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Efficacy Of Three Osseodensification Systems: An In Vitro Study.

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ABSTRACT

Osseodensification is a contemporary technique designed to enhance the primary stability of dental implants by increasing bone density around the implant site. This study aimed to evaluate and compare the performance of three distinct osseodensification systems: Densah (Versah), Full Access (IM3), and Bone Expander (Maximus), with a focus on their commercial and technical aspects.

Materials and Methods: Twenty tibial specimens were used, with a total of 60 Extract (Intraoss) model implants. Each tibia received three implants, each prepared using one of the osseodensification systems, resulting in 20 samples per system. Implant stability was assessed based on three key variables: insertion torque, removal torque, and resonance frequency analysis.

Results: Data analysis revealed that while the outcomes for implants placed with the different osseodensification techniques were comparable, there was significant variability within the measurements.

Conclusion: Statistical analysis did not show significant differences among the systems for the evaluated variables ($p > 0.05$). Although the in vitro results demonstrate promising potential, further clinical studies are necessary to validate these findings, particularly considering factors such as bone healing time and implant longevity.

Keywords : Osseodensification, Dental Implants, Implant Stability, Comparative Study.

INTRODUCTION

Primary stability is considered a fundamental prerequisite for osseointegration. It is a purely mechanical parameter determined at the time of implant insertion and is associated with the direct and frictional contact between the bone and the implant during installation (Barberá-Millán *et al.,* 2021).

Since the discovery of osseointegration by Professor Per-Ingvar Brånemark in the 1950s, research has focused on developing implant macro- and micro-geometry. These advancements have played a crucial role in treatment success by directly influencing primary stability, osseointegration, and load distribution (Bonfante *et al.,* 2019; Almutairi *et al.,* 2018).

Osseodensification is a more recent innovation, characterized by a non-subtractive mechanism of action. It involves condensing bone displaced during osteotomy laterally, promoting its expansion. This results in an increase in bone volume and density, enhancing the frictional contact with the implant surface and consequently elevating insertion torque levels. This approach aims to minimize micromovement, contributing to a more stable and effective integration of the implant into the bone tissue (Almutairi et al., 2018; Pai *et al.,* 2018).

Among the different osseodensification systems used in clinical practice, rotational or conventional osseodensification is widely employed. This system has demonstrated the ability to densify bone around the implant, thereby improving primary stability, and potentially serving as an alternative to traditional techniques (Gaikwad *et al.,* 2022; Oliveira *et al.,* 2018; Tretto *et al.,* 2019). Preparing the surgical alveolus through these systems has become increasingly common, especially in cases where the quantity and quality of regional bone tissue are insufficient for implant rehabilitation.

The emergence of various systems with similar osseodensification proposals highlights the need for studies to verify their actual efficacy. The use of standardized samples, such as porcine tibias with cup-shaped cut ends, has proven viable for simulating real clinical conditions in medullary bone with type III or IV density in in vitro studies (Barberá-Millán *et al.,* 2021). These studies are critical for better guiding clinical research.

In terms of potential clinical applications, it is essential to recognize that each osseodensification system has specific indications. These systems are particularly beneficial in cases of low bone density, where achieving primary stability poses a challenge (Tretto *et al.,* 2019; Oliveira *et al.,* 2018). Osseodensification has the potential to improve implant stability, accelerate the bone healing process, reduce treatment time, and enhance patient satisfaction (Witek *et al.,* 2019).

The inclusion of companies involved in this research is essential to ensure the transparency and reliability of the results. In this study, three companies producing osseodensification systems were selected based on specific criteria, including market reputation, time in operation, and availability of systems for research purposes (Almutairi *et al.,* 2018). To compare these osseodensification systems, an in vitro study was conducted with the primary aim of performing a comparative analysis of three conventional osseodensification systems, focusing on their efficacy and characteristics in achieving implant primary stability. However, further studies are necessary to confirm these preliminary findings and evaluate the clinical efficacy of different osseodensification systems (Elsayyad & Osman, 2019).

