INSTITUTO UNIVERSITÁRIO EGAS MONIZ

DOUTORAMENTO EM CIÊNCIAS BIOMÉDICAS

COMPARISON BETWEEN OSSEODENSIFICATION AND CONVENTIONAL OSTEOTOMY PROTOCOL FOR IMPLANT SITE PREPARATION

Trabalho submetido por
João Rui Carvalho Gaspar
para a obtenção do grau de Doutor em Ciências Biomédicas

dezembro de 2023

EGAS MONIZ SCHOOL of HEALTH & SCIENCE | INSTITUTO UNIVERSITÁRIO EGAS MONIZ

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Trabalho orientado por
Prof. Doutor José João Baltazar Mendes

e coorientado por
Dr. Rodrigo Neiva

dezembro de 2023

DEDICATÓRIA

"É bom ser importante, mas é mais importante ser bom."

Vovô João

(original de Walter Winchell)

Aos meus Pais, os pilares e referências da minha vida:

Ao meu Pai, por me inspirar pelo exemplo. A tua dedicação, compromisso, amizade, lealdade e ética são um modelo a seguir, não só a nível pessoal como a nível profissional. É impressionante ver a tua capacidade de trabalho ao fim de 40 anos de carreira como médico dentista. Obrigado por teres sido o responsável por poder exercer uma profissão que me realiza diariamente, por me motivares sempre a ser melhor, mas obrigado, sobretudo, por seres o melhor Amigo.

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RESUMO

A reabilitação oral com implantes endósseos é uma opção de tratamento eficaz e segura, que está associada a elevadas taxas de sucesso. A estabilidade do implante é um fator crítico para o sucesso clínico da reabilitação e divide-se em estabilidade primária (fixação mecânica obtida após a inserção no osso, mantendo o implante imóvel), e estabilidade secundária (fixação biológica que ocorre devido à formação de novo osso durante a cicatrização, resultando na osteointegração). De acordo com a literatura, a micromovimentação do implante que exceda 50 a 150 µm durante o período de cicatrização pode levar à interposição de tecido fibroso na interface osso-implante e consequente falha no processo de osteointegração. Deste modo e segundo vários autores, valores mais elevados de estabilidade primária estão associados a uma maior probabilidade da osteointegração ser bem-sucedida. Além disso, há diversos parâmetros que deverão ser tidos em conta durante a preparação do leito implantar, que deverá ser o mais atraumática possível de modo a manter a viabilidade celular. A preservação da estrutura óssea e da matriz de colagénio, juntamente com o aumento da estabilidade primária, demonstraram igualmente ter potencial para acelerar o processo de cicatrização pós-cirurgia.

Em 2015, surgiu um conceito inovador de preparação do leito implantar - osseodensificação (OD) - uma técnica de perfuração não subtrativa que, através do uso de brocas especificamente desenhadas para girar no sentido anti-horário, preserva a matriz óssea, contrariamente ao protocolo convencional. Neste modo, as brocas não têm capacidade de corte e a perfuração ocorre de uma forma gradual e incremental, preservando o colagénio e aumentando a densidade do osso através da sua compactação ao longo das paredes do leito. Vários autores relatam ainda que esta técnica pode ajudar a obter valores superiores de estabilidade primária e de torque de inserção dos implantes, especialmente em osso pouco denso. No entanto, se forem utilizadas no sentido horário, estas brocas cortam osso como qualquer outro sistema, tendo por isso uma dupla ação.

Uma vez que "empurra" o osso em vez de o remover, a OD tem um enorme potencial na área da implantologia em diferentes indicações, nomeadamente na expansão de cristas ósseas, colocação pós-extracional de implantes ou

elevação do seio maxilar (ESM) por abordagem crestal com alta previsibilidade e reduzida morbilidade, comparativamente com as técnicas alternativas. O principal objetivo deste projeto de doutoramento foi contribuir para aprofundar conhecimento relativamente à técnica de OD, e validar a sua versatilidade e aplicação em diferentes situações clínicas. Nesse sentido, começámos por realizar uma revisão sistemática e meta-análise, com o objetivo de avaliar a estabilidade implantar após preparação do leito com OD em comparação com o protocolo convencional de osteotomia. Este estudo de revisão foi o primeiro a analisar exclusivamente dados de humanos e demonstrou que a OD obteve consistentemente valores superiores de estabilidade primária e secundária (4-6 meses após a colocação dos implantes), comparativamente com a técnica convencional de osteotomia (**Capítulo 3**). Entretanto, tivemos a oportunidade de participar num estudo clínico retrospetivo internacional multicêntrico, com colegas de cinco nacionalidades, que permitiu confirmar a capacidade da OD na expansão do septo interradicular para a colocação pós-extracional de implantes em molares. Além disso, este estudo permitiu ainda a introdução de uma nova classificação de alvéolos de molares, que pode ser utilizada pela comunidade científica e facilitar a comunicação entre pares (**Capítulo 4**). Por fim, relativamente à ESM, de acordo com estudos já publicados, a OD parece ter, de facto, um enorme potencial. No entanto, existe ainda alguma escassez de estudos científicos com metodologia adequada que efetivamente permitam considerar a técnica de OD como uma alternativa válida à técnica clássica de janela lateral, sobretudo em casos muito reabsorvidos em que esta continua a ser considerada gold-standard. Assim sendo, decidimos realizar um ensaio clínico randomizado com o objetivo de comparar a eficácia e o impacto da ESM com OD versus a técnica clássica de janela lateral na qualidade de vida dos pacientes, ambas com colocação simultânea de implantes em casos com altura óssea residual inferior a 4 mm. Os resultados demonstraram que, apesar de ambas as técnicas terem sido igualmente eficazes, a OD superou significativamente a técnica de janela lateral em termos de experiência de dor, impacto na autopercepção de qualidade de vida, duração da cirurgia, edema pós-operatório e medicação analgésica (**Capítulo 5**).

Em conclusão, a OD veio mudar o paradigma na área da implantologia a nível da preparação do leito implantar. Esta tese confirma o seu potencial clínico e demonstra a sua versatilidade em diferentes situações, desde a otimização do leito implantar por si só, até à expansão óssea ou elevação do seio maxilar por abordagem crestal. Além disso, os resultados permitem encarar a OD como uma alternativa real e válida à técnica clássica de janela lateral em casos limite com muito pouca disponibilidade óssea, com uma melhoria significativa em termos da experiência do paciente.

Palavras-Chave: Osseodensificação, Preparação do leito implantar, Osteotomia, Expansão, Osso, Elevação do seio maxilar, Implantes imediatos

ABSTRACT

Oral rehabilitation with endosseous implants is a safe and effective treatment option which is associated with high success rates. Implant stability is a critical factor for the clinical success of rehabilitation and includes primary stability (mechanical engagement obtained upon insertion into the bone, holding the implant in place), and secondary stability (biological fixation that occurs due to the new bone formation during healing, resulting in osseointegration).

It has been shown in the literature that implant micromotion exceeding 50 to 150 µm during healing period can lead to fibrous tissue interposition at the bone-implant interface and consequent failure in the osseointegration process. Therefore, according to several authors, high degrees of primary stability are associated in the literature with superior and higher probability of osseointegration. Furthermore, there are several parameters that must be considered during the implant site preparation, which should be as atraumatic as possible to maintain cell viability. The preservation of the bone structure and collagen matrix, together with the increase in primary stability, also demonstrated the potential to accelerate the post-surgery healing process.

In 2015, a novel surgical technique for implant site preparation termed osseodensification (OD) has been introduced. It is a non-subtractive drilling technique that preserves bone by using specially designed burs in counterclockwise (CCW; noncutting motion) with copious irrigation. Contrary to conventional drilling techniques, OD promotes bone compaction along the osteotomy walls and into the trabecular spaces, increasing the bone density at the site. Several authors reported that this technique can help to obtain higher values of primary stability and implant insertion torque, especially in less dense bone. However, these drills have a dual-mode action since they may also be used in clockwise direction (CW) in which they have cutting capacity like any other system. Since it pushes the bone instead of removing it, OD has enormous potential in the field of oral implantology in different indications, namely in ridge expansion, post-extraction implant placement or maxillary sinus floor elevation (SFE) by crestal approach with high predictability and reduced morbidity, compared to alternative techniques.

The main objective of this doctoral project was to contribute to advance knowledge regarding the OD technique and to validate its versatility and application in different clinical situations. In this sense, we decided to perform a systematic review and meta-analysis, with the aim of comparing implant stability between site preparation with OD compared to the conventional osteotomy protocol. This review was the first to exclusively analyze human data and demonstrated that OD consistently achieved higher values of primary and secondary stability (4-6 months after implant placement) compared with conventional drilling (**Chapter 3**). In addition, we had the opportunity to participate in an international multicenter retrospective clinical study, with colleagues from five nationalities, which confirmed the ability of OD to expand the interradicular septum for the post-extraction implant placement in molars. Furthermore, this study also allowed the introduction of a new molar socket classification, which can be used by the scientific community and facilitate communication between peers (**Chapter 4**). Finally, according to the current evidence, OD appears to have, in fact, enormous potential for SFE. However, there is still a lack of scientific studies with adequate methodology that effectively allow the OD technique to be considered as a valid alternative to the classic lateral window technique (LW), especially in highly resorbed posterior maxilla in which it continues to be considered the *gold standard*. Therefore, we decided to conduct a randomized clinical trial with the aim of comparing the effectiveness and impact on patients' quality of life of SFE with OD versus LW, both with simultaneous implant placement when residual bone height (RBH) < 4 mm. The results showed that, although both techniques were similarly effective, OD significantly outperformed LW in pain experience, impact on self-perceived quality of life, surgery duration, postoperative edema and analgesics intake (**Chapter 5**).

In conclusion, OD represents a paradigm shift in implantology in terms of implant site preparation. This thesis confirms its clinical potential and versatility in different situations, from optimizing the implant site alone to bone expansion or SFE by crestal approach. Furthermore, our results position OD as a real and valid alternative to the LW technique in extreme cases with reduced RBH, with a significant improvement in patient experience.

Keywords: Osseodensification, Implant site preparation, Osteotomy, Expansion, Bone, Sinus floor elevation, Immediate implants

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ABBREVIATIONS LIST

AAA – Alveolar Antral Artery

BIC – Bone-to-Implant Contact

BMPs - Bone Morphogenetic Proteins

BPPV - Benign Paroxysmal Positional Vertigo

CTSK - Cathepsin K

CBCT – Cone-Beam Computed Tomography

CI – Confidence Interval

CCW – Counterclockwise

CW – Clockwise

CiiEM – Centro de Investigação Interdisciplinar Egas Moniz

HSCs - Hematopoietic Stem Cells

IOA – Infra-Orbital Artery

ISB – Interseptal Bone

ISQ – Implant Stability Quotient

IT – Insertion Torque

LW – Lateral Window Technique

MCC – Mucocilliary clearance

NSAIDs – Non-Steroidal Anti-Inflammatory Drugs

OD – Osseodensification

OHIP – Oral Health Impact Profile

OHRQoL – Oral Health-Related Quality of Life

OR – Odds Ratio

PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROMs – Patient-Reported Outcome Measures

PSAA – Posterior Superior Alveolar Artery

QoL – Quality of Life

RBH – Residual Bone Height

RCT – Randomized Clinical Trial

RFA – Resonance Frequency Analysis

SFE – Sinus Floor Elevation

STROBE - STrengthening the Reporting of OBservational studies in Epidemiology

VAS – Visual Analogue Scale

CHAPTER 1

GENERAL INTRODUCTION

1.1. Bone

1.1.1. Embryology and Bone Ossification

Bone tissue formation begins during embryonic development and is completed in early adulthood through a process termed bone ossification. It can be divided into two types, endochondral and intramembranous (1). Endochondral ossification occurs when a hyaline cartilage is replaced by bone and marrow and is the process responsible for the formation of most short and long bones of the human skeleton (2). In contrast, during intramembranous ossification, bone is formed directly from connective tissue without a cartilaginous precursor. The frontal, parietal, temporal, some parts of the occipital, maxilla and mandible bones are examples of bones formed through intramembranous ossification (1,3). This classification refers only to the mechanism of bone formation; in the adult, the structure of the bone tissue formed by the two ossification processes is identical (4).

1.1.2. Bone Composition

Bone is a mineralized connective tissue consisting of four types of cells (osteoblasts, osteocytes, bone lining cells and osteoclasts) and a calcified extracellular matrix (5–7). Osteoblasts, osteocytes and bone lining cells are derived from mesenchymal stem cells of the bone marrow, and osteoclasts are derived from hematopoietic stem cells (HSCs) of the mononuclear phagocyte system (5,6,8).

1.1.2.1. Bone cells

Osteoblasts are metabolically active cells that produce extracellular proteins, including alkaline phosphatase, osteocalcin and type I collagen which constitutes over 90% of the bone matrix protein (9). Osteoblasts are responsible for the synthesis of the organic components of the non-calcified bone matrix (osteoid) and their mineralization through the ability to accumulate calcium phosphate in the form of hydroxyapatite (7). Osteoblasts may be trapped by the newly formed bone matrix and become osteocytes. The previously secreted matrix is deposited around the cell body, forming lacunae where osteocytes are found (10). These lacunae are connected through a network of canaliculi which allow the diffusion of substances, cellular communication and nutrition through the bone (5,10). Osteocytes are fundamental to the maintenance of the bone matrix, and their death is followed by bone resorption. There are approximately 25,000 osteocytes per mm^3 of bone, representing around 90% of the total bone cells (10,11).

Bone lining cells demonstrate few signs of metabolic activity and are considered post-proliferative resting osteoblasts (5). Although there is still discussion in the literature regarding their function, it has been reported that bone lining cells may be reactivated to form osteoblasts, act as a barrier between bone and extracellular fluid, and regulate crystal growth in bone (5).

Osteoclasts are giant multinucleated mobile cells whose main function is to degrade and destroy bone through the secretion of acid and proteolytic enzymes such as cathepsin K (CTSK) (12). Osteoclasts migrate from the bone marrow to a specific skeletal site and can be found in small depressions in the bone matrix known as “Howship’s lacunae” which are the result of their resorption activity (11). This process contributes to bone remodelling, which is essential for preserving skeletal integrity by osteoclasts resorbing damaged bone, which is subsequently replaced by new bone produced by osteoblasts (10,13). In addition, bone resorption by osteoclasts releases calcium into the bloodstream which aids in the long-term regulation of blood calcium homeostasis (10).

1.1.2.2. Bone extracellular matrix

The bone extracellular matrix is composed of both organic and inorganic/mineral elements, although its exact composition may differ based on age, sex and health conditions (14). The inorganic component accounts for approximately 60% of the tissue compared to approximately 30% of the organic component, while the remaining 10% is water (6,10). Its inorganic content is primarily composed of calcium and phosphate in the form of crystalline hydroxyapatite $[Ca_3(PO_4)_2]_3Ca(OH)_2$ and small amounts of sodium, potassium and magnesium (4,10). The organic component consists predominantly of type I collagen (90%) but also includes noncollagenous proteins (10%) such as osteonectin, osteocalcin, growth factors and bone morphogenetic proteins (BMPs) (6,15,16).

The main function of collagen is mechanical support and it plays a significant role in determining bone strength (17). During the bone regeneration process, there is a dynamic interaction between the bone extracellular matrix, osteoblast-lineage cells and osteoclasts that regulates the formation of new bone (14).

1.1.3. Bone density and different types of bone

The success of dental implants depends not only on the quantity of bone available in the jaws but also on its quality (18). Bone density is defined by the quantity of minerals (essentially calcium and phosphorous) present in a certain volume of bone, which changes throughout life (19,20). It is significantly influenced by genetic factors and directly correlated with bone strength (21,22). Bone density may be measured preoperatively during implant surgery planning with cone-beam computed tomography (CBCT) through a quantitative bone density scale (Hounsfield scale) in Hounsfield units (HU) (23).

Bone tissue can be macroscopically classified as cortical (or compact) and trabecular (or cancellous) (4,22,24). Cortical bone is a dense tissue that forms a solid osseous protective layer around the medullary internal cavity. Its major function is to provide strength and protection to bones. On its external surface, cortical bone is covered by the periosteum, which is a thin layer of connective tissue, and on its inner surface it is covered by the endosteum. In contrast, trabecular bone is a spongy, porous, inhomogeneous, and anisotropic material, composed of a honeycomb-like network of trabecular struts and plates interposed between the bone marrow compartment (4).

