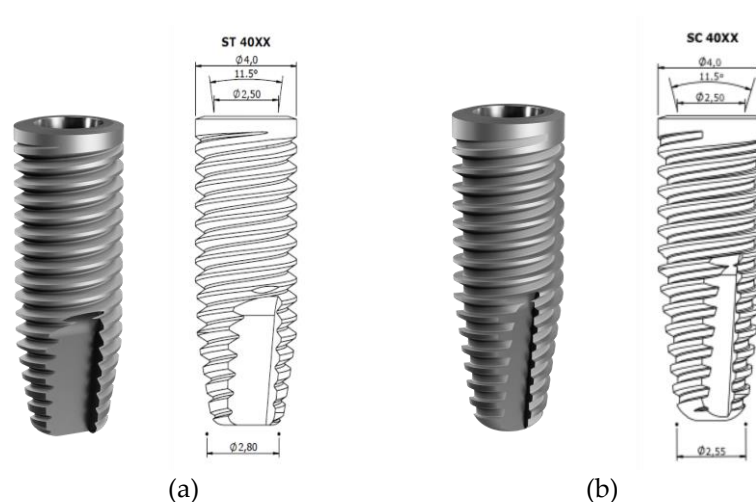


Figure 1. Implant characteristics and design: (a) Tryon St (SIN, São Paulo, Brazil); (b) Tryon Sc (SIN, São Paulo, Brazil).

The implants are being characterized by the same diameter, length and surface topography, the difference consisting only in macrogeometry- cylindrical or conical. Instrumentation was performed under abundant saline irrigation, at 1200 RPM, 50N torque, by means of an NSK Surgic Pro (NSK-Nakanishi, Tochigi, Japan) surgical motor, using a NSK 20:1 handpiece (NSK-Nakanishi, Tochigi, Japan) by the same operator, in order to avoid inter-operator discrepancies. All implants were installed at bone level (Figure 2).



Figure 2. Implants placed in porcine tibia.

2.2. IT, ISQ, and RT assessment

The surgical motor was used with an auto-setting of 10 RPM for implant insertion, with the torque adjusted at 10 Ncm. The value is being gradually increased by 5 Ncm after each stall of the handpiece, in order to allow registering the peak value of the IT, when the implant reaches bone level position. The last torque on the motor that stalled the handpiece was recorded. The ISQ values were assessed by using the Osstell Beacon (Osstell, Goteborg, Sweden), by registering the value on the four faces of each implant (anterior, posterior, medial and lateral, considering the anatomical position of the tibia) (Figure 3), and the average value was assigned for each implant [29]. The RT was noted as the last torque assigned on the motor, settled on reverse direction and starting at 5 Ncm, that would be able to move the implant in the counterclockwise direction, and was increased by 5 Ncm until the implant started moving. The motor was checked and calibrated after each test to assure the integrity of the results.



Figure 3. ISQ measurement of implant placed in the porcine tibia.

2.3. Statistical Analysis

The statistical analysis of the results was performed using a STATA 13 software (StataCorp LLC, College Station TX, USA). The ANOVA test was performed to evaluate the distribution of the continuous variable (IT, ISQ, RT) between groups. A p-value of 0.05 was established as the level of significance. Descriptive statistics (mean, median, standard deviation, interquartile range, minimum, maximum and statistical graphs) were calculated for quantitative variables. The premises for applying variance analysis (one-way ANOVA) were checked through normality tests, variance homogeneity tests and adjustments via statistical tests (Fisher test, in the case of homogeneity and Welch test in the case of heterogeneity) as well as visualizations of the results through graphs. The Shapiro-Wilk test was used to verify the normality of the samples in each group and in each quantitative variable. Fits were observed via tests and QQ-plot graphs. Bartlett's test was used to verify homogeneity of variances. In the case of statistical significance, in the presence of homogeneous variances, Tukey post-hoc tests were performed, and in the presence of non-homogeneous variance, Games-Howell tests were used. For all analysis, a statistical significance level of 5% was considered. The free Jamovi [30], R [31] and Python [32,33] software was used to create tables, graphs and statistical analysis.

3. Results

A total of 40 implant site instrumentations (n=10 for each group) were assessed in this study, divided in 4 groups (1a, 1b, 2a and 2b). All bone instrumentations and implant placements were performed by the same experienced operator.

ISQ value ranged between 44 for group 1a to 61.5 for group 2b. Mean values of ISQ were 48.6 ± 3.3 , 50.8 ± 3.0 , 53.2 ± 2.6 and 55.3 ± 3.1 for groups 1a, 1b, 2a and 2b, respectively. Inter-group analysis showed a significant difference between groups 1a vs 2a, 1a vs 2b, and 1b vs 2b. OD instrumentation groups (1b, 2b) reached higher ISQ values than conventional instrumentation groups (1a, 2a), and conical implants (group 2a, 2b) reached higher ISQ values than cylindrical implants (group 1a, 1b).

