



JOIS

CLINICAL STUDY

Effects of osseodensification on implant primary stability in sites with reduced bone density: a five-year multicenter retrospective clinical study

ESTUDO CLÍNICO

Efeitos da osseodensificação na estabilidade primária de implantes em sítios com densidade óssea reduzida: um estudo clínico retrospectivo multicêntrico de cinco anos.

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**Keywords:**

Osseodensification; dental implants; bone density; osseointegration.

Abstract

Objectives: This retrospective study aimed to evaluate primary stability of dental implants with different macro designs placed in sites with low bone density using osseodensification (OD) instrumentation.

Material and methods: A total of 254 implants with 6 different macro designs were placed in 184 subjects (Females: 93, Males: 91) in 4 different treatment centers. Follow-up assessments ranged between 13 and 65 months. Implant primary stability measured by insertion torque value (ITV), was the primary outcome variable measured. Secondary outcome measures included implant stability quotient (ISQ) at different implant locations (maxilla vs. mandible), and implant success rate post definitive loading over the duration of the study. ISQ was measured at implant insertion and on a weekly basis at 1, 2, 3, 4, 5, and 6 weeks.

Results: All osteotomies were performed in low density bone (D3-D4) using OD instrumentation. ITV obtained for all implant systems, regardless of its geometry, demonstrated ITV greater than 40Ncm in sites with reduced bone density (D3, D4). ISQ values measured from weeks 0-6 revealed that all implant systems demonstrated high stability values followed by a slight reduction by week 3. ISQ values at week 6 were comparable to baseline for all implants placed. The overall success rate observed was 97.7%.

Conclusions: This multicenter retrospective study demonstrated that OD instrumentation is a safe method to achieve optimal primary stability in areas with low bone density, irrespective of implant macro design and surface characteristics. OD instrumentation resulted in high implant success rate.

Resumo

Objetivos: Esse estudo retrospectivo visou avaliar a estabilidade primária de implantes dentários com diferentes macros geometrias instaladas em sítios de baixa densidade óssea usando os princípios da osseodensificação (OD).

Material e métodos: Um total de 254 implantes com 6 diferentes macros geometrias foram instalados em 184 pacientes (93 mulheres e 91 homens) em 4 diferentes centros de tratamento. As avaliações de acompanhamento variaram entre 13 e 65 meses. A estabilidade primária do implante, medida pelo valor do torque de inserção (ITV), foi a principal variável de desfecho avaliada. As medidas secundárias de desfecho incluíram o quociente de estabilidade do implante (ISQ) em diferentes localizações (maxila vs. mandíbula) e a taxa de sucesso dos implantes após a carga definitiva ao longo da duração do estudo. O ISQ foi medido no momento da inserção do implante e semanalmente nas semanas 1, 2, 3, 4, 5 e 6.

Resultados: Todas as osteotomias foram realizadas em osso de baixa densidade (D3-D4) utilizando instrumentação de OD. Os valores de ITV obtidos para todos os sistemas de implantes, independentemente de sua geometria, demonstraram valores superiores a 40 Ncm em sítios com densidade óssea reduzida (D3, D4). Os valores de ISQ medidos entre as semanas 0 e 6 revelaram que todos os sistemas de implantes apresentaram altos valores de estabilidade, seguidos por uma leve redução até a semana 3. Na semana 6, os valores de ISQ foram comparáveis aos valores basais para todos os implantes instalados. A taxa geral de sucesso observada foi de 97,7%.

Conclusões: Este estudo retrospectivo multicêntrico demonstrou que a instrumentação de OD é um método seguro para alcançar estabilidade primária ideal em áreas com baixa densidade óssea, independentemente da macro geometria e das características de superfície do implante. A instrumentação de OD resultou em uma elevada taxa de sucesso dos implantes.

Palavras-chave:

Osseodensificação;
Implantes dentários;
Densidade óssea;
Osseointegração.