MATERIALS AND METHODS

Ethical Considerations

This study was conducted following approval exemption from the Animal Ethics Committee of São Leopoldo Mandic Faculty (Campinas, SP, Approval No. 5.768.800 – Annex A).

Analysis of Companies Involved in the Study

The American company Versah provides the Densah osseodensification system, which uses specialized drills to densify bone at the implant site. Its pioneering system is considered the gold standard in the literature, known for enhancing the primary stability of dental implants while offering specialized technical support and training for professionals. The system includes 13 drills with the following references: Pilot, VT1525, VT1828, VS 2228, VT 2535, VT 2838, VS3238, VT 3545, VT 3848, VS 4248, VT4555, VT4858, VS5258. The depth markings are 3 mm, 5 mm, 8 mm, 10 mm, 11.5 mm, 13 mm, 15 mm, 18 mm, and 20 mm.

Conversely, IM3, a South Korean company respected in the dental market, developed the Full Access system, which also aims to promote osseodensification. This company invests heavily in research and development to continuously improve its system and provide innovative solutions for professionals in the field. The system comprises five expansion drills with the following references: L16 (pilot), L16(22)28, L22(28)34, L28(34)40, and L34(40)46.

The Brazilian company Maximus, an emerging player in implant dentistry, developed the Bone Expander system, characterized as a bone expander based on its blade configuration and usage orientation. This system is recognized for its innovative approach and continuous pursuit of improvements. It includes 14 drills with the following references: LC 150, ALO 16.TI, ALO18.TI, ALO 20TI, ALO 24.TI, ALO 26.TI, ALO 28.TI, ALO 30.TI, ALO 34.TI, ALO 36.TI, ALO 38.TI, ALO 40.TI, ALO 44.TI, and ALO 46.TI.

Sample Groups

The study evaluated three distinct sample groups, represented by the osseodensification systems: Bone Expander (Maximus), Densah (Versah), and Full Access (IM3). Each group consisted of 20 implants measuring 4.0 mm in diameter and 11.0 mm in length, from the Extract model by the company INTRAOSS.

This text is now appropriately improved, translated into English, and maintains the original citations. Let me know if you need any further adjustments.

Figure 1. Osseodensification kits: Densah (Versah), Full Access (IM3), and Bone Expander (Maximus).

Source:Author.

The study utilized 20 porcine bone specimens, represented by tibial heads that were axially sectioned into a cup-like shape. Circular markings in different colors were used to identify the designated areas for each system, ensuring similarity in the selected sites. Each specimen received three implants (Extract 4.0 x 11.0 mm with a treated surface), with each surgical alveolus prepared using a different system, following the manufacturer's guidelines. Subsequently, measurements were conducted for the following variables: insertion torque, removal torque, and resonance frequency.

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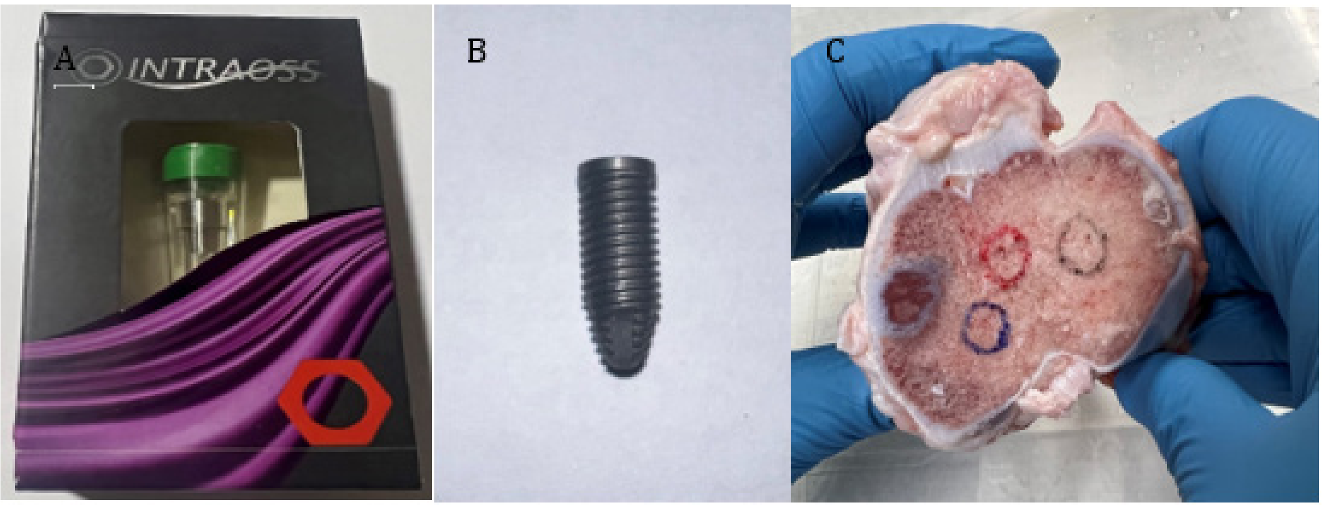
Figure 2. Implant and porcine tibia used in the study.