Regarding IT, its minimum values are quite similar for all groups, and its maximum values vary from 30 Ncm (group 1a) to 60 Ncm (group 2b). No significant difference was noted ($p > 0.05$). RT showed a significant difference between groups, with the lowest mean RT of 8.5 ± 4.7 for group 1a and the highest mean RT of 30.0 ± 18.1 for group 2b (Table 1, 2).

IT and RT showed a similar behavior, with group 1b reaching higher values than group 2a, which was not the case of ISQ measurements.

Figures 4, 5 and 6 show the values range for ISQ, IT and RT, respectively.

Table 1. Comparison of mean and median ISQ, IT and RT with minimum and maximum values for each group.

Parameter	Group	Mean \pm SD	Median \pm IQR	Minimum	Maximum	ANOVA P-Value
ISQ	1a Cylindrical conventional	48.6 \pm 3.3	49.5 \pm 4.4	44.0	54.0	0.0001
	1b Cylindrical OD	50.8 \pm 3.0	50.8 \pm 2.5	45.5	55.5	
	2a Conical conventional	53.2 \pm 2.6	53.8 \pm 4.6	50.0	56.5	
	2b Conical OD	55.3 \pm 3.1	54.5 \pm 3.5	51.5	61.5	
IT	1a Cylindrical conventional	16.5 \pm 5.8	15.0 \pm 3.8	10.0	30.0	0.0619
	1b Cylindrical OD	26.0 \pm 11.3	27.5 \pm 13.8	10.0	45.0	
	2a Conical conventional	24.5 \pm 12.4	25.0 \pm 15.0	10.0	45.0	
	2b Conical OD	30.5 \pm 14.0	27.5 \pm 17.5	15.0	60.0	
RT	1a Cylindrical conventional	8.5 \pm 4.7	7.5 \pm 5.0	5.0	20.0	0.0017
	1b Cylindrical OD	21.5 \pm 12.0	22.5 \pm 13.8	5.0	40.0	
	2a Conical conventional	18.5 \pm 11.6	17.5 \pm 15.0	5.0	40.0	
	2b Conical OD	30.0 \pm 18.1	22.5 \pm 26.3	10.0	65.0	

Table 2. Inter-group comparison of mean IT, ISQ and RT (one-way ANOVA).

Comparison	ISQ*		IT*		RT**	
	Mean Diff.	P_Value	Mean Diff.	P_Value	Mean Diff.	P_Value
1a vs 2a	-4.6	0.008	-8.0	0.400	-10.0	0.105
1a vs 1b	-2.3	0.346	-9.5	0.254	-13.0	0.035
1a vs 2b	-6.8	0.000	-14.0	0.062	-21.5	0.019
2a vs 1b	-2.4	0.309	1.5	0.991	3.0	0.940
2a vs 2b	-2.2	0.378	-6.0	0.638	-11.5	0.360
1b vs 2b	-4.5	0.009	-4.5	0.809	-8.5	0.614

* Tukey post-hoc test. **Games-Howell post-hoc test.

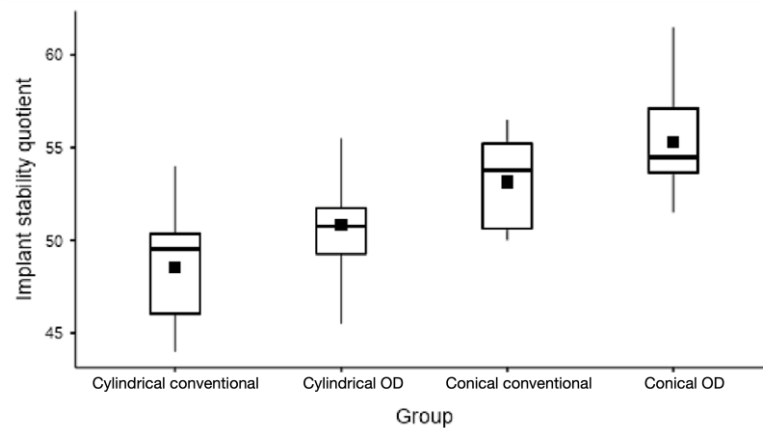


Figure 4. ISQ values divided by groups.