Introducion

Dental implants have been considered as a viable and predictable treatment option for the replacement of missing teeth¹⁻⁴. Implant macro design, bone-biomechanical interface, implant connection, and bone density are well reported factors in the literature to influence healing, adequate bone-to-implant contact (BIC), and osseointegration after implant insertion^{5,6}. Osseointegration is a histological term defined as a direct structural and functional connection between living bone and the surface of a load-bearing implant at light microscopy⁶. The clinical manifestation of osseointegration is the absence of implant mobility, and is known as functional ankylosis^{5,6}.

Implant primary stability results from the mechanical engagement of an implant with the surrounding bone⁷, whereas timely post-surgical bone deposition and remodeling determine the secondary (biological) stability of the implant⁸. The primary stability, which is essential for osseointegration, depends mainly on bone-to-implant adaptation and mechanical engagement⁹. It is clinically determined by insertion torque, which is an indicator that measures the axial friction resistance between the implant body and the osteotomy walls. Three main factors are known to affect primary stability: bone quantity and quality, the mechanical shape (macro design) of the fixture placed in the bone, and the surgical instrumentation¹⁰⁻¹³. Secondary stability involves uneventful initial healing process around the dental implant that leads to intramembranous bone deposition around the implant body¹⁴. It clinically assesses the implant micro deflection. It is measured by implant stability quotient (ISQ), which is a parameter related to time with a scale of 0-100, and is used to clinically assess implant stability over time during the early weeks of healing post implant placement¹⁰. The biological stability subsequently reaches its lowest parameter at three weeks post implant placement¹⁵, then progressively increases with time to reach its initial level as the surrounding bone heals and remodels¹⁶. This transition of biological stability occurs as bone apposition to the implant progresses, which securely stabilizes the implant in place¹⁷.

Studies investigating drilling methods for endosteal implant placement have relied mainly on subtractive drilling methods. A novel, non-subtractive universal bone drilling protocol known as Osseodensification (OD) has been developed¹⁸. It is defined as a dynamic non-subtractive bone instrumentation method that relies on bone plasticity to expand a pilot osteotomy and subsequently enhance bone density through compaction auto-grafting^{18,19}. It has been shown to cause a controlled plastic deformation of bone due to rolling and sliding contact

with specially designed densifying burs^{20,21}. These burs operate in both clockwise (CW) and counterclockwise (CCW) directions and have been compared to standard drills during osteotomy preparation¹⁸. When run in CCW directions, the densifying burs demonstrated significant bone compaction into the walls of the osteotomy sites when compared to the standard drills^{18,19}. Bone compaction has been reported as a method to improve early fixation stiffness and strength of implants^{18,19}. Compaction auto-grafting achieved with the densifying burs supplements the basic bone compression effect to further densify the osteotomy inner walls creating this density crust along the entire depth of the osteotomy, resulting in a well-adapted bone-to-implant surface²². The improvement of the early fixation strength is a result of both larger bone volume in the proximity of the implant and the gentle reversed compressive forces of the compacted bone towards the implant, also known as the "spring-back effect". It has been shown that bone compaction resulted in higher BIC and higher bone morphogenetic protein (BMP) expression, which accelerates bone formation by 50x (Regional accelerated phenomenon - RAP)²³. Perfect three-dimensional congruity will not exist between a surgically prepared bone site and the surface of a dental implant²⁴, since micro and macro-gaps or spaces at the interface will remain, as alluded by Brånemark^{5,6}. Gaps between the osteotomy and the body of the implant will be filled with a blood clot soon after surgery. If the implant remains stable, bone heals in these gaps by a process known as intramembranous bone formation²⁵. Intramembranous bone formation proceeds through a well-defined sequence of steps, including blood clot formation, angiogenesis, osteoprogenitor cell migration, woven bone formation, compaction of woven bone by deposition of parallel-fibered and lamellar bone, and eventually secondary remodeling of the woven bone¹⁷. Bone compaction through osseodensification not only improves implant primary stability but also reduces the level of implant micromotion and subsequently accelerate the process of the intramembranous bone formation around the implant body^{18,19}. In terms of healing time, it has been reported that bone goes through significant biological changes from the implant insertion day through the first six weeks of wound healing²⁶, it starts by the formation of new bone until bone remodeling at six weeks and continues until week 18²⁷. With osseodensification, the compaction autografting of autogenous bone provides spring back effect that leads to higher implants stability without the need to undersizing the osteotomies²⁸.