Caption: A) Implant (INTRAOSS); B) Macro geometry of the implant; C) Porcine tibia axially sectioned into a cup-like shape.
Source: Author's own work.

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A. Bone Expander System (Maximus)
The system was operated at 850 RPM (rotations per minute) under abundant irrigation in a clockwise direction. The sequence of drills ranged from Lance 1.6 to Drill 3.8, as specified by the manufacturer, based on bone density and implant diameter.

Figure 3. Instrumentation using the Bone Expander system (Maximus).

Source: Author's own work.

B.Densah System (Versah)
The system was operated at 1200 RPM (rotations per minute) under abundant irrigation in a counterclockwise direction. The drill sequence ranged from Lance 1.7 to Drill VT3545 (4.0), as specified by the manufacturer, based on bone density and implant diameter.

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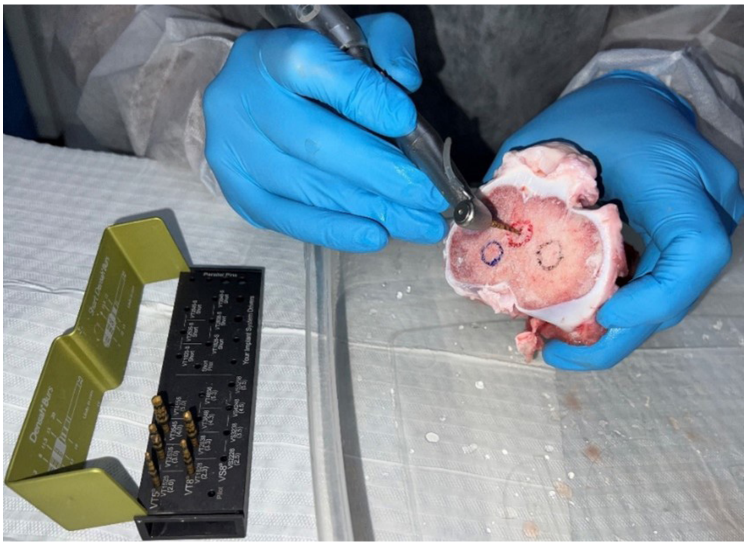
Figure 4. Instrumentation using the Densah system (Versah).



Source: Author's own work.

C. Full Access System (IM3)

The system was operated at 900 RPM (rotations per minute) under abundant irrigation in a clockwise direction with a torque of 60 N. The drill sequence ranged from Pilot 1.6 to Drill L28 34 (4.0), as specified by the manufacturer, based on bone density and implant diameter.

Figure 5. Instrumentation using the Full Access system (IM3).

Source: Author's own work.

D.Resonance Frequency

The resonance frequency analyzer used was the Osstell ISQ Model 100500, registered under ANVISA No. 10344420071, manufactured by Osstell AB, Sweden. This equipment measures the lateral stability of implants, enabling the determination of the osseointegration level and providing precise guidance on the appropriate timing for loading (delayed, early, or immediate activation).