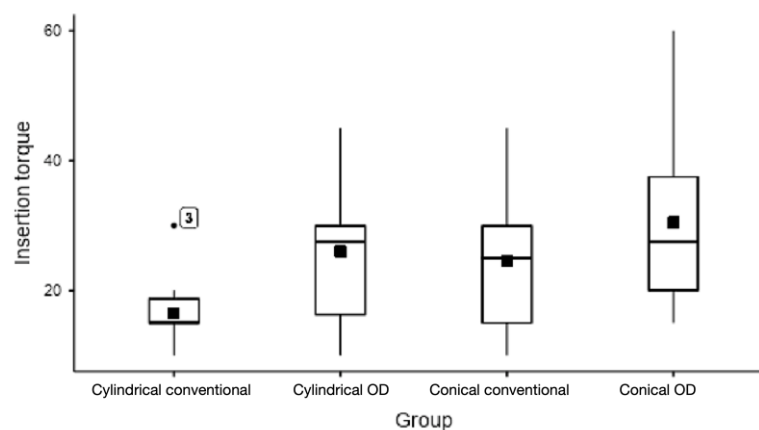


Figure 5. IT values (Ncm) divided by groups.

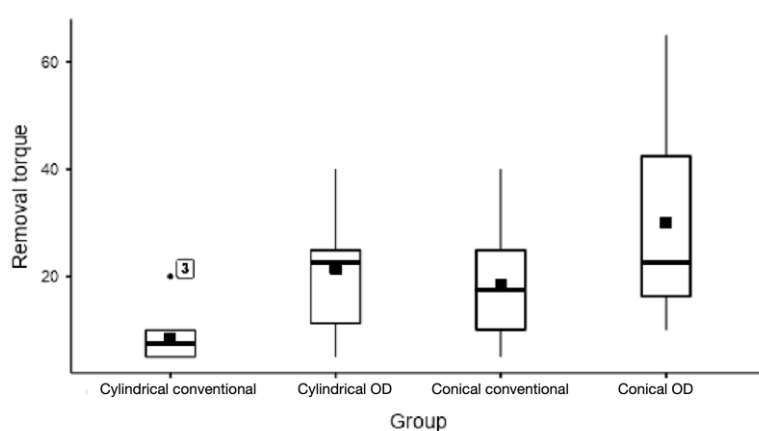


Figure 6. RT values (Ncm) divided by groups.

The measured values for all the samples and parameters are given in Appendix 1.

4. Discussion

The results of this study highlight that OD bone instrumentation for conical implants (group 2b) showed higher values for all analyzed variables. The second place for ISQ measurements belongs to the conventional bone instrumentation for conical implants (group 2a), while for IT and RT, OD bone instrumentation for cylindrical implants (group 1b) showed higher values. When comparing the techniques, OD showed improved parameters for both conical and cylindrical implant macrogeometries. These results are in accordance with previous published *in vitro* and *ex vivo* animal studies [18,19,29,34] which aimed to compare initial implant stability with/without OD bone instrumentation.

Conical implants are known to achieve better primary stability than cylindrical implants [35,36] which is an important factor for implant success [37-39]. The difference in results related to implant macrogeometry was evident in this study. When comparing group 1a with 2a, and 1b with 2b, significant differences in the ISQ values are to be found. Implants from the same manufacturer, with the same surface treatment, threads, diameter and length were compared, the only difference relying in their geometry, resulting in diminished bias.

Regarding IT and RT, the results of this study showed that the OD technique aided the cylindrical group (1b) to achieve higher values than the conical conventional one (2a). This result is in accord with recent studies which showed that OD could improve the bone to implant contact by dynamic condensation of the bone [40,41]. Both parameters had the same pattern in the results of all groups. Analyzing the results (Appendix A) for RT, both

OD groups (1b, 2b) achieved values closer to the IT ones, in comparison with the conventional instrumentation groups (1a, 2a), and, in some cases, even higher values were reported. This fact may be explained by the “spring-back effect” [18], caused by the OD bone instrumentation burs used in this study. This occurred when using both cylindrical and conical implants, and may be the reason why ISQ and RT resulted in significant differences between the groups, but not the IT.

Undersized instrumentation is a valid way to increase primary stability [12-14], this being the protocol indicated by the implant manufacturer (SIN, São Paulo, Brazil), and used in this study for low density bone. The OD protocol, however, suggests that the last drill should be a little closer to the diameter of the implant to be placed [18]. Nevertheless, both OD groups performed better than the conventional similar groups. The higher ISQ displayed by the conical conventional instrumentation (group 2a) compared to the cylindrical OD one (group 1b) is probably due to the undersized drilling of the first one, also because the design of the drill was made to fit with the implant design [42], but this improvement didn't reflect in IT and RT analysis.