Furthermore, this compaction autografting also allows for faster formation of woven bone and subsequent deposition of bone, which enhances the implant healing process¹⁸.

Osseodensification has been clinically documented as a universal bone instrumentation method that enhances alveolar bone vertical and lateral quantity as well as its quality for optimal implant primary and secondary stability in both the mandible and maxilla. The aim of this study was to retrospectively evaluate OD protocols on implants primary stability, in sites with reduced bone density, and examine the long-term survival rate of implants with different macro designs.

Materials and Methods

This retrospective analysis was carried out in accordance with the Ethical standard according to 1964 Declaration of Helsinki and the directives given by IntegReview Institutional Review Board, which has determined retrospective this retrospective clinical study is considered exempt. An informed consent form was signed by all patients included in the study, both for the clinical procedure and follow-up appointments. All treatment steps and data collection were part of the routine procedures at the centers, and no extra measures were taken for the purpose of the study. All examiners were blind, since a random case number was allocated to the extracted data, ensuring patient anonymity and data protection. The study was structured following the STROBE statement.

A total of 254 implants were placed in 184 patients treated between May 2012 and December 2017 in four centers, by four early adopters of osseodensification (OD) protocols. These early adopters were calibrated on clinical bone density assessment according to Misch's classification as well as extensive calibration and training in OD protocols. No prior sample size calculation was performed due to the retrospective nature of the study. Inclusion criteria included ASA I and II patients, including subjects with controlled systemic conditions (well-controlled diabetes mellitus, hypertension) and light smokers (< 10 cigarettes/day) to have a realistic representation of the average dental implant patient population. Patients not systemically stable to undergo surgical procedures as assessed by primary care provider, heavy smokers (> 20 cigarettes/day), and without adequate bone volume for implant placement (< 8mm vertical, <5mm horizontal) were excluded from this study.

When low bone density was suspected through CBCT examination (D3 or D4 bone density),

osseodensification (OD) protocols for implant site preparation were implemented following the use of a standard pilot drill, according to manufacturer Densifying Reference Guide¹. Implants were placed in native bone or in sites that had been previously grafted (at least 3 months before implant placement for hard tissue augmentation and at least 2 months for soft tissue augmentation), in the maxilla and mandible. After a crestal incision, mucoperiosteal flaps were elevated to access the osteotomy site. If soft bone (D3-D4) was confirmed clinically with the pilot drill and according to Misch's bone density classification, osteotomy preparation progressed with specific OD protocols for each implant macro design was followed according to manufacturer¹. Six different implant macro designs were used: Tapered body with triple-lead cutting threads (TSV)², Tapered body with non-cutting 0.6mm thread depth (MA)³, Tapered body with buttress threads (ID), Tapered body with V-shaped threads (NR), Straight body with double threads (NO)⁴, and Straight body with V-shaped threads (EV)⁵. All patients received post-operative instructions to maintain a cold and soft diet for forty-eight hours and not to brush the surgical site for two weeks. Post-op medications were as follows: Amoxicillin 875mg 2x/day for 5 days and Tylenol 500mg PRN for pain control. Penicillin-allergic patients were prescribed Clindamycin 300mg 6h for 5 days. Implants were evaluated weekly for ISQ⁶ values. Restorative treatment was initiated when ISQ reached ≥ 70 .