In 1985, Lekholm and Zarb (25) classified alveolar bone quality into four types: type 1, homogeneous cortical/compact bone; type 2, thick cortical layer surrounding a core of dense trabecular bone; type 3, thin cortical layer surrounding dense trabecular bone; and type 4, thin cortical layer surrounding a sparse low-density medullary bone (25).

In 1988, Misch proposed four bone types (D1-D4) based on their density and correlated them with the different regions of the mouth in which they are more often encountered (26). D1 bone type consists almost entirely of dense cortex and is mostly found in the anterior mandible. On a Hounsfield scale, D1 measures 1250 HU or more. D2 is a combination of dense-to-porous cortical bone on the crest and trabecular bone from 40% to 60% on the inside, and is more frequently found in the anterior and posterior mandible. Normally, D2 bone measures around 850-1250 HU. D3 consists of a thinner porous crestal layer of cortical bone and reasonable trabecular bone. It is commonly found in the anterior and posterior maxilla but may also be present in the posterior mandible. On the Hounsfield scale, D3 density is around 350-850 HU. D4 bone is basically trabecular with no cortical crestal bone and is essentially found in the posterior maxilla. This type of bone is associated with a higher implant failure rate. On the Hounsfield scale, 150-350 HU indicate D4 bone. Due to the extremely low-density bone, BIC and implant primary stability are often compromised so the surgical technique for implant site preparation must be delicate and precise to overcome this. Furthermore, it takes the longest time for osseointegration to occur (26,27). To be a good candidate for dental implant placement, the patient must have adequate bone quantity and quality. Historically, the posterior maxilla has been associated with a higher implant failure rate (28). In addition to the low bone density, a frequent limitation for implant placement in this location is the reduced residual bone height (RBH) below the maxillary sinus, which is often associated with its pneumatization. These cases require an additional surgical procedure well-established in the literature termed sinus floor elevation (SFE), to increase the amount of bone in the maxillary sinus either through a lateral or crestal approach (29–33).

1.2. Paranasal Sinuses

The paranasal sinuses are air-filled cavities located within the skull that surround and communicate with the nasal cavity. There are four paired sinuses: maxillary, ethmoid, frontal and sphenoid sinuses. The function of the paranasal sinuses remains only partially understood and is still under debate. Nevertheless, it is assumed that they participate in reducing skull weight, play a role in respiration, immunological defense and olfactory function, and increase the resonance of the voice (34,35).

1.2.1. Maxillary Sinus

1.2.1.1. Anatomical Considerations

The maxillary sinus is a large pyramidal cavity situated within the body of the maxilla and is normally the largest paranasal sinus. It was initially illustrated by Leonardo da Vinci in 1489 (36) and later described in more detail by Nathaniel Highmore in 1651, which is why it is frequently referred to as the Antrum of Highmore. The average dimensions of the sinus in adults are: width 25-35 mm, height 30-45 mm, anteroposterior 36-42 mm, and its average volume is around 15 ml (37,38). It is limited by: the infratemporal and pterygopalatine fossae posteriorly; the fragile orbital floor superiorly; the zygomatic process laterally; the uncinate process, fontanelles and inferior turbinate medially; and the hard palate and the alveolar processes inferiorly.

The maxillary sinus is lined with mucoperiosteum, also known as the Schneiderian membrane (Figure 1). Histologically, it can be described as a double-layer membrane consisting of pseudostratified ciliated columnar epithelium on the inner side and periosteum on the outer side. It has been demonstrated that mesenchymal stem cells from the sinus membrane have the capacity to form bone (39) which is particularly relevant in SFE procedures. The natural mean thickness of a healthy Schneiderian membrane is approximately 1 mm but it is usually found to be thicker in radiographic evaluation of asymptomatic patients (40,41).

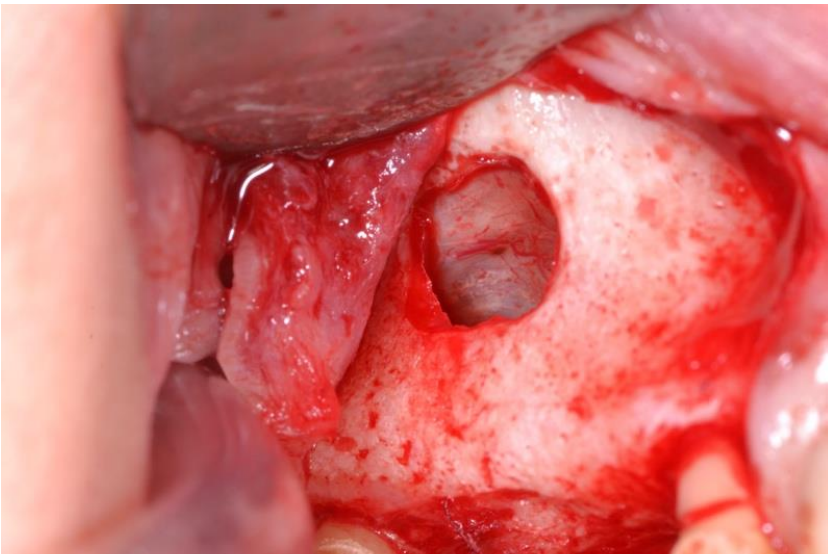

Figure 1. Schneiderian membrane elevation during lateral window approach

The ostium of the maxillary sinus is located on the highest part of the medial wall of the sinus and is usually around 5 mm in diameter (42). It opens into the posterior half of the ethmoidal infundibulum, passing through the semilunar hiatus and finally into the middle meatus of the nasal cavity (43) (Figure 2). In approximately 10% of the population, accessory maxillary ostia may occur unilaterally or bilaterally and are usually located in the posterior fontanelle area (44).

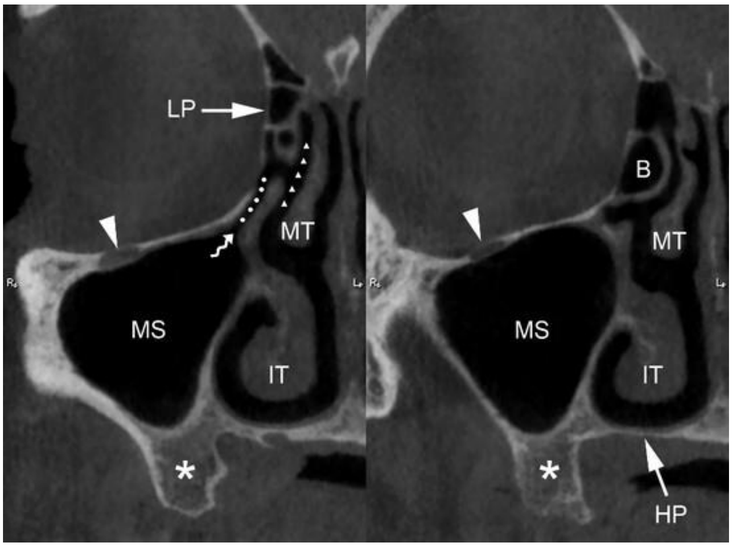

Figure 2. Cross-sectional CBCT images at the level of the ostiomeatal complex, showing the infraorbital canal (arrowhead), maxillary sinus ostium (wavy arrow), ethmoidal infundibulum (dotted line), middle meatus (small triangles), and maxillary alveolar process (asterisk). B, ethmoidal bulla; HP, hard palate; IT, inferior turbinate; LP, lamina papyracea; MS, maxillary sinus; MT, middle turbinate. Source: Sinonasal Complications of Dental Disease and Treatment: Prevention–Diagnosis–Management. Felisati G, Chiapasco M, ed. 1st Edition. Stuttgart: Thieme; 2015. doi:10.1055/b-006-149711

A variable number of ridges and septa, also called Underwood's septa, are a frequent anatomic condition that can be found within the maxillary sinus. According to computerized tomography (CT) studies, its prevalence may range from 16% to 58%, although they are more frequent in edentulous cases (45–47). Septa may be classified into primary (which are congenital and evolve during the growth of the maxilla) and secondary (which are acquired from the irregular pneumatization of the sinus floor following tooth loss) (46). These walls of cortical bone represent a challenge when sinus augmentation procedures are required, due to the greater risk of membrane perforation during its elevation (41,47). This risk may be even higher when the Underwood's septa divide the sinus cavity into two or more compartments, although this is rarely found (41,47).

1.2.1.2. Anatomical Relationship between the Maxillary Sinus and Teeth

The anatomical relationship between the maxillary sinus and the teeth is highly variable. Normally, the sinus floor extends from the mesial part of the first premolar to the distal part of the third molar and has its lowest location at the first and second molar (43,48). The molars are usually separated from the sinus by a layer of compact bone, although this layer may be thin or absent in some cases (43).

1.2.1.3. Vascularization and Innervation

The maxillary sinus mucosa is irrigated by branches of the maxillary artery, namely the posterior superior alveolar artery (PSAA), the infraorbital artery and the posterior lateral nasal artery (43). The alveolar antral artery (AAA), the dental branch of the PSAA, usually has an intraosseous horizontal course through the superior alveolar canal along the anterolateral wall of the maxillary sinus and anastomoses with the infraorbital artery (IOA) (49) (Figure 3).

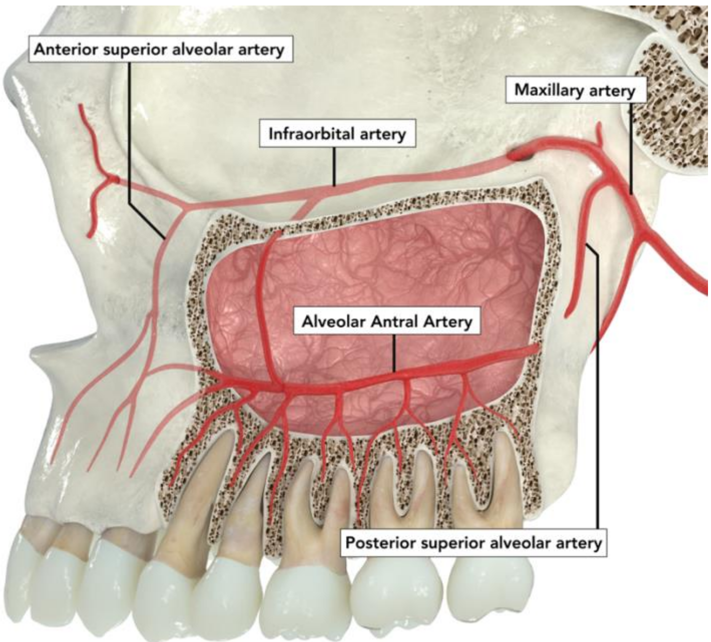

Figure 3. Vascularization of the maxillary sinus. (Original image)

The AAA represents an important arterial branch due to the potential risk of damage during sinus floor elevation by lateral approach (Figure 4). In a CBCT study, the superior alveolar canal could be identified in 82% of the cases with a mean diameter of 1.1 mm (range between 0.2 and 2.6 mm) (50). Therefore, proper diagnosis and preoperative analysis of 3D imaging (CBCT) are mandatory to minimize intraoperative complications (49).

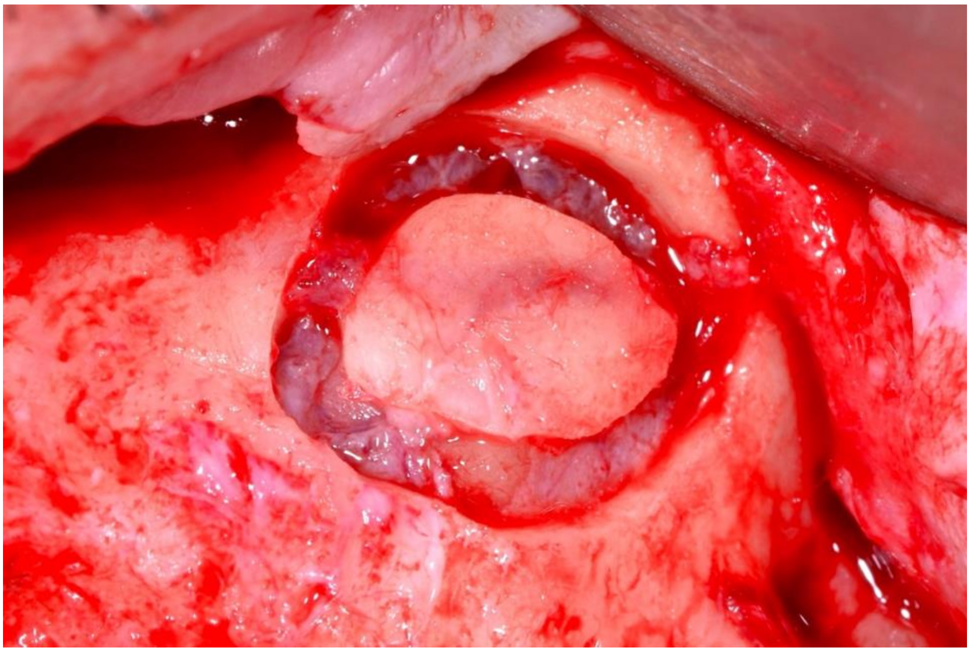

Figure 4. Alveolar antral artery (AAA) observed during sinus floor elevation by lateral window approach.

The venous drainage is provided by veins that arise from the dense venous network of the sinus mucosa and course in multiple directions. The infraorbital vein is responsible for part of the drainage and reaches the cavernous sinus, which explains the potential for extension of maxillary sinus infection to this area (51).

Sensory innervation of the maxillary sinus is provided by the infraorbital nerve and its main proximal branches (anterior, middle and posterior superior alveolar nerves) (43). The posterior superior alveolar nerve normally has two to three branches and is responsible for most innervation of the sinus mucosa, whereas the middle superior alveolar branch supplies secondary mucosal innervation. The anterior superior alveolar branch runs on the anterior wall of the maxilla and innervates the anterior portion of the maxillary sinus (43).

1.2.1.4. Schneiderian Membrane - Microscopic Anatomy and Defensive Role

Recently, there has been a growing interest on research regarding the maxillary sinus membrane, primarily attributed to its involvement in osteogenesis following SFE (52,53). The Schneiderian membrane consists of pseudostratified ciliated columnar epithelium and is composed of three types of cells: ciliated cells (approximately 80%), goblet cells (approximately 20%) and a small number of basal cells that can differentiate into other epithelial cells (54).
The histomorphological composition of the Schneiderian membrane leads to its classification as mucosa. However, several studies have identified additional layers within the Schneiderian membrane, including a vascular-rich lamina propria and a layer of dense fibrous tissue adjacent to the bone surface, similar to a periosteum-like structure (55,56). Consequently, there is a prevailing agreement that the Schneiderian membrane exhibits both the characteristics and functions of mucosa, while also demonstrating the features and functions reminiscent of periosteum (Figure 5).