This measurement is achieved by emitting electromagnetic waves from the device, which are captured by a SmartPeg specifically adapted to the implant platform. These waves travel along the implant and resonate with the bone in contact.

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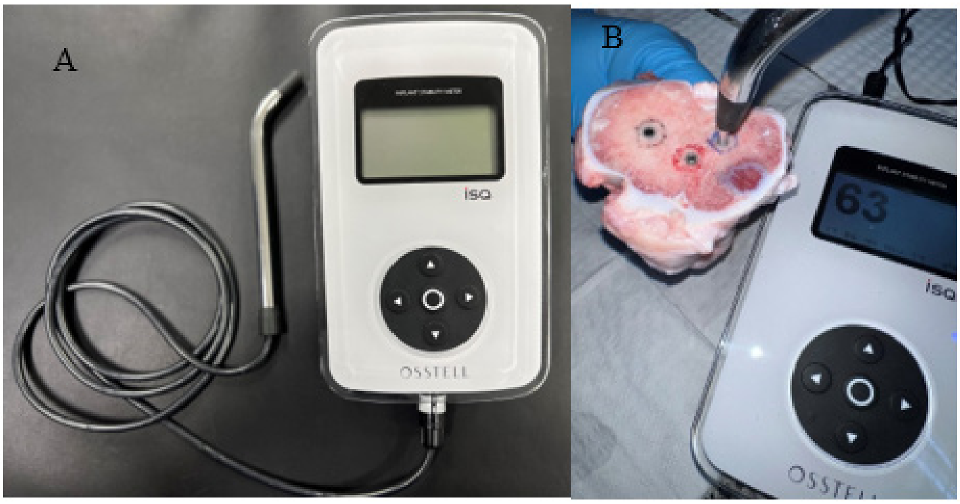
Figure 6. Osstell device used to measure implant stability through resonance frequency.



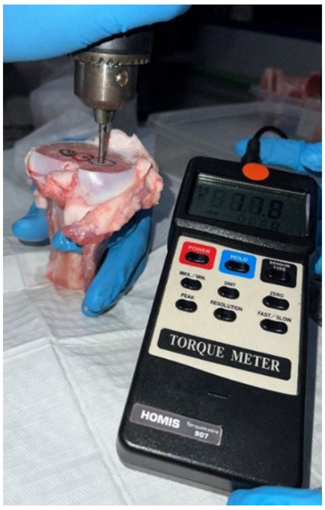
Source: Author's own work.

Caption: A) Osstell device; B) Osstell measuring implant stability through resonance frequency.

E. Torque and Detorque

The digital portable torque meter used was the Lutron TQ-8800 Torque Meter. This device allows torque measurement in three different units: Kgf/cm, Lbf/in, or N/cm.

Figure 7. Digital torque meter measuring torque and detorque of implants.



Source: Author's own work.

Statistical Analysis

Descriptive and exploratory data analyses were conducted, which revealed that classical Analysis of Variance (ANOVA) was not suitable for analyzing the data in question. Given this scenario, Generalized Linear Models were used to analyze resonance frequency (OSSTELL) and torque, due to their flexibility in handling various data distributions. For the detorque variable, which does not conform to a known distribution, the non-parametric Kruskal-Wallis test was employed, as it is a distribution-free statistical method.

RESULTS

The results of the resonance frequency analysis (OSSTELL) evaluated for the three osseodensification systems are presented in **Table 1 and Figure 1**.

Data analysis revealed no statistically significant differences between the analyzed systems ($p > 0.05$). Additionally, no statistically significant differences were observed in the torque and detorque measurements among the evaluated systems

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(p > 0.05), as detailed in **Table 2** and illustrated in **Figures 2 and 3**.