The reason of using a porcine tibia [18,19,29,34] for this study, is because it consists mostly of type III and IV bone density, being a highly cancellous bone, that mimics the lower bone density areas of human jaws (upper posterior region), and this requires an increased primary stability of implants. Furthermore, it has been established that, in order to be condensed, the region of bone instrumentation must have less cortical and more medullar structure [17-21]. By increasing the ratio of bone to implant contact, primary stability increases and consequently the ability of the implant to withstand micromovements, which could lead to flaws in the osseointegration process [43,44]. By avoiding this problem, the transition from primary to secondary stability may occur by bone remodeling around a dental implant [20]. Because even the micro and nanogeometry of the implant surface may interfere with the process, our decision was to use implants with the same surface treatment, and even the same thread pattern [45,46], to eliminate as much bias as possible in the study. Other studies have compared results on primary stability of implants placed on synthetic polyurethane blocks [42-50]. But if we consider OD, these materials aren't the best choice for a real evaluation, as there is no collagen in the synthetic blocks, and it has been established that this is crucial for the technique [18]. Therefore, studies of OD carried out on synthetic blocks usually don't show the same results as *ex vivo* animal [18,19,29,34,51], *in vivo* animal [20-23], or clinical studies [24-26,40,41].

The limitation of this study is due to the method used for IT and RT measurement, which doesn't deliver an exact numerical value, but a closer one, jumping from each 5 Ncm. However, this methodology proved to be easily accessible for clinicians and surgeons on a daily implant practice. Another point is that ISQ is a valid parameter to assess the mechanical implant stability over time, and is considered to have predictive power for the clinical outcome [52,53], but may be questionable in static studies [53]. More clinical long-term studies are necessary to confirm the effects of OD on osseointegration.

5. Conclusions

Considering the limitations of this study it can be concluded that OD bone instrumentation increased the level of ISQ, IT and RT, compared to conventional bone instrumentation, in bone type III and IV. It can also be concluded that cylindrical implants inserted with OD display improvements when compared to conical implants inserted with conventional instrumentation.

Author Contributions: Conceptualization, M.C.F. and J.A.S.; methodology, M.C.F.; validation, J.A.S., R.S.S. and H.D.P.S.; formal analysis, H.D.P.S.; investigation, L.C.A.; resources, B.G. and L.C.A.; data curation, M.C.F. and J.A.S.; writing-original draft preparation, M.C.F. and L.C.A.; writing-review and editing, J.A.S. and A.P.; visualization, M.C.F.; supervision, J.A.S. and L.C.A.; project administration, M.C.F.; funding acquisition, B.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: The datasets used and/or analyzed during the current study are available in Appendix A.

Acknowledgments: The authors would like to thank SIN Implants for providing the implants used in this study.

Conflicts of Interest: The authors declare no conflict of interest.

Appendix A

Table A1. Values of ISQ, IT and RT, for conventional cylindrical instrumentation (group 1a).

Cylindrical Conventional Group 1a (sample number)	ISQ (mean for each implant)	IT (Ncm)	RT (Ncm)
1	49.5	20	10
2	51.5	15	10
3	54	30	20
4	50.5	15	5
5	46	10	5
6	49.5	20	10
7	44	10	5
8	44.5	15	5
9	46	15	5
10	50	15	10

Table A2. Values of ISQ, IT and RT, for OD cylindrical instrumentation (group 1b).

Cylindrical OD Group 1b (sample number)	ISQ (mean value for each implant)	IT (Ncm)	RT (Ncm)
1	45.5	15	10
2	55	40	40
3	55.5	45	40
4	50	25	25
5	51	10	5
6	50.5	30	25
7	52	30	20
8	48.5	20	15
9	49	15	10
10	51	30	25

Table A3. Values of ISQ, IT and RT, for conventional conical instrumentation (group 2a).

Conical Conventional Group 2a (sample number)	ISQ (mean value for each implant)	IT (Ncm)	RT (Ncm)
1	50	15	10
2	50	20	15
3	51	10	5
4	56.5	15	10
5	55.5	30	25
6	56	30	20
7	50.5	10	5
8	54.5	45	40

9	54.5	40	30
10	53	30	25

Table A4. Values of ISQ, IT and RT, for OD conical instrumentation (group 2b).

Conical OD Group 2b (sample number)	ISQ (mean value for each implant)	IT (Ncm)	RT (Ncm)
1	53.5	20	15
2	54.5	15	10
3	57.5	30	25
4	52	20	20
5	54	25	20
6	54.5	30	35
7	51.5	20	15
8	55.5	40	45
9	58.5	45	50
10	61.5	60	65

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