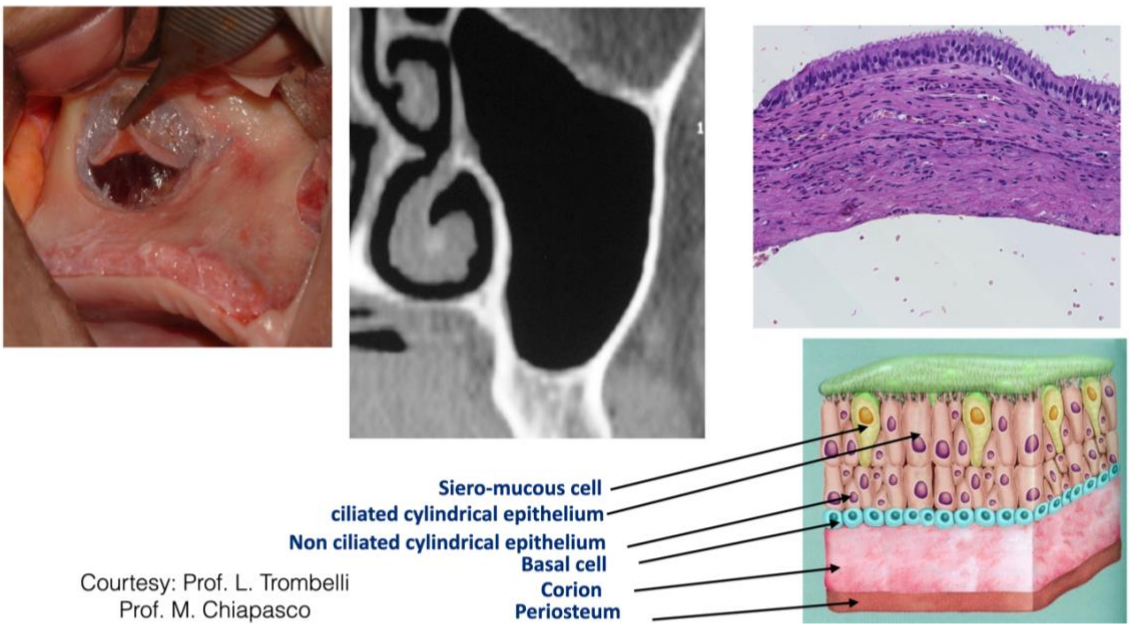

Figure 5. Schneiderian membrane anatomy and histology. Image cortesy of Prof. Leonardo Trombelli and Prof. Matteo Chiapasco

The ciliated cells are columnar epithelial cells with specialized ciliary adaptations located at their apical portions. In the absence of infection and under normal body temperature, the cilia beat synchronously at a frequency of 10 to 20 times per second, propelling the mucus produced by goblet cells from the periphery of the sinuses to the middle meatus through the ostium (57,58). Subsequently, as the secreted mucus reaches the nasal cavity and drainage occurs, it is ingested and transported to the stomach, where most of the pathogenic microbes trapped in the mucus are destroyed through a process referred to as mucociliary clearance (MCC) (59,60). MCC serves as a vital host defense mechanism that provides homeostasis by protecting the body from invading foreign particles, including bacteria (60). Goblet cells are simple glandular cells that produce mucus. This production is regulated by both the parasympathetic and sympathetic nervous systems, and tends to increase after exposure to irritating substances or pathogens. While the density of goblet cells in the sinusal cavities is notably lower than that in the nasal cavities, research has indicated that they are more abundant in the maxillary sinus than in the other sinuses. This ensures a suitable quantity of mucus production in the sinuses, preventing excessive epithelial dryness and facilitating effective mucosal clearance (59,60). Adequate maintenance of MCC and ostium patency within the normal limits is fundamental for the success of SFE (61,62).

CHAPTER 2

PURPOSE

The Introduction section provides a comprehensive overview of the biological and anatomical factors relevant to the dissertation's focus. The overall purpose of this thesis was to explore the potential of osseodensification (OD) as a novel surgical technique for implant site preparation in comparison with the traditional osteotomy protocol. In addition, we aimed to demonstrate the versatility of this technique by validating its application and efficiency in different clinical scenarios, namely for immediate implant placement in molar extraction sockets and for sinus floor elevation (SFE) by crestal approach.

To achieve this, we structured the research project into three stages:

1. **Systematic review and meta-analysis (Chapter 3)**

   To appraise the available evidence on the clinical characteristics produced by OD drilling compared to the conventional drilling technique.

   Publication: Gaspar J, Proença L, Botelho J, Machado V, Chambrone L, Neiva R, Mendes JJ. Implant Stability of Osseodensification Drilling Versus Conventional Surgical Technique: A Systematic Review. Int J Oral Maxillofac Implants. 2021 Nov-Dec;36(6):1104-1110. doi: 10.11607/jomi.9132. PMID: 34919606.

2. **Participation in an international multicenter retrospective clinical study (Chapter 4)**

   To assess the effectiveness of interradicular septum expansion with OD site preparation for immediate implant placement in molar extraction sockets.

   Publication: Bleyan S, Gaspar J, Huwais S, Schwimer C, Mazor Z, Mendes JJ, Neiva R. Molar Septum Expansion with Osseodensification for Immediate Implant Placement, Retrospective Multicenter Study with Up-to-5-Year Follow-Up, Introducing a New Molar Socket Classification. J Funct Biomater. 2021 Nov 25;12(4):66. doi: 10.3390/jfb12040066. PMID: 34940545; PMCID: PMC8708493.

3. Randomized clinical trial (Chapter 5)

To compare patient-reported outcome measures and additional surgical outcomes after SFE with OD *versus* lateral window technique (LW), both with simultaneous implant placement.

Publication: Gaspar J, Botelho J, Proença L, Machado V, Chambrone L, Neiva R, Mendes JJ. Osseodensification versus lateral window technique for sinus floor elevation with simultaneous implant placement: A randomized clinical trial on patient-reported outcome measures. Clin Implant Dent Relat Res. 2024 Feb;26(1):113-126. doi: 10.1111/cid.13294. Epub 2023 Nov 28. PMID: 38018261.

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CHAPTER 3

IMPLANT STABILITY OF OSSEODENSIFICATION DRILLING VERSUS CONVENTIONAL SURGICAL TECHNIQUE: A SYSTEMATIC REVIEW

Implant Stability of Osseodensification Drilling Versus Conventional Surgical Technique: A Systematic Review

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Purpose: This systematic review aimed to appraise the available evidence on the clinical characteristics produced by osseodensification drilling compared with the conventional drilling technique. ***Materials and Methods:*** Five databases (PubMed, Google Scholar, LILACS, EMBASE, and CENTRAL) were searched up to July 2020. Randomized clinical trials (RCTs) and nonrandomized studies of interventions (NRSIs) that compared osseodensification drilling with conventional drilling in humans were included. Random-effects meta-analyses of standardized mean difference (MD) with 95% confidence intervals (CI) and risk ratio were performed. ***Results:*** Three NRSIs fulfilled the inclusion criteria, and all were scored as low risk of bias. Meta-analysis showed that the osseodensification drilling technique presented higher average implant stability quotient (ISQ) scores at baseline (MD: 13.1, 95% CI: 10.0 to 16.1, $P < .0001$) than conventional drilling, with complete homogeneity ($I^2 = 0.0\%$). Furthermore, osseodensification drilling presented higher average ISQ scores at follow-up (MD: 5.99, 95% CI: 1.3 to 10.6, $P < .0001$) than conventional drilling, with high homogeneity ($I^2 = 73.0\%$). ***Conclusion:*** This systematic review showed that osseodensification presented consistently higher ISQ at baseline and at 4 to 6 months after implant placement compared with conventional drilling. However, these results should be carefully interpreted since only three studies were selected in this meta-analysis. In the future, RCTs will be necessary to confirm the consistency of these results. *Int J Oral Maxillofac Implants 2021;36:1104–1110. doi: 10.11607/jomi.9132*

Keywords: biomechanics, bone, conventional drilling techniques, implant site preparation, meta-analysis, osseodensification, systematic review

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Oral rehabilitation of partial or complete edentulism with endosseous titanium implants is a safe and predictable treatment option associated with high success rates.[1–3] Implant stability is a critical aspect for clinical success of rehabilitation[1] and includes primary stability (mechanical engagement that is achieved upon insertion in bone, holding the implant in place) and secondary stability (biologic stability that occurs due to new bone formation during healing, resulting in osseointegration).[4,5] Successful osseointegration depends on established primary stability, described as adequate contact between the implant and bone upon instrumentation.[6] It has been shown in the literature that implant micromotion exceeding 50 to 150 μm might induce peri-implant bone resorption or implant failure.[7,8] Therefore, high degrees of primary stability are associated in the literature with superior and higher probability of osseointegration.[9] Higher implant primary stability is particularly important with immediate and early loading protocols. Ottoni et al[10] showed a 20% reduction in the osseointegration failure rate of immediately temporized single implants for every 9.8-Ncm increase in insertion torque.

Numerous techniques have been described to increase bone quantity and quality and to enhance primary stability, especially in low-density bone. These include underpreparation drilling protocols,[11] use of osteotomes and condensers,[12] bicortical fixation,[13] or piezoelectric devices.[14] Although providing good success rates, all these techniques have downsides. Severe undersizing of implant site preparation may induce bone necrosis, potentially impeding secondary stability or osseointegration.[6,15] Conversely, the use of osteotomes creates a layer of compacted bone at the implant interface but has several limitations associated with it, namely, surgical trauma, patient vertigo, or accidental fracture, which may delay healing compared with conventional drilling protocols.[16–18]

More recently, to address these potential limitations, an innovative technique for implant site preparation, osseodensification, has been introduced.[19] Based on a nonsubtractive multistepped drilling process through specially designed burs to rotate in the counterclockwise direction, this technique promotes bone preservation by compacting bone along the osteotomy wall and plastically expanding the bony ridge.[20–22] Thus, counterclockwise drilling is indicated for densification in low-density bone, while clockwise regular motion is used for higher-density bone.[21] Osseodensification drilling is suggested to enhance implant primary stability due to the presence of residual bone chips associated with autografting compaction,[19,21] increasing bone-to-implant contact (BIC) after implant insertion. Additionally, nucleating osteoblasts on the instrumented bone may accelerate new bone formation,[21,23] thereby potentially shortening the healing period.[19] Recently, a number of systematic reviews appraised the potential characteristics of this surgical technique,[24,25] but none was able to synthesize results on implant clinical characteristics, and therefore, such analysis would be of great interest.

This systematic review aimed to appraise the available evidence on the clinical characteristics produced by osseodensification drilling compared with conventional drilling techniques. The following focused question was addressed: "Is the implant stability different between osseodensification drilling and the conventional surgical technique?"

MATERIALS AND METHODS

Protocol and Registration

This systematic review was structured following the Cochrane Handbook of Systematic Reviews of Interventions,[26] and reported according to the PRISMA guidelines.[27]

Eligibility Criteria

To address this PICO question (patients requiring implant placement [P: patients]; osseodensification surgical technique [I: intervention]; conventional surgical technique [C: comparison]; implant stability quotient [ISQ; O: outcome]), the following inclusion criteria were applied:

- Randomized clinical trials (RCTs) and nonrandomized studies of interventions (NRSIs)
- Studies comparing osseodensification drilling with conventional drilling
- Studies reporting implant stability (ISQ) through resonance frequency analysis (RFA)
- Studies with immediate outcome and follow-up of at least 3 months after placement of the dental implant

In addition, nonintervention studies, studies not reporting osseodensification drilling, studies without a conventional (control) group, studies not reporting the conventional drilling system, and studies in patients undergoing radiation treatment of the head and neck or with systemic pathologic conditions were not considered eligible for inclusion in the review.

Information Sources and Search

To streamline the identification of potentially eligible studies for inclusion in this systematic review, PubMed via MEDLINE (Medical Literature Analysis and Retrieval System Online), Google Scholar, CENTRAL (The Cochrane Central Register of Controlled Trials), LILACS, and EMBASE were searched up to, and including, July 2020 without language restriction. Keywords and subject headings were combined in accordance with the thesaurus of each database, and exploded subject headings were applied. The search strategy was based on the algorithm developed for MEDLINE: "(Osseodensification OR densification) AND (Dental implants [MeSH] OR dental implantation [MeSH] OR osseointegration [MeSH] or bone-implant interface [MeSH] OR stability OR survival rate [MeSH] OR success rate OR marginal bone loss OR bone density OR volume)." Moreover, the reference lists of relevant articles and reviews were manually searched. Gray literature was examined through proper registers and databases.

Study Selection, Data Items, and Data Extraction Process

Study selection was independently performed by two authors (J.G., J.B.), who assessed the titles and/or abstracts of selected studies. Interexaminer reliability after full-text screening was computed (kappa statistics). Any divergences were solved through debate with a third author (V.M.). Final study selection was based on the aforementioned inclusion criteria. Additionally, data extraction was independently conducted by one author (J.G.), through a predefined table, including the author's name, publication year, study design, number of participants, outcomes, and additional notes.

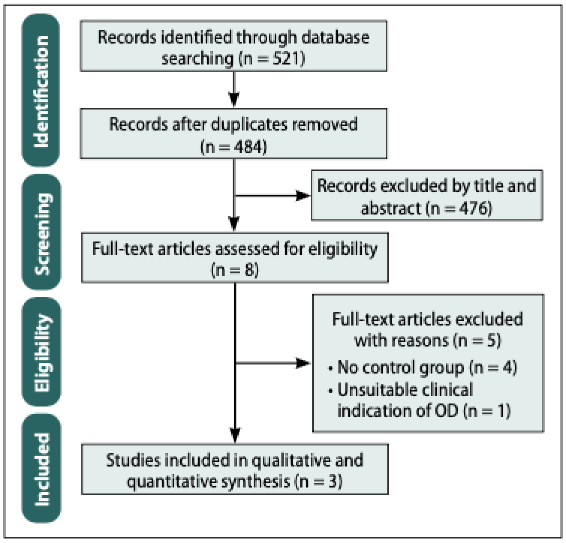


Fig 1 PRISMA flowchart representing the results of the workflow to identify eligible studies.

Risk of Bias in Individual Studies

The ROBINS-I tool (Risk of Bias in Non-randomized Studies - of Interventions) was used to appraise the risk of bias of the included NRSIs.[28] The risk of bias was appraised for each field and rated in its overall assessment as low, moderate, serious, or critical for all included studies.

Data Synthesis

Data were gathered into evidence tables. Mean values and standard deviations (SD) of ISQ measures for immediate and 4 to 6 months of follow-up after implant placement were used and evaluated with mean differences (MD) and 95% confidence intervals (CIs) using the DerSimonian-Laird random-effects model[29] in accordance with Schwarzer et al[30] in R version 3.4.1 (R Studio Team, 2018). To visualize the pooled estimates and 95% CIs, forest plots were rendered. The "meta" package was used to produce random-effects meta-analysis and forest plots.[30] The magnitude of the effect size (ES) dispersion was quantified with I^2, and the chi-square (χ^2) test appraised the homogeneity level.[26] All tests were two-tailed, with an alpha level set at .05, except for the homogeneity test, whose significance level cutoff was set at .10 due to the low power of the χ^2 test in the context of a reduced number of eligible studies. The 95% CIs were reported along with the pooled estimates.

RESULTS

Study Selection

The search method identified 521 possibly related publications. After duplicate exclusion, 484 studies were judged against the appropriateness criteria, and after title and/or abstract screening, 476 were rejected. Among the eight articles selected for full paper review, five articles were excluded, and the respective reasons for exclusion are specified in Fig 1. Thus, three NRSIs were included for qualitative analysis. Good interexaminer reliability at the full-text assessment was recorded (kappa score = 0.978, 95% CI: 0.963 to 0.992).

Study Characteristics

The three studies included comprised an overall sample of 54 patients (and 64 implants[31–33]; Table 1). These studies were derived from Asia, two from Egypt,[32,33] and one from India.[31] All implants were placed in the maxilla with the osseodensification technique and compared with conventional drilling.

In Sultana et al,[31] 20 patients were included and distributed in two groups (in group 1, 10 implants were placed using the traditional drilling technique, and in group 2, 10 implants were placed using the osseodensification drilling technique). Primary stability was measured by means of RFA (Osstell, Osstell) in both groups at baseline (immediately postoperative) and after 6 months, while crestal bone levels were measured at baseline and at 6 and 8 months postoperatively.

In Ibrahim et al,[32] 20 implants were placed in 10 patients (split-mouth design) with at least two teeth missing in the maxillary posterior region. ISQ was measured immediately and 4 months after implant placement.

In Arafat and Elbaz,[33] 24 patients requiring one to two implants in the posterior maxilla with at least 5 mm of residual bone height were included and randomly allocated into two groups. Group 1 (n = 12) received conventional osteotomy and osteotome technique to elevate the sinus membrane; group 2 (n = 12) received osseodensification for both implant site preparation and crestal sinus elevation. In both groups, simultaneous implant placement was performed. No bone graft was used in any group. ISQ was measured after implant placement (primary stability) and 6 months postoperatively (secondary stability).

Risk of Bias Within Studies

Overall risk of bias was considered low for the three included NRSIs, in terms of confounding, selection, classification, missing data, deviations from interventions, outcomes measurement, and selection of reported results (Table 2).

Synthesis of Results

Implant stability. In the present analysis, the osseodensification drilling technique presented higher average scores of baseline ISQ (MD: 13.1, 95% CI: 10.0 to 16.1, $P < .0001$) than conventional drilling, with complete homogeneity ($I^2 = 0.0\%$; Fig 2).