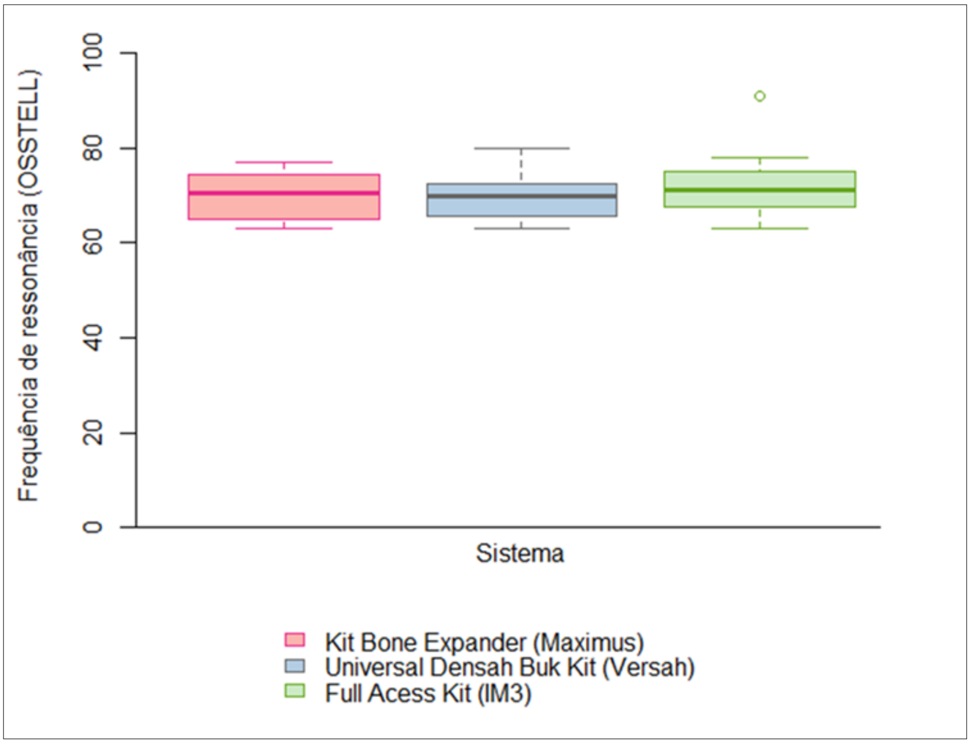
Table 1. Resonance frequency (OSSTELL) for the osseodensification systems.

System	Mean (standard deviation)	Median (minimum and maximum)
Bone Expander Kit (Maximus)	69.8 (4.7) a	70.5 (63.0; 77.0)
Universal Densah Buk Kit (Versah)	69.7 (4.8) a	70.0 (63.0; 80.0)
Full Access Kit (IM3)	71.6 (6.5) a	71.0 (63.0; 91.0)

Source: Author.

Legend: p = 0.7104. Same letters indicate no statistically significant differences between the osseodensification systems (p > 0.05).

Figure 1. Box plot of resonance frequency (OSSTELL) for the osseodensification systems.



Source: Author.

Table 2. Torque and detorque for the osseodensification systems.