Insertion torque value (ITV) was the primary outcome variable in this study and was measured utilizing standard insertion torque indicators. Implant stability quotient (ISQ) at 0, 1, 2, 3, 4, 5, and 6 weeks after implant placement in maxilla and mandible, and implant success rate were the secondary outcome variables. Implant success was defined as absence of mobility, pain, radiolucency, marginal bone loss > 1.5 mm, and suppuration.

Data was analyzed with specific software for statistical analyzes⁹. Unpaired two-tailed T-test was used at the implant level; also repeated measure ANOVA and Dunnett's multiple comparison test for intragroup analysis among the different time points within the same implant system; and one-way ANOVA and Tukey's multiple comparison test for inter-group analysis within the same point in time. Failed implants were excluded from the stability analysis but were including as part of the implant success rate reporting.



Results

Subject age ranged from 19 to 94 years-old and patient population included both males and females. Subject demographics is summarized in **(Table 1)**. All osteotomies were performed in low density bone (D3-D4) in both mandibular and maxillary sites, using OD protocols. No postoperative complications at the surgical sites were observed, except for six implants that failed to integrate during early healing (3 in the maxilla

and 3 in the mandible) and were surgically removed **(Table 2)**. Failed implants did not have weekly ISQ readings. Two other implants could not have weekly ISQ readings since they were placed according to a 2-stage protocol since bone augmentation procedures were performed at the time of implant placement. Overall implant success rate observed was 97.7%.

Table 1: Demographics

	TSV	MA	ID	NO	NR	EV
Males	20	10	15	10	15	22
Females	16	15	29	10	4	16
ASA I	14	14	27	12	12	29
ASA II	22	11	17	8	7	9
Non-smoker	27	19	35	13	16	27
Light Smoker	7	6	9	7	3	11
Mean Age	57.5 (23-79)	61.2 (43-94)	61 (19-82)	58.5 (31-73)	61.5 (47-78)	57.4 (23-79)

Table 2. Distribution of Implants Placed

Groups	Implants	Maxilla	Failed	Mandible	Failed
TSV	62	28	1	34	2
MA	57	26		31	1
ID	45	35	1	10	
NO	26	29		16	
NR	26	17	1	9	
EV	38	21		17	

TSV: ZimVie Taper Screw Vent; MA: Megagen Anyridge; ID: Implant Direct; NO: NeOss; NR: Nobel Replace; EV: AstraTech EV



When comparing ITV at the time of implant placement between maxilla and mandible for each implant system, TSV and ID achieved the highest ITV in both mandible and maxilla (Figure 1). However, all implant systems revealed ITV greater than 40Ncm at the time of placement in sites where soft bone (D3-D4) had been detected. When comparing ISQ values at the time of implant placement between maxilla and mandible for each implant system, TSV and MA achieved the highest ISQ values in the maxilla (Figure 2). In the mandible, the highest values were achieved by ID

and EV (Figure 3). However, all implant systems revealed mean ISQ values equal or greater than 70 at the time of placement in sites where low density bone had been detected. All implant systems revealed high ISQ values at the time of placement, with the most significant reduction at week 3, and an increase in secondary (biological) stability after that. Values at week 6 were comparable or greater to baseline for the 6 implant systems, confirming clinical functional ankylosis or osseointegration.