Table 1 Characteristics of the Included Studies

Study	Methods	Participants	Interventions	Outcomes ISQ (mean ± SD)	Notes
Sultana et al[31] (2020)	NSRI	20	**Group I**—Conventional drilling 10 implants **Group II**—OD drilling 10 implants	**Immediate postoperative** Conventional drilling ISQ: 59 ± 17.28 OD ISQ: 65.7 ± 12.36 **6 mo** Conventional drilling ISQ: 65.8 ± 7.39 OD ISQ: 65.6 ± 5.23	India Swami Vivekanand Subharti University Funding: No
Ibrahim et al[32] (2020)	NSRI	10	**Split mouth design** **Conventional drilling (control):** 10 implants **OD drilling (test):** 10 implants	**Immediate postoperative** Conventional drilling ISQ: 59.65 ± 5.39 OD ISQ: 74.25 ± 4.95 **4 mo** Conventional drilling ISQ: 68.25 ± 5.14 OD ISQ: 76.9 ± 4.05	Egypt Alexandria University Funding: NA
Arafat and Elbaz[33] (2019)	NSRI	24	**Group 1**— Conventional drilling 12 implants **Group 2**—OD drilling 12 implants	**Immediate postoperative** Conventional drilling ISQ: 52.83 ± 6.29 OD ISQ: 65.17 ± 4.39 **6 mo** Conventional drilling ISQ: 67.83 ± 4.78 OD ISQ: 75.92 ± 2.94	Egypt MSA University Funding: NA

Table 2 Risk of Bias of Nonrandomized Studies of Interventions (NRSI)

	Domain							
	1	2	3	4	5	6	7	
Study	Confounding	Selection	Classification	Deviations from interventions	Missing data	Measurement of outcomes	Selection of reported result	τ Overall
Sultana et al[31] (2020)	Low	Low	Low	Low	Low	Low	Low	Low
Ibrahim et al[32] (2020)	Low	Low	Low	Low	Low	Low	Low	Low
Arafat et al[33] (2019)	Low	Low	Low	Low	Low	Low	Low	Low

Further, osseodensification drilling presented higher average scores of follow-up ISQ (MD: 5.99, 95% CI: 1.3 to 10.6, $P < .0001$) than conventional drilling, with high homogeneity ($I^2 = 73.0\%$; Fig 3).

DISCUSSION

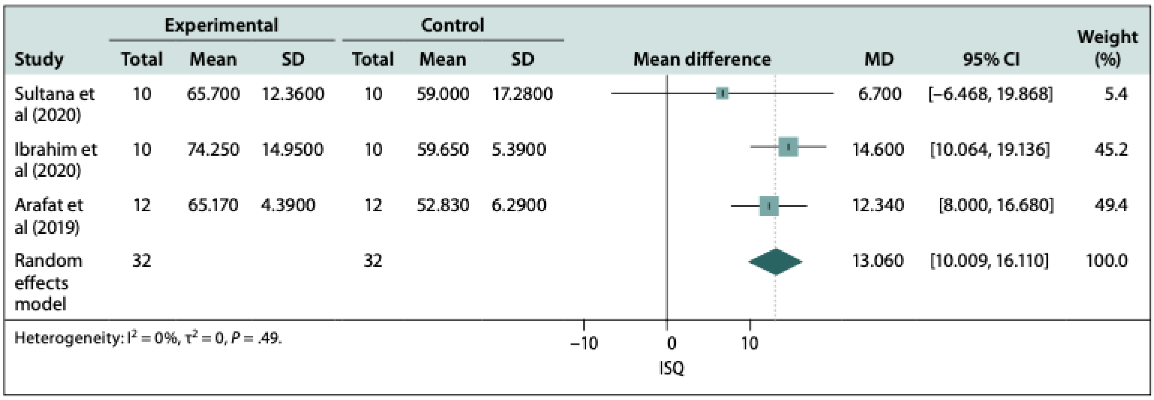
Summary of Main Findings

To the best of the authors' knowledge, this systematic review is the first to investigate such clinical comparison through the means of meta-analysis; therefore, these results are novel. Overall, both individual study outcomes and pooled estimates identified that osseodensification presented consistently higher ISQ values at baseline and follow-up compared with conventional drilling.

Quality of the Evidence, Limitations, and Potential Biases in the Review Process

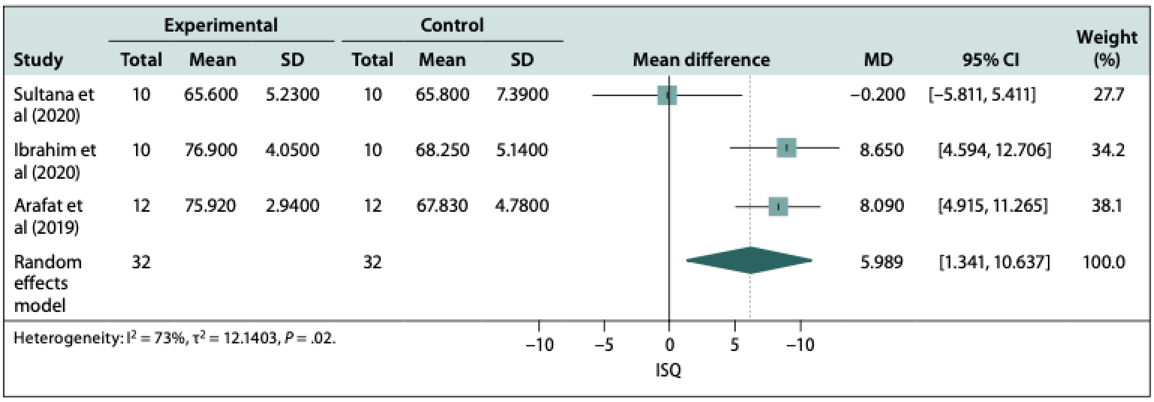
Overall, the quality of the evidence of this review is limited because there are some study limitations present, yet there is a large magnitude of effect that should be considered. The obtained result might be explained by the characteristics of the osseodensification counterclockwise drilling technique, where implant stability is hypothesized due to the spring-back effect,[34] and bone adaptation, which is why there is no need to undersize the osteotomy with these specially designed densifying burs.[19]

Comprehensively, the results of this systematic review point to a biologic rationale in which bone densification at the osteotomy walls along with the presence of residual bone chips results in an enhanced contact between the implant and surrounding bone. This will



Study	Experimental Total	Experimental Mean	Experimental SD	Control Total	Control Mean	Control SD	MD	95% CI	Weight (%)
Sultana et al (2020)	10	65.700	12.3600	10	59.000	17.2800	6.700	[−6.468, 19.868]	5.4
Ibrahim et al (2020)	10	74.250	14.9500	10	59.650	5.3900	14.600	[10.064, 19.136]	45.2
Arafat et al (2019)	12	65.170	4.3900	12	52.830	6.2900	12.340	[8.000, 16.680]	49.4
Random effects model	32			32			13.060	[10.009, 16.110]	100.0

Fig 2 Meta-analysis results of baseline ISQ of osseodensification drilling versus conventional drilling.



Study	Experimental Total	Experimental Mean	Experimental SD	Control Total	Control Mean	Control SD	MD	95% CI	Weight (%)
Sultana et al (2020)	10	65.600	5.2300	10	65.800	7.3900	−0.200	[−5.811, 5.411]	27.7
Ibrahim et al (2020)	10	76.900	4.0500	10	68.250	5.1400	8.650	[4.594, 12.706]	34.2
Arafat et al (2019)	12	75.920	2.9400	12	67.830	4.7800	8.090	[4.915, 11.265]	38.1
Random effects model	32			32			5.989	[1.341, 10.637]	100.0

Fig 3 Meta-analysis results of follow-up ISQ of osseodensification drilling versus conventional drilling.

not only produce higher degrees of implant primary stability due to physical interlocking but also result in potentially improved and accelerated bone healing due to osteoblast nucleation on the instrumented bone.[21,23,35] In addition, osseodensification might induce alterations in the biomechanics of bone as previously described by Tretto et al.[36] In this review, the authors evaluated the influence of the instrument used for implant site preparation on the bone-implant interface. Among the tested instruments (conventional drills, osteotomes, Er:YAG LASER, piezoelectric device, and osseodensification), the osseodensification technique showed a substantial improvement in biomechanical properties in comparison to conventional drilling, with favorable and encouraging outcomes.

Preclinical studies in sheep have demonstrated the biologic potential of osseodensification. In one study, osseodensification drilling enhanced the osseointegration of machined implants to values equivalent to surface-textured implants placed with traditional subtractive osteotomy in low-density bone.[37] In another study in the same animal model, implant site preparation with osseodensification was able to compensate the osteoconductive disadvantage from the absence of surface treatment of the machined-surfaced implants, suggesting that nontreated implant surfaces associated with osseodensification drilling may achieve comparable levels of osseointegration to surface-treated implants placed with conventional drilling methods.[38]

On the other hand, a study in a murine model by Wang et al assessed the effect of condensation on peri-implant bone density and remodeling.[39] According to their results, although condensation was able to increase bone density, it caused marginal bone resorption and excessive strains rather than improvement in implant stability. The authors extrapolated their findings to the osseodensification technique. However, caution is recommended in the interpretation and extrapolation of the results since conventional osteotomes instead of osseodensification drills were used to prepare 0.5-mm-wide osteotomies in mice. The bone structure in rats and humans has significant biochemical dissimilarities, which suggests that bone research data originating from this animal model should be transferred to the clinical situation with extreme precaution.[40] In another study in a murine model, Coyac et al[41] reported that excessive osseodensification can lead to osseodestruction. However, the authors did not use osseodensification drills for implant site preparation. Instead, they used conventional drills to undersize the osteotomy in relation to the diameter of the implants, thereby creating a misfit between both, which led to peri-implant compression and a high insertion torque.

Human clinical studies have demonstrated favorable and predictable outcomes of osseodensification. Huwais et al,[42] in a retrospective multicenter study of 261 implants with an up-to-5-year follow-up, concluded that osseodensification represents an effective method to facilitate crestal sinus elevation, with a 97% implant survival rate in a wide range of residual bone heights. Gaspar et al[43] conducted an observational study with 97 implants to evaluate the outcome of osseodensification in four different groups: ridge expansion, crestal approach sinus elevation, immediate implant placement, and full-arch cases with immediate loading. The results were favorable for all clinical situations, namely, in terms of bone expansion capacity of osseodensification, which may be clinically significant in reducing peri-implant bone fenestrations or dehiscences.[43]

This systematic review respected a thorough protocol with up-to-date international reporting guidelines and a comprehensive literature review, and all the articles included were considered as low risk of bias. However, several shortcomings are worth mentioning. The results are derived from NRSIs, which may limit the interpretation of these conclusions. In addition, the follow-up interval was not standardized, which may explain the heterogeneity in that particular result. Even so, the results of the first meta-analysis presented complete homogeneity, though the low number of included studies may explain this optimistic result. Another limitation is the sample size included; nevertheless, this result may be key in sample size calculation for future investigations. Finally, the present study was only able to provide estimates regarding ISQ values, so in the future, it would be important to broaden to other clinical characteristics.

Agreements and Disagreements with Previous Reviews and Studies

Concerning the agreement with previous reviews, this study was the first to analyze data from exclusively human subjects. Until now, several systematic reviews have provided important insights; however, they have either analyzed only animal studies or combined data from animal preclinical and human clinical studies.[24,25,36,44] Current histologic evidence in animal studies indicates an increase in BIC and bone-area fraction with osseodensification.[25] Moreover, a significant improvement in the biomechanical properties is observed with osseodensification that shows encouraging results to be further investigated in clinical research.[36,44] However, well-designed human studies are necessary to fully determine the clinical advantages of this promising technique.[24,25,36,44,45]

CONCLUSIONS

This systematic review demonstrated that osseodensification presented consistently higher ISQ at baseline and at 4 to 6 months after implant placement compared with conventional drilling. However, these results should be cautiously interpreted since only three studies were selected in this meta-analysis. Nevertheless, within the limitations of the results of this study, the osseodensification technique for implant site preparation might be particularly useful in low-density bone and when immediate temporization is intended. It is also important to mention that none of the studies reported inferiority of clinical outcomes of osseodensification compared with conventional drilling methods.

Future studies should expand to RCT designs to evaluate the potential of this technique in maxillary sinus elevation, ridge expansion, postextraction sites, and its behavior within guided bone regeneration comparing clinical follow-ups with conventional drilling.

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CHAPTER 4

MOLAR SEPTUM EXPANSION WITH OSSEODENSIFICATION FOR IMMEDIATE IMPLANT PLACEMENT, RETROSPECTIVE MULTICENTER STUDY WITH UP-TO-5-YEAR FOLLOW-UP, INTRODUCING A NEW MOLAR SOCKET CLASSIFICATION

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Molar Septum Expansion with Osseodensification for Immediate Implant Placement, Retrospective Multicenter Study with Up-to-5-Year Follow-Up, Introducing a New Molar Socket Classification

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Abstract: The ideal positioning of immediate implants in molar extraction sockets often requires the osteotomy to be in the interradicular septum, which can be challenging in some cases, with traditional site preparation techniques. Patients who had undergone molar tooth extraction and immediate implant placement at five different centers, and followed up between August 2015 and September 2020, were evaluated. Inclusion criteria were use of the osseodensification technique for implant site preparation. The primary outcome was septum width measurement pre-instrumentation and osteotomy diameter post expansion. Clinical outcomes, such as implant insertion torque (ISQ) and implant survival rate, were also collected. A total of 131 patients, who received 145 immediate implants, were included. The mean overall septum width at baseline was 3.3 mm and the mean osteotomy diameter post instrumentation was 4.65 mm. A total of ten implants failed: seven within the healing period and three after loading; resulting in a cumulative implant survival rate of 93.1%. This retrospective study showed that osseodensification is a predictable method for immediate implant placement with interradicular septum expansion in molar extraction sockets. Furthermore, it allowed the introduction of a new molar socket classification. In the future, well-designed controlled clinical studies are needed to confirm these results and further explore the potential advantages of this technique.

Keywords: osseodensification; immediate implant placement; septum expansion; osteotomy; osseointegration

1. Introduction

Immediate implant placement (IIP) into fresh extraction sockets has aroused interest since it was initially described [1] and has been considered a predictable therapeutic approach for both anterior and posterior sites, with survival rates comparable to implants placed in healed ridges [2–5]. An 11-year retrospective study of 300 implants immediately placed in molar extraction sockets reported an overall survival rate of 97.3% [6]. Furthermore, a systematic review [7] of outcomes following immediate molar implant placement demonstrated a survival rate of 98%, with no significant differences between maxilla and mandible. More recently, another systematic review and meta-analysis [8] of immediate implants in molar extraction sites demonstrated success rates of 93.3% after 1 year of follow-up.

This treatment alternative offers several advantages in comparison to the classic delayed approach, namely a single surgical intervention, with a reduction in overall treatment time and, therefore, increased patient satisfaction [9,10]. However, its success was reported to be influenced by several factors, including the need for atraumatic extraction to preserve favorable socket anatomy, as well as the effect of site instrumentation to achieve an adequate initial implant stability [9]. Implant primary stability and adequate insertion torque are considered critical aspects for successful IIP [5,6,11,12]. Several challenges have been described in achieving initial stabilization in molar extraction sockets. These include the width of the extraction socket, poor bone quality, inadequate interradicular bone septum width, and anatomical limitations beyond the apex of the roots, such as the inferior alveolar canal in the mandible or the maxillary sinus in the maxilla [13]. Thus, flapless tooth extraction with minimal trauma and gentle separation of the roots is essential to preserve a favorable anatomy and to allow the placement of the implant within the socket itself, when needed [10,14]. In addition, implant primary stability and insertion torque is related to the density of the bone pre and post site preparation. Bone density is known to have a direct effect on implant stability, as the denser the bone surrounding the osteotomy walls, the higher the insertion torque and the ISQ values [15]. Both these parameters are influenced by the drilling protocol [16,17], so enhancing the bone density during osteotomy preparation may improve clinical success, especially in the maxilla, due to its typically lower bone density compared to the mandible [18].

Smith and Tarnow [14] classified molar sockets based on the amount of interradicular septal bone in relation to implant placement into three types: Type A sockets have sufficient septal bone bulk to circumferentially contain the implant. Type B sockets have enough septal bone bulk to stabilize the implant, but not fully surround it. On the other hand, Type C sockets have insufficient septal bone to stabilize the implant without engaging the socket walls, so this would either indicate the placement of ultra-wide diameter implants or a delayed placement approach. According to several authors [19–21], immediate implant placement in molar extraction sockets using ultra-wide implants demonstrates a predictable outcome, with reduced bone loss and stable soft and hard tissue conditions. However, in a systematic review [7] conducted in 2016, ultra-wide implants (>6–9 mm) were found to have a significantly higher failure rate than implants of 4 to 6 mm diameter. More recently, Ragucci et al. [8] also recommended the use of implants of <5 mm diameter for immediate placement in molar extraction sockets. Therefore, implant placement in the interradicular septum is usually considered the best option for an immediate molar implant, not only in terms of correct 3D positioning, but also regarding implant survival [10].