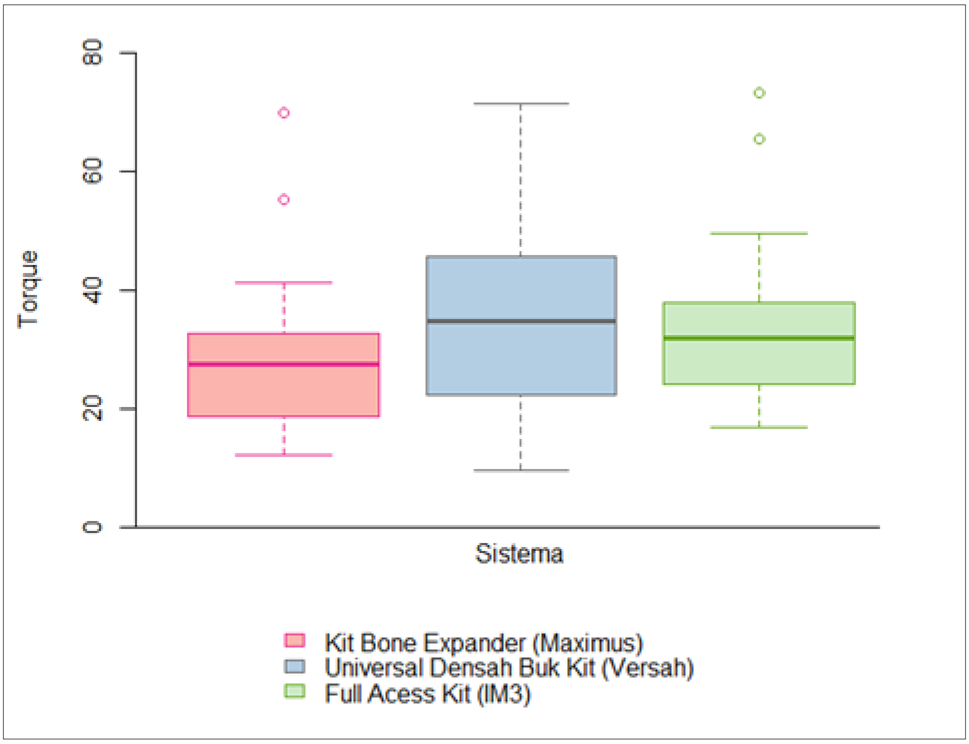
System	Torque	Detorque
	Mean (standard deviation)	**Median (minimum and maximum)**
Bone Expander Kit (Maximus)	29.24 (13.96) a	27.50 (12.20; 70.00) a
Universal Densah Buk Kit (Versah)	34.24 (16.53) a	34.80 (9.80; 71.40) a
Full Access Kit (IM3)	34.42 (14.91) a	32.00 (17.00; 73.30) a

p-value: 0.4222 (Torque), 0.5972 (Detorque).

Legend: Same letters in the vertical column indicate no statistically significant differences between the osseodensification systems (p > 0.05).

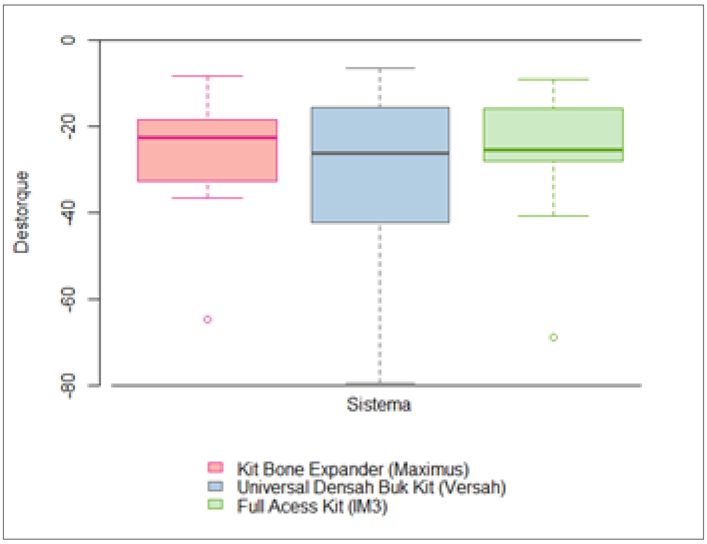
Source: Author.

Figure 2. Box plot of torque for the osseodensification systems.



Source: Author.

Figure 3. Box plot of detorque for the osseodensification systems.



Source: Author.

There was no significant difference among the three osseodensification systems in terms of resonance frequency (OSSTELL), torque, and detorque ($p > 0.05$).

DISCUSSION

This in vitro study introduces a novel comparative analysis of three osseodensification systems. The methodology employed included comparative testing between the systems, utilizing animal models to simulate clinical bone conditions with medullary predominance. The axial sectioning of the specimens, removing the cortical portion, was critical to reduce potential bias. Each system was evaluated for its impact on the primary stability of implants. This methodology aligns with previous studies by Barberá-Millán et al. (2021) and Huwais & Meyer (2017), which also used porcine tibias for their analyses.
The involvement of companies producing the systems played a fundamental role in ensuring the transparency and reliability

of the results. Similar to the study by Almutairi et al. (2018), the selection of companies was based on specific criteria, including market reputation, operational longevity, and the availability of their systems for research purposes.