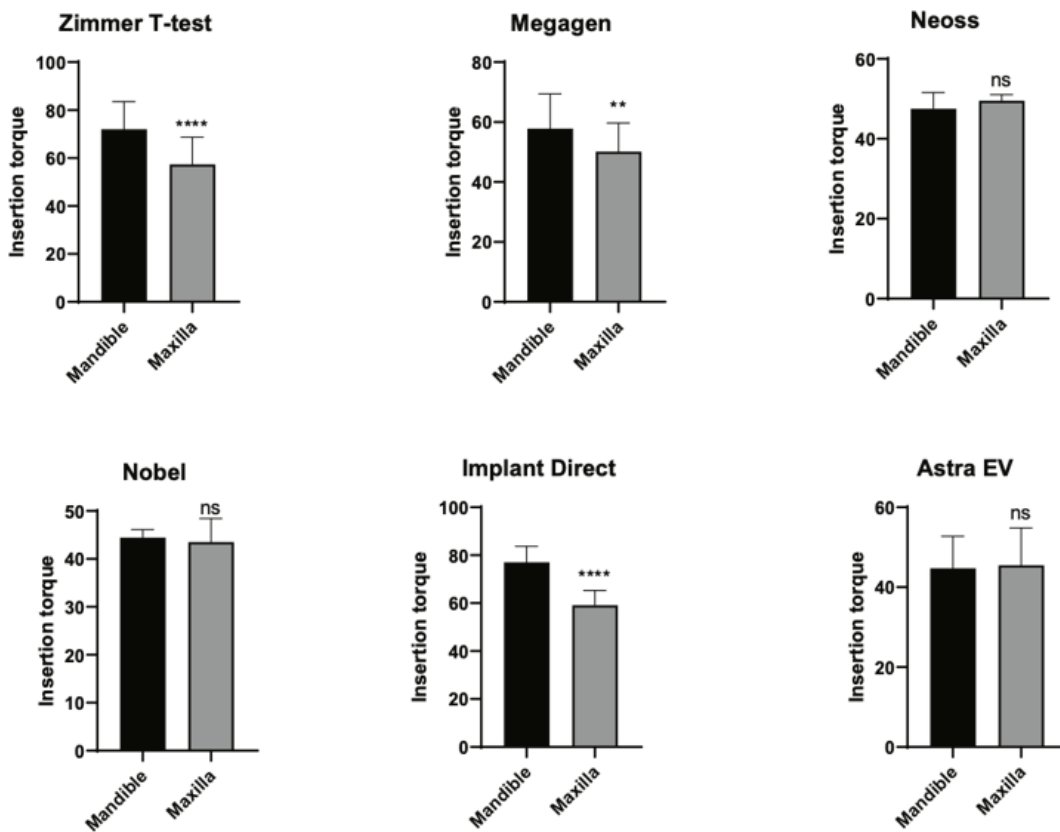


Figure 1 – ITV among the different implants systems in maxilla vs. mandible
 Unpaired two-tailed T-test for measurements at the implant level. Significance is compared to mandible. Failed implants were excluded from analysis. **p<0.01; ****p<0.0001; ns – not significant.