Recently, a novel non-subtractive surgical technique for implant site preparation termed osseodensification (OD) was introduced [22]. Contrary to traditional extractive drilling protocols, it preserves bone and enhances its plasticity, utilizing specially designed burs that rotate in a non-cutting (counter-clockwise) direction to gradually expand the osteotomy, while simultaneously compacting bone into its trabecular spaces, increasing the density of the site [22–25]. Furthermore, OD was shown to enhance implant primary stability, due to the compaction auto-grafting and the associated spring-back effect [22,26]; increasing bone-to-implant contact (BIC) upon implant placement [24,25]. These auto-grafted bone particles in the trabecular spaces act as nucleation for faster bone formation around the implant, potentially shortening the healing time [23–25,27]. Large-animal histological studies have demonstrated that this high stability at the day of surgery is maintained throughout the implant healing process, regardless of the implant macro- or micro-geometry [24,25,27]. In a recent multicenter controlled clinical trial, OD also demonstrated significantly higher insertion torque and ISQ values compared to conventional subtractive drilling for all implant dimensions, with the exception of short implants, regardless of the jaw and area operated, and irrespective of the evaluation period [28]. Osseodensification's ability to plastically expand trabecular bone with compaction autografting, to facilitate implant placement with sufficient stability and adequate healing in sites with less than optimum bone quantity and quality, was documented in both in vivo and clinical data [23,29]. Trisi et al. [23] was able to demonstrate, in a large animal histological study, the predictability of placing a 5-mm implant in 5-mm wide ridge in sheep iliac crest with adequate healing. Koutouzis and Huwais [29] confirmed his findings in a clinical controlled study that demonstrated a 93% success rate for 38 implants placed in plastically expanded alveolar ridges via osseodensification in 21 patients. In addition to ridge plastic expansion, osseodensification has also been reported to enhance dental implant's short and long-term success rate, regardless of their macro- or micro-geometry, in several clinical scenarios, including immediate loading [30–32], as well as to facilitate implant placement in conjunction with crestal sinus graft, with a high success rate [33–35].

The aim of the present multicenter retrospective study was to assess the effectiveness of interradicular septum expansion with osseodensification site preparation for immediate implant placement in molar extraction sockets.

2. Materials and Methods

This retrospective analysis followed the World Medical Association Declaration of Helsinki and the directives given by the Egas Moniz Ethics Commission (CEEM) at Egas Moniz Cooperativa de Ensino Superior, Monte de Caparica, Portugal, which does not require ethical approval for retrospective clinical studies.

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 [36].

2.1. Selection Criteria and Surgical Technique

Patients who had undergone molar tooth extraction and immediate implant placement with osseodensification at five different centers (S.B., J.G., S.H., C.S., Z.M.), followed up between August 2015 and September 2020, were evaluated. Inclusion criteria included patients with molar extraction sockets that had an interradicular septum of at least 2.5 mm width, use of the osseodensification technique for implant site preparation, and follow-up of a minimum of 12 months after loading with a definitive implant-supported restoration. Exclusion criteria comprised an initial septum width <2.5 mm, history of radiotherapy, bisphosphonate medication, active periodontal disease, uncontrolled diabetes, heavy smoking (>20 cigarettes/day), and local acute apical abscess. All patients had a cone beam computed tomography (CBCT) prior to surgical procedure.

All interventions were performed by experienced surgeons, who followed standardized surgical technique. After local anesthesia with articaine (4%) and epinephrine (1:200,000), flapless tooth extraction, as atraumatic as possible, was performed after separation of the roots with a long thin diamond bur, in order to preserve the interradicular bone and the general socket anatomy. The socket was then thoroughly curetted to detach any granulation tissue that could potentially impair healing.

Septum width was directly measured post molar extraction. Measurement was recorded at the narrowest width of the septum. Implant site preparation started with a pilot drill, in clockwise motion, in the center of the septum, until 1 mm deeper than the planned implant length. Densah® Burs (Versah, LLC, Jackson, MI, USA) were then sequentially used in OD mode (counterclockwise, drilling speed 800–1500 rpm, with copious irrigation) in small increments to gradually expand the osteotomy, until reaching the desired width for the planned implant diameter (Figure 1).

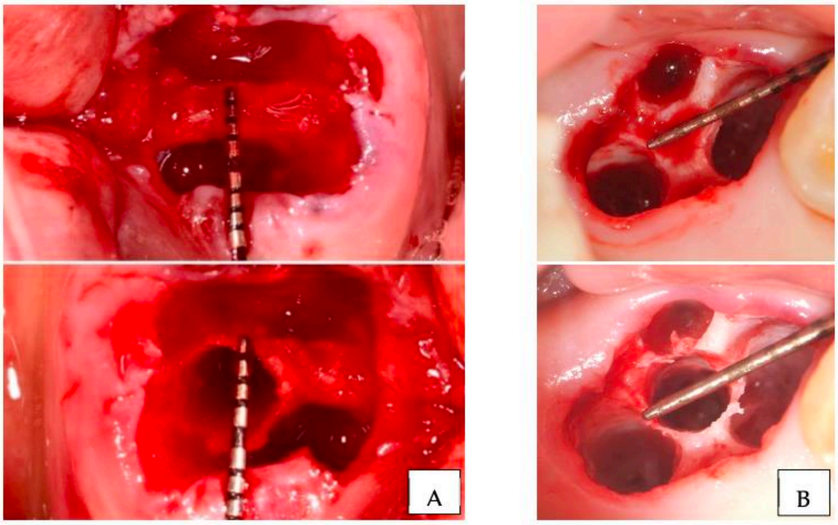

Figure 1. Clinical examples of interradicular septum expansion after implant site preparation with osseodensification ((**A**). Mandibular first molar; (**B**). Maxillary second molar).

Osteotomy diameter as a reflection of septum width expansion was then directly measured and recorded after site instrumentation. Although each center used the implant company of their choice, all implants placed were conical, bone-level, and with internal connection (Table 1). After implant placement at the adequate depth, the gaps were filled with allograft or alloplastic, depending on each center's preference and either a customized or a large stock sealing healing abutment was placed, with no attempt to coronally advance the flaps for primary intention healing. The insertion torque value was registered, and implant stability was measured using resonance frequency analysis, immediately after implant insertion (primary stability) and after healing, before final impression (secondary stability).

Table 1. Overview of implants included in the retrospective analysis.

Implant Company	Number of Implants Placed	Number of Implants Failed
Dentium	35	1
Adin	35	3
Megagen	26	1
Neobiotech	21	2
Zimmer	14	3
Paltop	6	0
IDI	5	0
Nobel Biocare	3	0
Total	145	10

The osseointegration period varied according to the decision of each clinician, based on the records mentioned above and on bone quantity and quality, with a minimum of 3 months. Despite not following a standardized medication protocol, all patients were prescribed post-operative antibiotics for 7–10 days, based on each center's preference.

2.2. Variables and Statistics

Data regarding patient characteristics (age and gender); tooth location; date of surgical and restorative procedure; septum width before and after site preparation and expansion; insertion torque and ISQ at baseline and after osseointegration; implant width and length; time of loading; osseointegration success rate; and final follow-up appointment were collected from the patients' clinical files. The primary outcome was septum width measurement pre-instrumentation and osteotomy diameter post expansion. Descriptive statistics were conducted using IBM® SPSS® Statistics software (SPSS for Mac, Version 26.0. SPSS Inc. Chicago, IL, USA). A Kaplan–Meier curve was used to analyze the survival rate of implants placed. This curve was adjusted to 12 months, because it was the minimum follow-up common to all implants.

3. Results

A total of 131 patients, 90 women and 41 men, with a mean age of 52 years (range 27–80), who received 145 immediate implants in molar extraction sockets, were included (Figure 2). The mean follow-up of the included patients was 36 months (range 12–60 months). Reasons for tooth extraction were endodontic treatment failure, root fracture, or non-restorable teeth. No extracted teeth sockets for periodontal reasons were included.

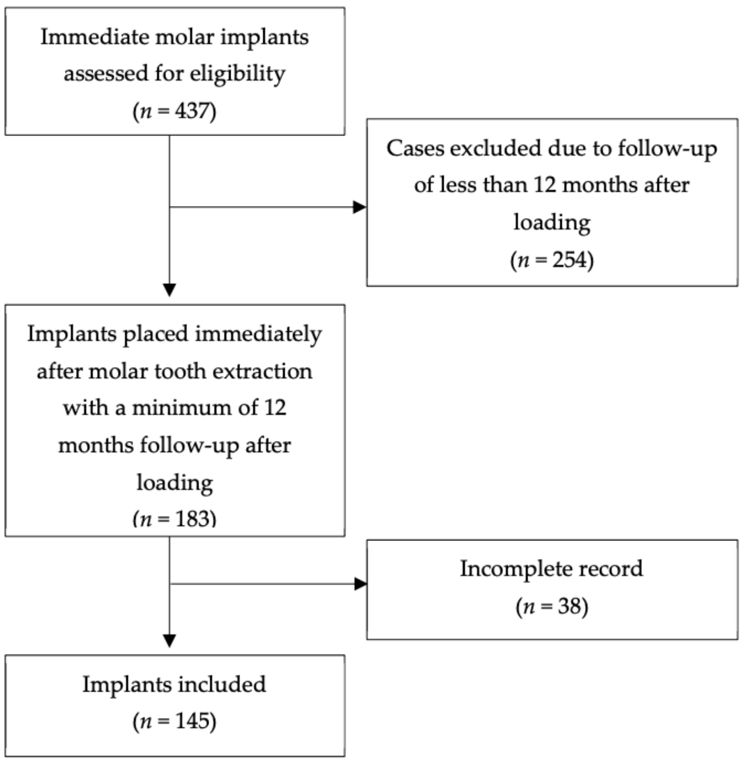

Figure 2. Flowchart representative of implants included in the retrospective analysis.

A total of 87 implants were placed in the mandible (72 in first molar sites and 15 in second molar sites) and 58 in the maxilla (53 in first molar sites and 5 in second molar sites), as shown in Figure 3. Maxillary sockets had higher mean values of interradicular septum width compared to those in the mandibular, as described in Figure 4.

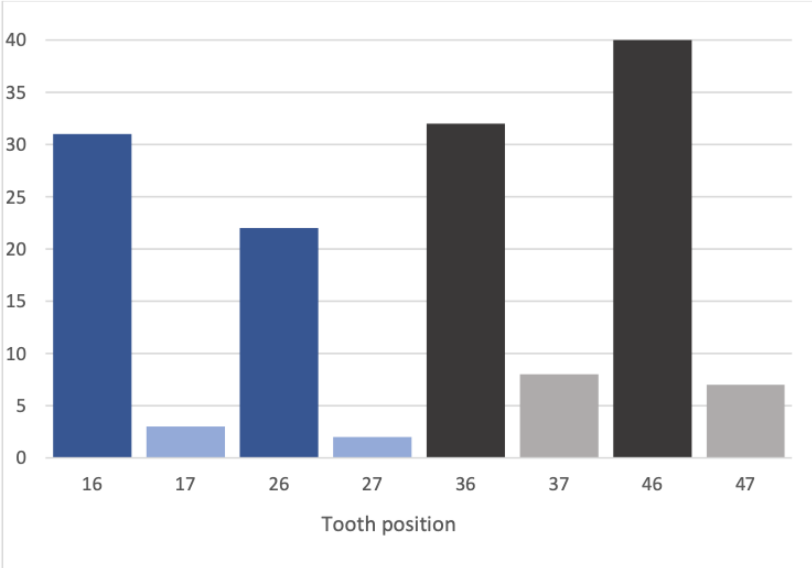

Figure 3. Number of implants placed, according to tooth position.

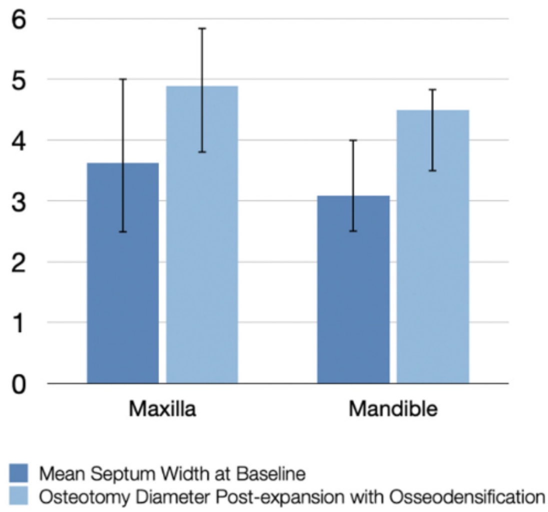

Figure 4. Mean septum width before instrumentation and osteotomy diameter post-expansion with osseodensification.

The mean overall septum width at baseline was 3.3 mm, and the mean osteotomy diameter post instrumentation was 4.65 mm after expansion with osseodensification (Figure 5).

Implant stability was measured by both insertion torque (ITV) and ISQ values. ITV was higher in the mandible (mean 46.72 N cm; range 30–60 N cm) than in the maxilla (mean 41.12 N cm; range 20–60 N cm), with an overall mean value of 44.48 $\pm$ 8.2 N cm (Figure 6).

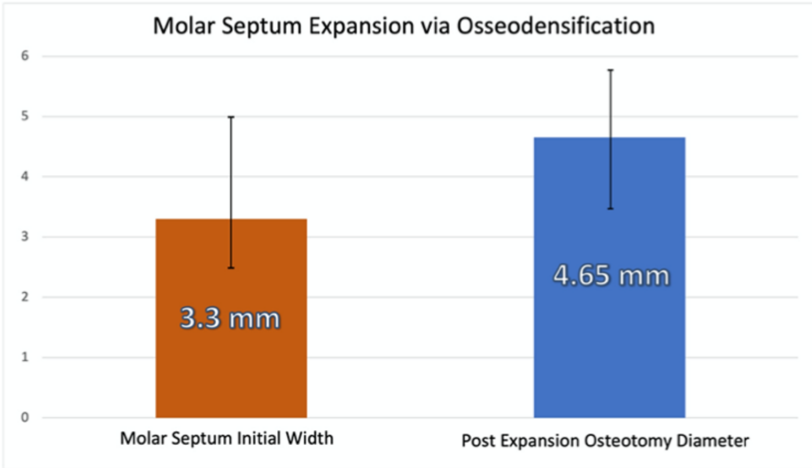

Figure 5. Mean overall septum width at baseline and osteotomy diameter post-expansion with osseodensification.

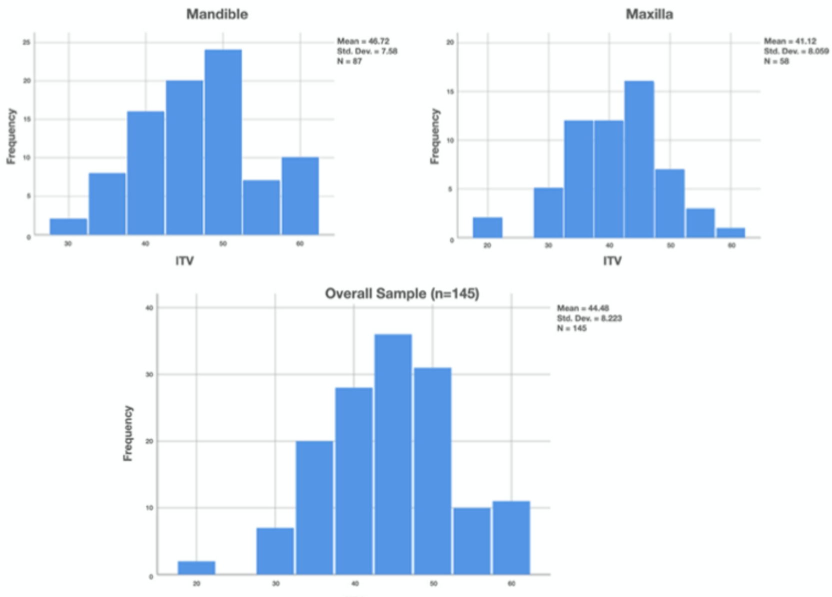

Figure 6. Insertion torque value (ITV) of implants placed.