Primary stability is a critical requirement for successful osseointegration (Barberá-Millán et al., 2021; Pai et al., 2018; Oliveira et al., 2018; Huwais & Meyer, 2017). This study demonstrated that the implants, despite not having macro-geometry features specifically designed for medullary bone, achieved satisfactory torque levels, corroborating the effectiveness of the osseodensification systems. All groups showed favorable primary stability results, reinforcing the intended purpose for which these systems were developed.

A systematic review identified a minimum insertion torque of 30 Ncm as an important parameter for implant placement (Papaspyridakos et al., 2014), with the same threshold adopted for immediate loading protocols (Degidi & Piattelli, 2003; Lorenzoni et al., 2003). For partially edentulous areas, torque above 35 Ncm has been suggested (Schrott et al., 2014). The findings of this study, showing insertion torque above 30 Ncm across all evaluated systems, support their indication for immediate loading, even in low-density bone.

Schrott et al. (2014) and Oliveira et al. (2018) emphasized the need for higher torque levels to ensure treatment success, particularly in low bone density scenarios. Their preclinical evidence suggested that osseodensification enhances local bone conditions. In this context, this study is one of the first to evaluate the efficacy of three distinct osseodensification systems. While Densah (Versah) was selected as a positive control due to its recognition as a gold standard in the literature, it did not yield statistically superior results compared to the Bone Expander and Full Access systems.

Orth et al. (2022) conducted a non-randomized clinical study comparing Densah (Versah) and Bone Expander (Maximus). Their findings indicated that Densah outperformed Bone Expander in terms of primary implant stability, reporting a torque of 46 ± 10 Ncm for Densah versus 37 ± 13 Ncm for Bone Expander ($p = 0.02$). This contrasts with the present study, where Densah showed an average insertion torque of 34 ± 16 Ncm, compared to 29 ± 14 Ncm for Bone Expander ($p > 0.05$).

Osseodensification systems have demonstrated clinical effectiveness; however, their advantages and disadvantages must be considered against traditional subtractive drilling systems (Oliveira et al., 2018). Subtractive drilling, while widely used and predictable, can cause bone damage, leading to bone loss and compromised long-term implant stability. In contrast, osseodensification systems provide superior bone compaction and reduced tissue damage (Lahens et al., 2019; Huwais & Meyer, 2017).

An in vitro study comparing four implant preparation techniques (conventional drilling, compressive osteotomes, osseodensification, and piezoelectric instruments) assessed bone architecture changes using Micro-CT, temperature, and torque. The findings demonstrated osseodensification as superior in terms of insertion torque and low temperature, supporting its use for enhanced implant outcomes (Bhargava et al., 2023). Huwais & Meyer (2017) also highlighted additional benefits of osseodensification, such as minimal bone trauma, autografting, secondary stability improvement, and ridge expansion.

The innovative counterclockwise rotation technique of osseodensification drills proved highly effective in plastically deforming and expanding alveolar bone, creating an elastic rebound effect (“spring back effect”). This phenomenon enhances primary implant stability immediately after placement (Koutouzis et al., 2019). However, in the present in vitro study, this effect was not observed. The detorque results were lower than the torque values, possibly due to the bone specimen preparation method, which might have limited internal pressure during drilling.

While this study employed in vitro models, its methodology is consistent with similar studies (Barberá-Millán et al., 2021; Almutairi et al., 2018). Despite being a well-known topic, the comparative analysis of different osseodensification systems remains underexplored in the literature. This study contributes valuable insights, showing no significant differences between the systems for the evaluated variables. Nonetheless, further clinical validation studies are warranted.

CONCLUSION

Based on the results obtained in this study, it can be concluded that there were no statistically significant differences among the three evaluated osseodensification systems in terms of torque, detorque, and resonance frequency. However, as this was an in vitro study, further clinical studies are required to validate these findings.

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Conflict Of Interest

The authors declare no conflict of interest related to this study.

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