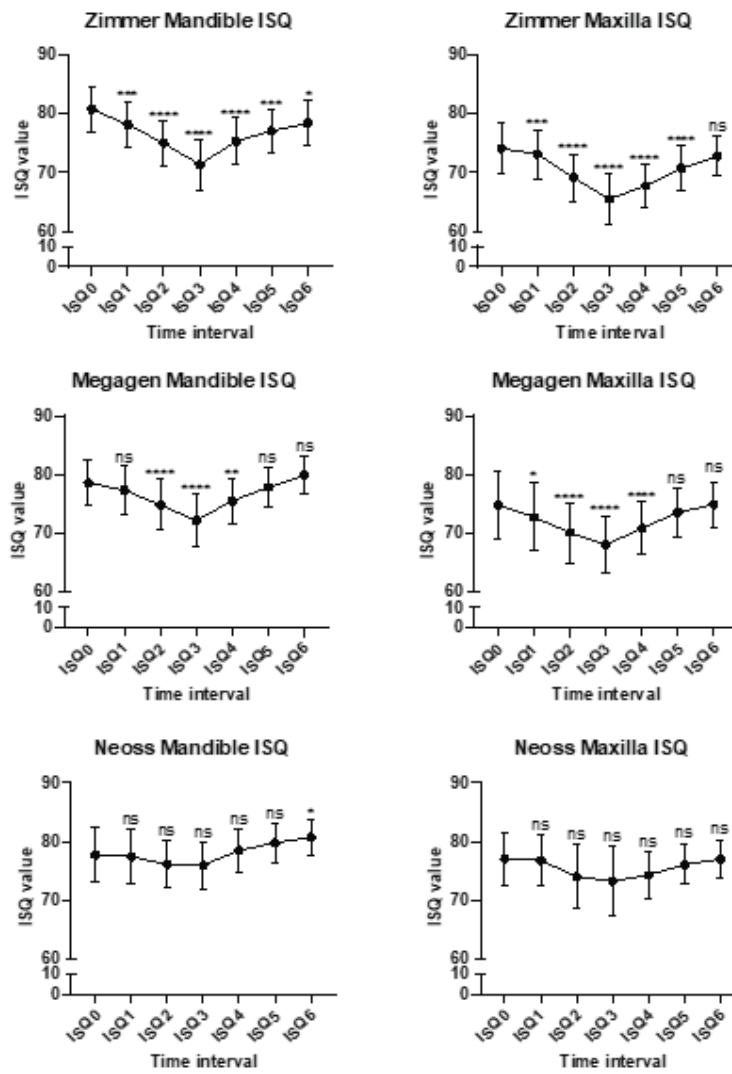


Figure 2 – ISQ values in the mandible from 0-6 weeks after implant placement

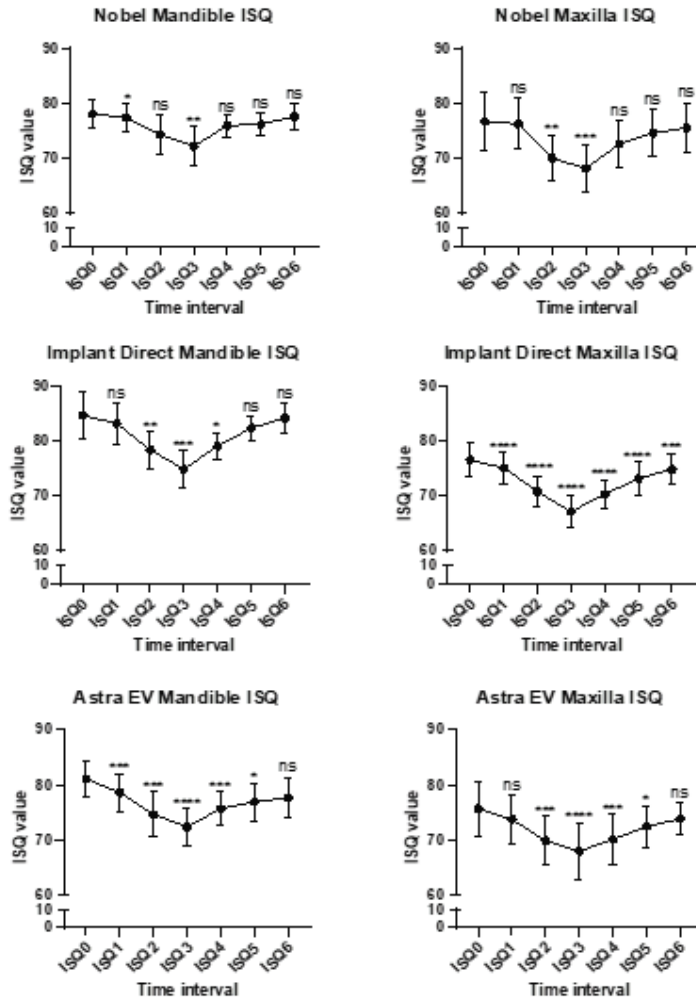


Figure 3 - ISQ in the Maxilla from week 0-6 weeks after implant placement. Repeated measure ANOVA and Dunnett's multiple comparison test; significance is compared to ISQ0 values. Failed implants were excluded from analysis. *p<0.05; **p<0.01; ***p<0.001; ****p<0.0001; ns - not significant.