Only 6.2% of the implants had an ITV <3 5 N cm, while 35.9% had an ITV $\geq$ 50 N cm. Mean ISQ was 72.8 (range 60–82) at baseline on the day of surgery (ISQS) and 78.9 (range 70–88) after the osseointegration period, before final impression (ISQR), as described in Table 2. Implant diameter ranged from 4.2 to 6.4 mm, and length ranged from 10 to 13 mm, depending on the implant system used in each center. A total of ten implants (four in the mandible and six in the maxilla) failed (Table 3): seven within the healing period before final impression and three after loading, resulting in a survival rate of 93.1%. Only two centers included smoker patients (n = 6), who did not experience implant failure; therefore, no correlation could be assessed between smoking and implant failure. The Kaplan–Meier estimator predicted a 93.1% survival rate at 12 months follow-up (Figure 7).

Table 2. Mean ISQ measurement on day of surgery and in restorative phase after osseointegration period.

		ISQS	ISQR
Maxilla	Mean	71.47	77.26
	N	58	54
	Std. Deviation	4.231	3.004
Mandible	Mean	73.72	79.88
	N	87	84
	Std. Deviation	4.358	3.730
Total	Mean	72.82	78.86
	N	145	138
	Std. Deviation	4.434	3.684

ISQS–ISQ in day of surgery; ISQR–ISQ in restorative phase.

Table 3. Description of failed implants.

Implant Company	Diameter	ITV	ISQ	Septum Pre	Septum Post	Timing of Failure
Neobiotech	5	55	76	3.5	4.8	After
Neobiotech	5	35	65	3.4	4.8	Before
Dentium	5	40	68	2.8	4.5	Before
Zimmer	5.2	20	63	5	5.5	Before
Zimmer	5	20	62	4	5.5	Before
Zimmer	4.7	30	60	2.5	4.5	After
Megagen	5.0	30	70	3.5	4.8	After
Adin	4.3	50	75	3	4.5	Before
Adin	5	45	70	3	4.5	Before
Adin	4.3	50	74	2.5	3.8	Before
Mean	4.85	37.5	68.3	3.32	4.7	

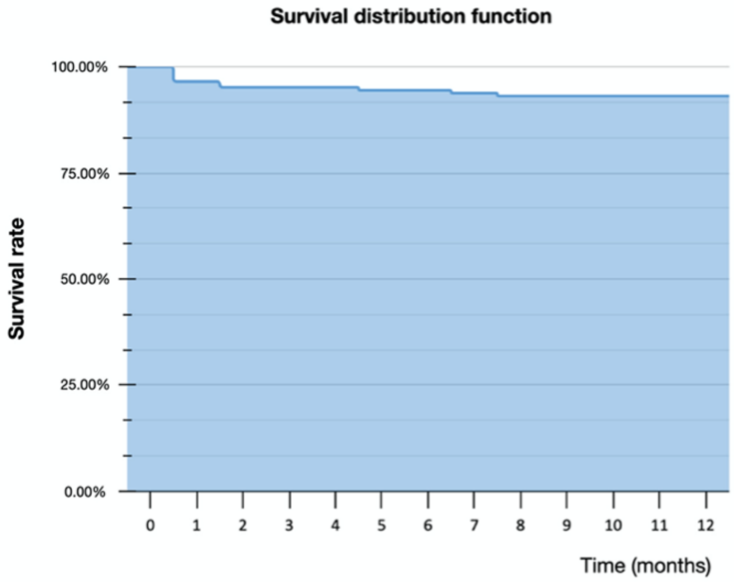

Figure 7. Kaplan–Meier survival curve for survival estimate.

4. Discussion

According to a recent systematic review and meta-analysis [8], the suggested approach for IIP in molar extraction sockets includes a flapless procedure, a one-stage implant placement, grafting the gap, and the use of implants with <5 mm diameter. Flapless surgery may not only contribute to decreased operative time, but also to faster healing, reduction of peri-implant tissue collapse, less postoperative complications, and improved patient comfort [8]. This approach was followed by all centers in this study, except for the implant diameter. In fact, 64.2% of the implants placed by all centers had a diameter $\geq$ 5 mm. The mean overall septum width at baseline was 3.3 mm and the mean implant diameter of all implants placed was 4.96 mm, which demonstrates the potential of the osseodensification technique to preserve the bony housing and expand the septum; thus, allowing predictably placing wider diameter implants compared to the conventional osteotomy technique.

Walker et al. [11] assessed the relationship between insertion torque values and clinical outcomes and reported an implant survival rate in immediate molar implants of 86%, when insertion torque was low, and 90% to 96% when IT was medium to high, respectively. This tendency was also observed in our study, since four out of the nine implants that had an insertion torque < 35 N cm failed. Moreover, the mean insertion torque of the implants that failed (n = 10) was 37.5, while the mean insertion torque of the successful implants (n = 135) was 45. Regarding ISQ, implants that ended up failing had lower mean ISQ values (68.3) on the day of surgery, compared to implants successfully integrated and loaded (73.2). In a recently published multicenter controlled clinical trial [28], OD drilling demonstrated significantly higher IT and temporal ISQ values relative to more conventional subtractive drilling techniques for all implant dimensions, with the exception of short implants. Therefore, we may assume that the implant survival would probably be lower with a traditional drilling protocol.

All sockets evaluated in this retrospective analysis were grafted with either allograft or alloplast (Novabone®). Bone grafting of the remaining socket voids adjacent to an immediate implant is not essential for osseointegration to occur, especially if the outer walls of the socket are intact [10,37,38]. However, its combination with a customized healing abutment, acting as a prosthetic socket seal device minimizes the amount of ridge contour change after tooth extraction and IIP, thereby contributing to better esthetics and restorative contour [10,38], as observed in this study (Figure 8).

Pre-operative CBCT is an essential and effective diagnostic method to evaluate socket anatomy and to define the most suitable treatment approach for each case, as well as minimizing the risk of damaging vital structures [39]. Historically, a minimum 3 mm width of interradicular septal bone (ISB) was deemed important to achieve initial stabilization of an immediate molar implant [40]. In this study, twenty-three extraction sockets had an ISB width of 2.5 mm and one had 2.8 mm. Nevertheless, the osseodensification technique used for implant site preparation allowed adequate septum expansion of all these sites, to create osteotomies diameters in a range of 3.5–4.5 mm, thereby providing adequate implant stability upon insertion. Moreover, since it pushes bone in a both lateral and apical direction, instead of removing it, osseodensification also predictably allows sinus elevation using a crestal approach in maxillary molar sockets with reduced residual bone height below the sinus floor [33].

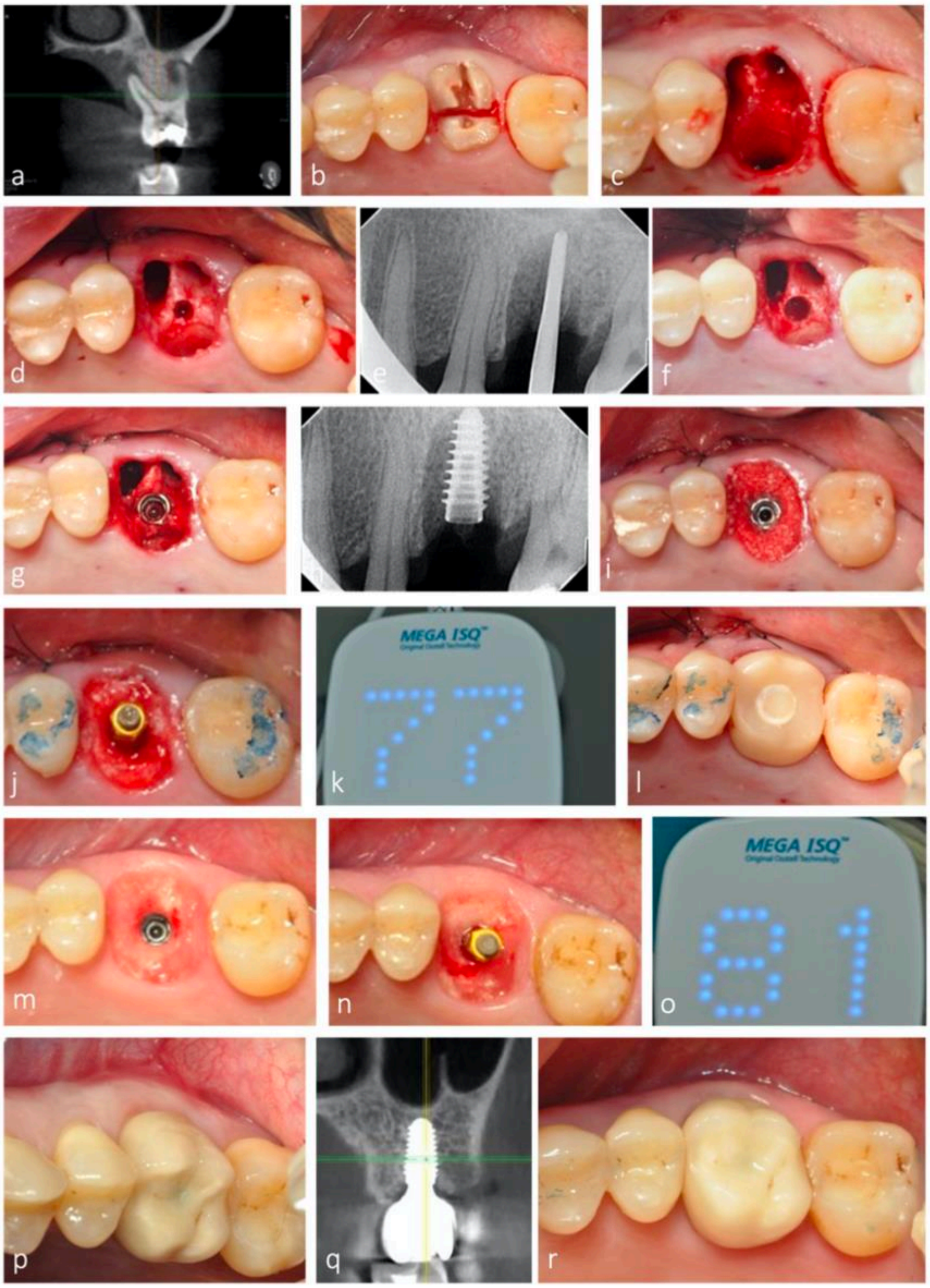

Figure 8. Representative clinical case with 3-year clinical and radiographic follow-up. (**a**) CBCT of maxillary left first molar showing periapical infection with extensive bone loss buccally and palatally. (**b**) Root section for tooth extraction as atraumatic as possible. (**c**) Septum preservation after extraction. (**d**,**e**) Initial osteotomy depth at 10 mm. (**f**) Implant site preparation, optimized with osseodensification. (**g**,**h**) Implant placed in the expanded septum. (**i**) Allograft placed in the root sockets to fill the extraction socket. (**j**–**l**) Adequate implant stability allowed for the placement of a fully contoured customized socket sealing healing abutment out of occlusion. (**m**) Healing after 3 months, with contour maintenance. (**n**,**o**) ISQ measurement after osseointegration period. (**p**–**r**) Clinical and radiographic follow-up after 3 years.

Traditionally, Smith and Tarnow classification type B sockets [14] with narrow septa are commonly managed by clinicians through the placement of an immediate implant into the palatal root socket of maxillary molars or into one of the two mandibular molar root sockets [41]. However, this may lead to potential food impaction and tissue inflammation, due to poor emergence profile of the restoration. Furthermore, Smith et al. [42] observed, in a retrospective study of 300 implants, that there is a direct correlation between the horizontal implant–tooth distance and the incidence of adjacent tooth decay. Therefore, immediate implant placement in the mesial or distal molar root sockets may significantly increase the risk of decay in the furthest tooth. Accordingly, the ideal implant positioning in molar sockets will most often require the osteotomy to be in the septum. Osseodensification may facilitate the preservation and the expansion of the interradicular septum, thus enhancing the ability to predictably place implants with adequate stability in both type B and C sockets, as shown in this study (Figure 9).

The traditional classification of molar extraction sockets by Smith and Tarnow [14] is based on the amount of interradicular septal bone remaining post instrumentation around immediately placed implants, but it does not take into account the specific measurement of the septum width pre-instrumentation nor pre-implant placement. Furthermore, the specific type of the socket in this classification is dependent on the diameter of the implant placed. Therefore, the authors of the present study propose a new diagnostic classification that is based on the initial septal bone width prior to site preparation and implant placement, which would allow adequate treatment planning. The new classification (Figure 10) includes four categories: S-I: septum initial width >4 mm; S-II: septum initial width = 3–4 mm; S-III: septum initial width = 2–3 mm; and S-IV: septum initial width < 2 mm/no septal bone. The relevance of this new diagnostic classification is related to the fact that, with osseodensification instrumentation, and due to bone preservation and plastic expansion, it is possible to convert type B sockets into type A, and type C into type B [14], as was observed in this study. According to our classification, only S-IV sockets represent an exclusion criterium for septum expansion with osseodensification. This would either indicate the placement of ultra-wide implants or a delayed placement approach. In fact, our results showed that osseodensification allowed immediate implant placement in the first three categories (S-I, S-II, and S-III) of this new classification, with adequate implant stability.

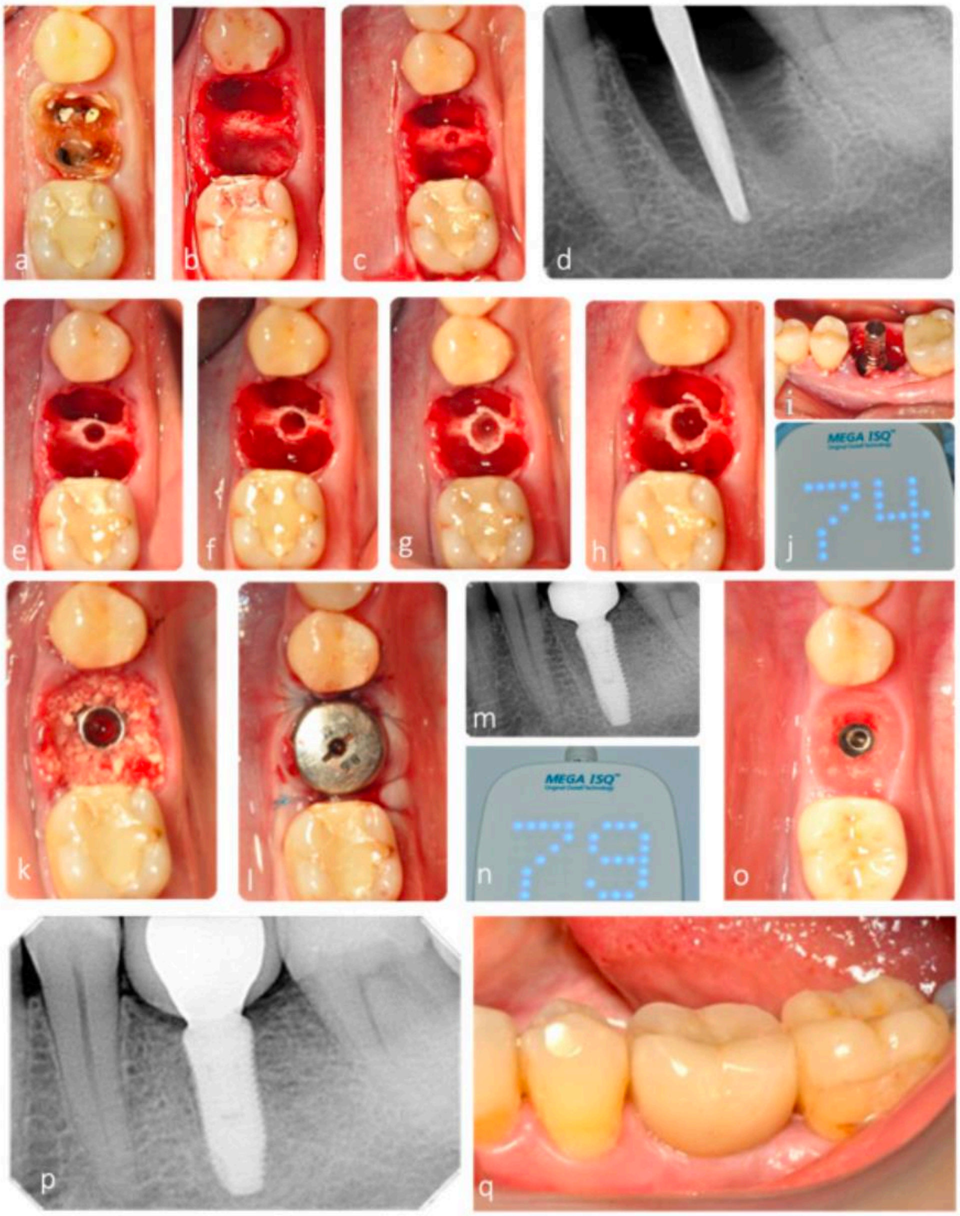

Figure 9. Representative clinical case with 4-year clinical and radiographic follow-up. (**a**) Initial radiograph with 4 mm of residual alveolar bone height. (**a**) Clinical situation at baseline. (**b**) Occlusal view after gentle tooth extraction with maintenance of interradicular septum. (**c**–**h**) Septum expansion after sequential instrumentation with osseodensification. (**d**) Radiograph of densifying bur VT1525 (2.0) in interradicular septum. (**i**,**j**) ISQ measurement after implant placement (primary stability). (**k**–**m**) Grafting of the gap and socket sealing with large healing abutment. (**n**) ISQ measurement after osseointegration period (secondary stability). (**o**) Contour maintenance after healing. (**p**,**q**) Clinical and radiographic follow-up after 4 years.