Inter-group analysis revealed statistically significant higher ITV at the time of placement for TSV and ID in the mandible and for ID in the maxilla (Figure 4). Inter-group analysis of ISQ after 6 weeks revealed statistically significant superior ISQ

values for ID in the mandible and for NO in the maxilla (Figure 5). The ISQ values among the other implant systems were not statistically significant.

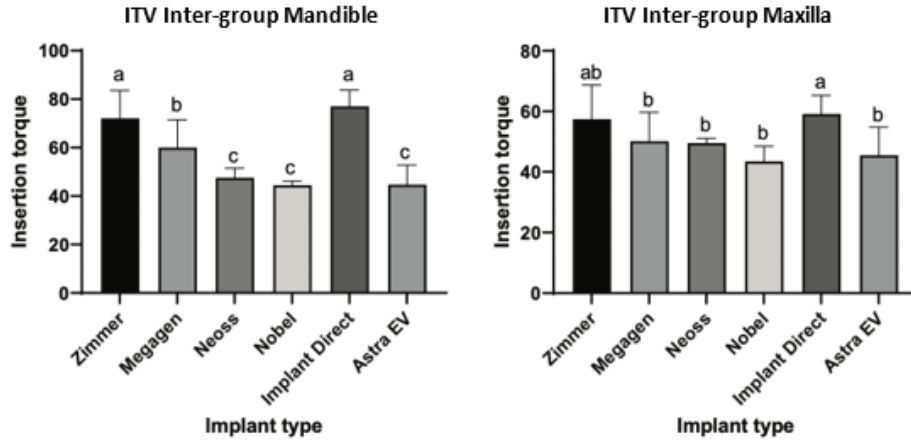


Figure 4 - ITV inter-group analysis in maxilla and mandible according to the implant type. One-way ANOVA and Tukey's multiple comparison test; significant grouping is denoted by (a, b, c). Failed implants were excluded from analysis. Groups with same letter (a and a) are statistically insignificant. Groups with different letters (a vs. b) are different implant systems with statistical significance. Groups with two letters (eg. ab) are statistically insignificant from group a and b. In the mandible, a > b > c, and each group is statistically significant from one another. In the maxilla, ab shares characteristics from both a and b, but it is not statistically significant from either group. There is no single P value since this is a multi-group comparison (eg. some comparison gives p<0.05, some p<0.001).

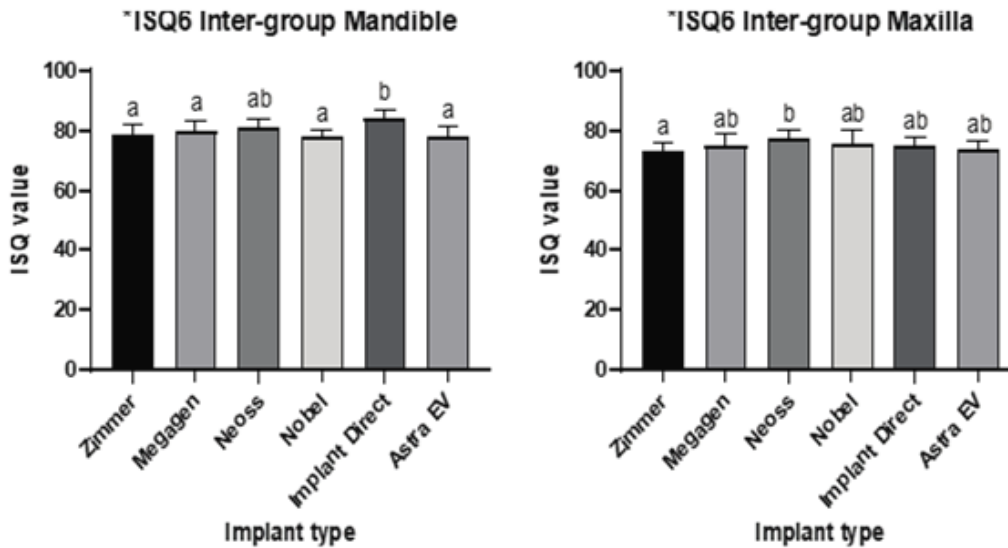


Figure 5 - ISQ inter-group analysis at 6 weeks after implant placement in Maxilla and Mandible according to the implant type. One-way ANOVA and Tukey's multiple comparison test; significant grouping is denoted by (a, b, c). Failed implants were excluded from analysis. Groups with same letter (a and a) are statistically insignificant. Groups with different letters (a vs. b) are different implant systems with statistical significance. Groups with two letters (eg. ab) are statistically insignificant from group a and b.



Discussion

The purpose of this study was to retrospectively evaluate the effects of OD protocols on implant primary and secondary stability of dental implants with different macro thread designs, placed in sites with low bone density.

Higher insertion torque and higher ISQ values are positive indications for diminished implant micromotion, which is critical for enhanced osseointegration and implant immediate loading^{29, 30}. Contrary to the historical theory, which has not been proven in either large animal or clinical studies that high ITV above 30 Ncm may create bone compression beyond its physiological limits and may lead to pressure necrosis³¹, numerous large animal histological and human clinical studies have confirmed that optimal primary stability measured by high ITV does not prompt or cause implant failure or negatively affect osseointegration³²⁻³⁴. Furthermore, implants placed in large patient populations with ITV < 30 Ncm are 14 times more likely to have an early failure than implants placed with ITV > 30 Ncm³⁵. Previous studies have found that compaction of autogenous bone with osseodensification preparation provides enhanced implant stability in areas of reduced bone density and leads to optimized implant osseointegration^{18,19,36}. The densifying burs, when used in the counterclockwise (CCW) direction, autograft bone particles into open trabecular spaces within the osteotomy walls to increase overall bone density, creating an intimate contact between bone and the implant surface^{18,19,36}. It has been demonstrated that if the osteotomy is left empty post OD, a 91% reduction in its diameter was observed due to the viscoelastic nature of the bone and the occurred spring-back effect^{18,37}.

In the present study, osteotomies created with OD protocols in low density bone, where optimal ITV and high ISQ values are not expected to be obtained, resulted in ITV above 40 Ncm and optimal ISQ ≥ 70 up to 6 weeks after implants placement with different macro designs³⁸⁻⁴⁰. Hence, it can be concluded that OD protocols increased bone density and implant total stability in these

sites, in accordance with previous reports^{18,36}. This study also observed that secondary stability, devoted by continuous optimal ISQ values, was achieved for all implant systems during the initial critical 6 weeks of healing, in areas where reduced bone density was previously detected. OD protocols optimized implant primary and secondary stability in low bone density sites. These results are in agreement with previous comparative studies in which OD increased the insertion torque from 25Ncm for implants placed using conventional osteotomy to ≥ 50 Ncm in sites with low density bone³⁵.

Potential limitations of this study include the absence of a control group for each implant macro design with implants placed following traditional drilling protocols. However, comparisons of conventional to OD protocols have previously reported superior ITV and ISQ values with OD protocols³⁶ in low bone density sites. Since OD densifying burs used are not implant system-specific and are considered universal, the main goal of this multicenter retrospective study was to determine if similar results would be obtained when placing implants with different macro designs. This study confirmed this hypothesis since implants with different body designs (tapered/straight) and thread patterns achieved similar results. Hence, within the limitations of this multicenter retrospective study, it can be concluded that the application of OD protocols in sites with low bone density is a safe, viable, and reproducible method of achieving optimal primary and predictable secondary implant stability using implants of different macro designs, leading to high success rates and predictable treatment outcomes. Future controlled longitudinal clinical trials are encouraged to confirm these findings.

Conclusion

This multicenter retrospective study demonstrated that OD instrumentation is a safe method to achieve optimal primary stability in areas with low bone density, irrespective of implant macro design and surface characteristics. OD instrumentation resulted in high implant success rate.



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