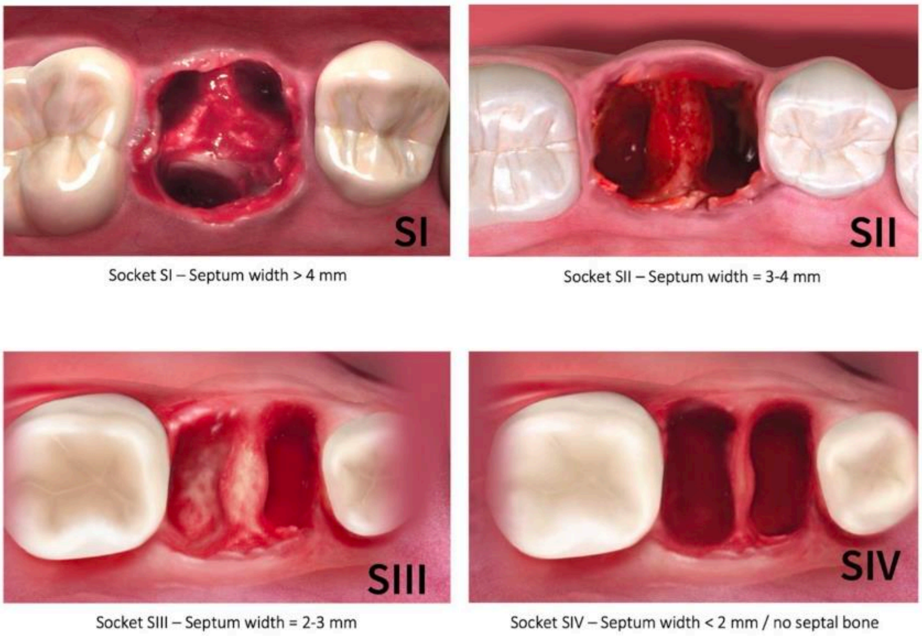

Figure 10. New molar socket classification according to the initial interradicular septum width. (SI—septum width > 4 mm; SII—septum width = 3–4 mm; SIII—septum width = 2–3 mm; SIV—septum width < 2 mm/no septal bone).

5. Conclusions

This up-to-5-year follow-up retrospective study showed that osseodensification is a viable and predictable method for interradicular septum expansion and immediate implant placement with adequate stability in molar extraction sockets. Furthermore, it allowed the introduction of a new molar socket classification, based on the available septum width prior to instrumentation. In the future, well-designed controlled clinical studies are needed to confirm these results and further explore the potential advantages of this site preparation technique.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data can be requested to the corresponding author upon reasonable request.

Conflicts of Interest: S.H. developed the novel osseodensification technique and invented the patented multifluted densifying burs that were utilized. None of the remaining authors report any conflict of interest.

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CHAPTER 5

OSSEODENSIFICATION VERSUS LATERAL WINDOW TECHNIQUE FOR SINUS FLOOR ELEVATION WITH SIMULTANEOUS IMPLANT PLACEMENT: A RANDOMIZED CLINICAL TRIAL ON PATIENT-REPORTED OUTCOME MEASURES

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ORIGINAL ARTICLE

WILEY

Osseodensification versus lateral window technique for sinus floor elevation with simultaneous implant placement: A randomized clinical trial on patient-reported outcome measures

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Abstract

Objectives: To compare patient-reported outcome measures and additional surgical outcomes after sinus floor elevation (SFE) with osseodensification (OD) versus lateral window (LW), both with simultaneous implant placement.

Materials and Methods: Twenty participants requiring single-implant rehabilitation with residual bone height (RBH) ≤4 mm were enrolled. Pain experience, quality of life (QoL) via the Oral Health Impact Profile-14 (OHIP-14), analgesics intake, and other symptoms were self-reported for a week on a daily basis. Surgery duration, complications, and implant stability quotient at baseline (ISQ T_0) and after 6 months (ISQ T_6) were registered. Participants were followed up for 1 year.

Results: From Day 0 (day of surgery) to Day 3, pain experience was significantly lower ($p < 0.05$) in the OD group. OHIP-14 score was significantly lower ($p < 0.05$) in the OD group on all postoperative days, except on Day 5. Average analgesics intake was significantly lower ($p < 0.001$) in the OD group. Surgery mean duration was significantly higher ($p < 0.001$) in LW compared to OD (71.1 ± 10.4 vs. 32.9 ± 5.3 min). After osseointegration period, all implants were successfully restored with screw-retained crowns.

Conclusions: Within the limitations of this study, it can be concluded that OD and LW techniques were similarly effective in SFE with simultaneous implant placement when RBH ≤ 4 mm. However, OD significantly outperformed LW in pain experience, impact on self-perceived QoL, surgery duration, postoperative edema, and analgesics intake.

KEYWORDS
implants, lateral window, osseodensification, pain, postoperative, sinus floor elevation

Summary Box

What is known

Lateral window technique is a safe and predictable treatment modality for sinus floor elevation and is still considered the *gold standard* approach when residual bone height ≤4 mm. However, it has some drawbacks since it is often associated with considerable patient morbidity.

What this study adds

This study demonstrated that osseodensification is as effective as the lateral window technique for sinus floor elevation with simultaneous implant placement when residual bone height ≤4 mm, but with significantly improved patient-reported outcome measures.

1 | INTRODUCTION

The edentulous posterior maxilla is often associated with limited bone availability, particularly in terms of residual bone height (RBH) below the maxillary sinus floor. This happens not only due to the resorption of the alveolar ridge following tooth extraction but also due to sinus pneumatization which may occur.[1,2] Furthermore, bone density in this area is usually low which represents an additional challenge for proper implant placement.[3] Maxillary sinus floor elevation (SFE) is an effective and safe surgical procedure to vertically increase bone height either through a lateral or crestal approach,[4–6] which are both associated with high implant survival rates.[6–8] The classical SFE procedure by a lateral window (LW) approach was first presented in the 1970s by Tatum[9] and later published and described in more detail by Boyne and James in 1980.[10] It is still widely used nowadays and historically considered the *gold-standard* technique in cases with RBH <5 mm.[11–13] However, this surgical approach has some drawbacks since it is often associated with substantial patient morbidity. It requires a wide mucoperiosteal flap with at least one vertical releasing incision for the creation of a bony window in the lateral wall of the maxillary sinus which may result in an increased risk of postoperative pain, facial edema, delay in healing, bleeding, and postoperative infection.[14–16] The more conservative transcrestal SFE approach was first proposed in 1976[9] and later modified by Summers in 1994[17] through the use of tapered osteotomes to fracture the maxillary sinus floor and elevate the Schneiderian membrane. Traditionally, this technique has been recommended in patients with at least 5 mm of RBH[11,13,18] and is not indicated in cases with an oblique sinus floor due to the high risk of membrane perforation.[18] Moreover, the repeated tapping of the osteotomes with the uncontrolled force for the fracture of the sinus floor may provoke benign paroxysmal positional vertigo (BPPV), which can be incapacitating causing considerable stress to the patient.[19,20] Nevertheless, besides the limited intraoperative visibility, SFE by crestal approach has several advantages compared with the LW approach, namely being less surgically invasive, having less potential for risk of infection,[8] and allowing the preservation and full maintenance of the buccal bone (with possible increase in the healing speed).[21–23] Thus, several transcrestal alternative techniques have emerged to overcome the disadvantages from the original Summers' method.[24,25] Despite reported successful outcomes, these conventional methods for SFE are not able to enhance bone density, which is often reduced in the posterior maxilla.[26]

Osseodensification (OD) is a novel surgical technique for implant site preparation that preserves bone by using specially designed burs in counterclockwise (CCW; noncutting motion) with copious irrigation.[26] Contrary to conventional drilling techniques, OD promotes bone compaction along the osteotomy walls and into the trabecular spaces, increasing the bone density at the site. A recent multicenter controlled clinical trial showed that OD demonstrated significantly higher implant insertion torque (IT) and primary stability values than standard subtractive drilling, regardless of the jaw and area operated.[27] This is in accordance with a recent systematic review in which OD presented consistently higher implant stability quotient (ISQ) at baseline and 4–6 months after implant placement compared with conventional drilling.[28] With OD site preparation, the osteotomy is gradually expanded both in lateral and apical direction[26,29–31] so it can be used not only for ridge expansion but also for sinus lift by crestal approach in a safe and predictable way with reduced morbidity.[25,32]

Although OD has demonstrated good results in sinus elevation in cases with very reduced RBH,[25,33] the minimum bone height for the safe use of this technique is not yet well established in the literature. Considering the several advantages over the classic LW technique, especially in terms of potentially reducing patient morbidity, it would be interesting to understand to what extent it is possible to use this technique in more extreme cases in which the LW is still considered the gold standard approach.[11–13] Thus, the aim of this randomized clinical trial was to compare pain experience after SFE with OD versus LW, both with simultaneous implant placement in similar conditions (RBH ≤4 mm). Secondary outcome measures included other patient-reported outcome measures (PROMs), implant stability, surgery duration, intraoperative and postoperative complications, and analgesics intake.

2 | MATERIALS AND METHODS

2.1 | Study design

This randomized controlled clinical trial was conducted at the University Clinic of Egas Moniz School of Health and Science (Almada, Portugal), between September 2020 and February 2023. Ethical approval was provided by the Egas Moniz Ethics Committee (no. 859/2020) in accordance with the Helsinki Declaration, as revised in 2013. All participants were fully informed about the study and provided a written informed consent before participation in the trial. The study was registered in the ISRCTN registry (registration number ISRCTN35171361) and is reported according to the Consolidated Standards of Reporting Trials 2010 guideline (CONSORT, www.consort-statement.org). Surgeries were performed between September 2020 and July 2022.

The null hypothesis was established as: in maxillary SFE with simultaneous implant placement when RBH ≤4 mm, OD shows similar pain experience to the LW technique.

2.2 | Participants

Panoramic radiographs and cone-beam computed tomography (CBCT) were used for initial participants screening. Participants were recruited according to the following inclusion criteria: (1) age ≥18, systemically healthy; (2) absence of tooth in the posterior maxilla; (3) RBH ≤4 mm; and (4) crestal bone width >6 mm. The exclusion criteria were: (1) RBH >4 mm; (2) smoking more than 10 cigarettes/day; (3) uncontrolled and/or untreated periodontal disease; (4) pregnant or lactating women; (5) history of alcoholism or drug abuse during the past 5 years; (6) hypertension or uncontrolled diabetes; (7) maxillary sinus pathology; (8) temporomandibular joint pathology; (9) patients with malignant tumors; (10) patients taking bisphosphonates or daily steroids; (11) patients with a history of chemotherapy or radiation therapy in the past 5 years. RBH was measured on CBCT in the sagittal section corresponding to the digitally planned implant position. Participants were followed up for 1 year.

2.3 | Randomization and blinding

Participants enrolled in the study were randomly allocated in a 1:1 ratio into either the test group (OD) or the control group (LW) with a computer-generated randomization list (https://www.randomizer.org/). Allocation concealment was performed using sealed and opaque numbered envelopes which were opened by the surgeon immediately before the surgery. Participants were blinded to group allocation.

2.4 | Surgical procedure

All surgical and prosthetic procedures were performed by one experienced clinician (J.G.). Both SFE techniques (OD and LW) were performed with simultaneous implant placement.

2.4.1 | Presurgical phase

All participants underwent prophylactic antibiotics (2 g of amoxicillin 1 h presurgery). Patients rinsed with chlorhexidine digluconate solution (0.2%) for 1 min.

2.4.2 | Surgical phase

All surgeries were performed under local anesthesia with articaine hydrochloride 4% with epinephrine (1:100.000).

2.4.3 | LW protocol

1. Mid-crestal incision and a mesial vertical releasing incision using a #15 blade, followed by an intrasulcular incision around the distal tooth. In the absence of a tooth distally to the edentulous area, a small vertical incision was performed.
2. After elevation of a full-thickness mucoperiosteal flap and exposure of the alveolar crestal and the lateral wall of the maxillary sinus, a window was created using a piezoelectric device with a round diamond tip to reach the Schneiderian membrane (Figure 1B). If buccal bone thickness was >1.5 mm, a rotating diamond bur mounted in a handpiece was used for the initial window outline before the final refinement with the piezoelectric tip.
3. Schneiderian membrane was then carefully elevated with hand curettes until reaching the medial sinus wall, along with the outlined window which was pushed inwards the sinus cavity. The eventual occurrence of membrane perforations was evaluated during the surgical procedure. Whenever a minor perforation was observed, a resorbable collagen membrane (Bio-Gide®; Geistlich Pharma, AG, Switzerland) was used for its repair. If a large perforation (>10 mm) with massive communication to the sinus cavity occurred, the patient was withdrawn from the study. After adequate membrane elevation, implant site preparation was performed with a traditional undersized drilling protocol (Figure 1C).
4. Sinus was then grafted with a synthetic particulate bone substitute composed of calcium phosphosilicate (NovaBone® Morsels) followed by the placement of a conical implant with a platform switched morse-taper connection (ID^{CAM} ST, Implant Diffusion International, Montreuil, France), which was left submerged according to a two-stage protocol (Figure 1D).
5. A resorbable collagen membrane (Bio-Gide®; Geistlich Pharma, AG, Switzerland) was then applied to cover the created window, and the flap was repositioned and sutured with nonresorbable monofilament suture (Seralon® 4–0, Serag-Wiessner, Naila, Germany) by primary intention closure (Figure 1E).
6. Implants were submerged and no provisional restoration was used during the healing period. Periapical radiographs and CBCT were taken immediately after the surgery and sutures were removed after 7–10 days.

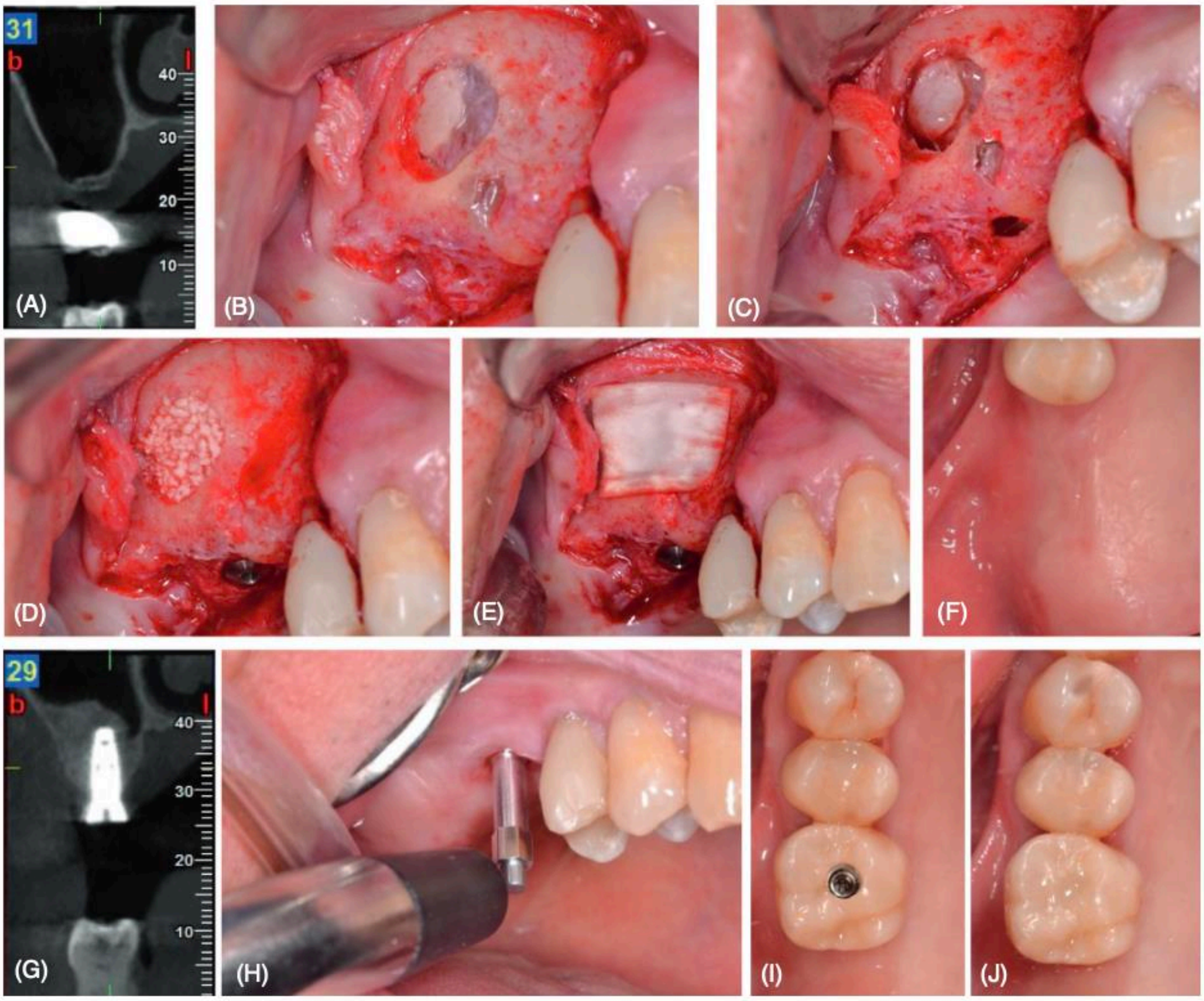

FIGURE 1 Schematic representation of the surgical procedure in the control (LW) group. (A) Preoperative CBCT. (B) Lateral window outlined. (C) Implant site preparation after the elevation of Schneiderian membrane. (D) Sinus cavity grafted and implant placed. (E) Collagen membrane covering the window. (F) Occlusal view 6 months after SFE. (G) CBCT after 6 months. (H) ISQ measurement before final impression. (I, J) Occlusal view of screw-retained final crown. CBCT, cone-beam computed tomography; ISQ, implant stability quotient; LW, lateral window; SFE, sinus floor elevation.

7. Patients received then the postoperative instructions and medication.

2.4.4 | OD protocol

1. A limited full-thickness mucoperiosteal flap to expose the alveolar crest was elevated after a mid-crestal and intrasulcular incisions on the adjacent teeth (Figure 2C).
2. The implant site was prepared with Densah® Burs (Versah, LLC, Jackson, MI, USA) running in CCW, at 1200 rpm with copious irrigation, according to the manufacturer instruction (described in Densah Sinus Lift Protocol III provided by Versah®). Due to the reduced RBH and according to the protocol, the use of a pilot drill and narrower Densah® burs (2.0 and 2.3) is not recommended. The Densah® bur used to advance past the sinus floor and propel the graft material was chosen based on the implant diameter selected for the site (Figure 2D).
3. After gently interrupting the sinus floor, the last densifying bur of the sequence was used in CCW at 100 rpm without irrigation to propel the synthetic bone graft (NovaBone® Dental Putty), advancing no more than 3 mm beyond the initial bone height regardless of the intended elevation (Figure 2C).
4. After the placement of a 0.5-cc cartridge, a periapical radiograph was taken intraoperatively to assess the need for additional grafting prior to implant placement.
5. Implants were submerged and no provisional restoration was used during the healing period. Periapical radiographs and CBCT were taken immediately after the surgery and sutures were removed after 7–10 days (Figure 2E,F).

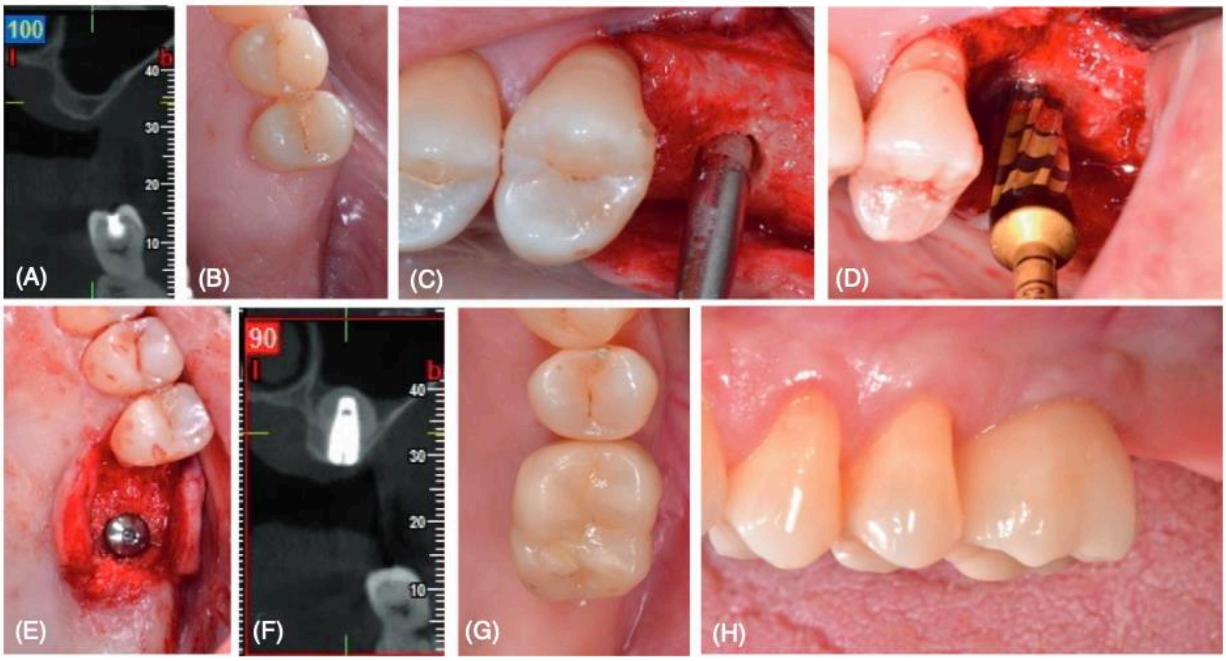

FIGURE 2 Schematic representation of the surgical procedure in the test (OD) group. (A) Preoperative CBCT; (B) occlusal view at baseline; (C) application of grafting material through crestal approach; (D) propelling of grafting material with Densah bur; (E) implant placed; (F) postoperative CBCT; (G) occlusal view of final zirconia crown screw-retained; (H) lateral view of final zirconia crown screw-retained. CBCT, cone-beam computed tomography; OD, osseodensification.

6. Patients received then the postoperative instructions and medication.

2.5 | Postoperative instructions and medication protocol

Participants were instructed to use a cold-pack for the first 24–36 h and a mouth rinse with 0.12% chlorhexidine digluconate solution twice daily for 7 days. Antibiotics were prescribed for all patients (1 g amoxicillin every 12 h for 7 days). A rescue tablet of 600 mg ibuprofen was given to all patients immediately after the surgery. For post-surgical pain control, patients were instructed to take painkillers pro re nata, as deemed necessary (ibuprofen 600 mg every 12 h, supplemented by paracetamol 1000 mg in case of pain peaks). Analgesics use was recorded from the day of the surgery until 7 days after surgery.

2.6 | Outcomes

2.6.1 | Pain experience and other patient-reported outcome measures

Pain experience after surgery was defined as the primary outcome of this study and daily measured by the participants using a visual analogue scale (VAS) score (0–10, from "No pain" to "Worst pain ever experienced") in the first postoperative 7 days, with Day 0 being the day of the surgery. Before going to sleep, patients were asked to mark the VAS that best represented the average pain they had experienced during the day. Furthermore, PROMs were additionally appraised by means of postoperative patients' quality of life (QoL). QoL was measured through a modified version of the Oral Health Impact Profile-14 (OHIP-14) questionnaire (see Supplementary Information) which was also daily filled in by the participants in the first 7 days following surgery. The OHIP-14 questionnaire covers 7 domains out of 14 items of oral health impact: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Each item is rated on a 5-point Likert scale coded as follows: 0, never; 1, hardly ever; 2, occasionally; 3, fairly often; and 4, very often. The OHIP-14 total score is then calculated as the sum of the 14 scores (from 0 to 56), with a higher score indicating more negative impact and a lower oral health-related quality of life (OHRQoL). Symptoms such as edema/swelling, hematoma, and epistaxis were also self-reported by patients for 7 days after surgery using a 5-point Likert scale (none, little, moderate, intense, and very intense).

2.6.2 | Secondary outcome measures

1. ISQ, recorded using resonance frequency analysis (Osstell™; Osstell AB, Gothenburg, Sweden) immediately after implant placement (ISQ T_0—primary stability) and following implant exposure after 6 months of healing (ISQ T_6—secondary stability), as the

average between buccolingual and mesiodistal measures. If ISQ T_6 was ≥68, the final impression was made and implants were loaded with screw-retained zirconia crowns. If ISQ T_6 value was lower, patients were recalled for a new measurement every 3 weeks until reaching the minimum value established for the final restoration.

2. Implant IT measured by surgical drill unit or manual torque wrench.
3. Implant osseointegration success rate.
4. Patients' registration of analgesics intake during the first week after surgery.
5. Duration of surgical procedure, from the initial incision to the completion of the suture.
6. Intraoperative complications as Schneiderian membrane perforation or excessive bleeding.
7. Postoperative complications as infection, BPPV, early exposure of cover screw or implant failure.

2.7 | Sample size

Due to the lack of trials focusing on pain self-report between OD and LW as primary outcome, the relatively limited number of eligible patients within the eligibility criteria and reasonable difference between a minimum invasive approach (OD) and a more invasive one (LW), we considered a Cohen's large effect size ($d = 1.4$), between LW and OD VAS score distribution. For a power of 80% and a significance level of 5%, the minimum number of participants was determined as 8 participants per group. Assuming a possible 20% dropout during the follow-up period, the final number was established 10 participants per group, in a total of 20 participants.

2.8 | Statistical analysis

Data were analyzed by using descriptive and inferential statistical methodologies. For inter-group comparison, the inferential procedure was chosen according to variable typology and data distribution. A nonparametric comparison procedure (Mann–Whitney test) was considered for ordinal variables and for continuous variables since these exhibited no adequacy to normality. Chi-square and Fisher's exact test were used to evaluate association for categorical variables. R ggplot2 package was used for data visualization. Specifically, scatterplots and radar plots were used to visualize data distribution between the groups. A 5% significance level was established for all inferential analyses.

3 | RESULTS

3.1 | Participants and baseline data

Twenty participants (8 men and 12 women) with a mean age of 47.9 years old (±12.7; range from 24 to 66) were enrolled in the study (Table 1). We did not observe dropouts and all participants completed the follow-up appointments. There were no significant differences ($p > 0.05$) between the groups according to gender, age, RBH, or missing tooth. Mean RBH was 2.9 ± 0.5 mm (range: 2–3.5 mm) in the OD group and 2.4 ± 0.7 mm (range: 1.5–3.5 mm) in the LW group ($p = 0.098$). All implants placed in both groups were 10 mm in length.

3.2 | Patient-reported outcomes

3.2.1 | Pain experience and analgesics intake

Figure 3 shows the evolution of pain experience daily self-reported by patients using a VAS. From Day 0 (the day of the surgery) to Day 3, pain experience was significantly lower ($p < 0.05$) in the OD (Table 2). Average analgesics intake during the week after surgery was significantly lower ($p < 0.001$) in OD (two tablets of 600 mg ibuprofen) compared to LW (eight tablets of 600 mg ibuprofen + 1 tablets of 1000 mg paracetamol). Only participants from the LW group (30%; $n = 3$) took paracetamol in addition to the nonsteroidal anti-inflammatory drugs (NSAIDs).

3.2.2 | Oral health-related quality of life

The evolution of the overall score and each super-domain of OHIP outcomes between OD and LW groups is shown in Figure 4. According to

TABLE 1 Participants characteristics for test (OD) ($n = 10$) and control (LW) ($n = 10$) groups.

	OD	LW	*p*-value
Age (years), mean (SD) [min–max]	51.2 (12.6) [23–66]	44.6 (12.5) [28–66]	0.197
Gender, *n* (%)			
Males	5 (50.0)	3 (30)	0.648
Females	5 (50.0)	7 (70)	
Maxillary tooth location			
16	4 (40)	3 (30)	0.478
26	5 (50)	7 (70)	
17	1 (10)	0 (0)	
Residual bone height, mean (mm)	2.9 (0.5)	2.4 (0.7)	0.098

Abbreviations: LW, lateral window; OD, osseodensification.

FIGURE 3 Scatterplot comparing the evolution of the self-reported pain perception between OD and LW groups. Values are presented as the absolute mean and 95% confidence interval values. LW, lateral window; OD, osseodensification.

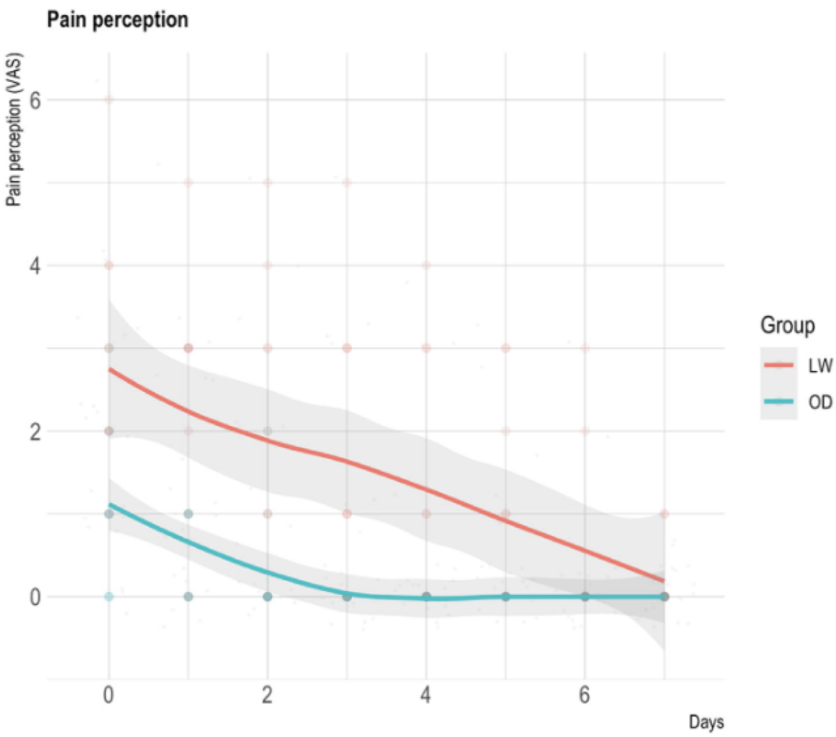

TABLE 2 Pain perception daily self-reported using a VAS.

Pain (VAS)	LW mean (SD)	OD mean (SD)	*p*-value
Day 0	2.8 (1.0)	1.1 (1.7)	0.0126
Day 1	2.1 (0.9)	0.7 (1.6)	0.0494
Day 2	1.9 (0.7)	0,3 (1.9)	0.0312
Day 3	1.7 (0.0)	0.0 (1.9)	0.0082
Day 4	1.2 (0.0)	0.0 (1.6)	0.0588
Day 5	1.0 (0.0)	0.0 (1.3)	0.0588
Day 6	0.5 (0.0)	0.0 (1.1)	0.4497
Day 7	0.2 (0.0)	0.0 (0.4)	0.4497

Abbreviations: LW, lateral window; OD, osseodensification; SD, standard deviation; VAS, visual analogue scale.

OHIP-14 total score, the impact in participants' QoL after surgery was significantly lower ($p < 0.05$) in the OD group on all seven postoperative days, except on Day 5. These results were also observed for OHIP physical and psychological super-domains. Regarding the OHIP social super-domain, the score was only significantly different ($p < 0.01$) on Day 0 and Day 1 (Table 3). Figure 5 and Table 4 show the differences between the two groups for each OHIP-14 domain (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap).

3.2.3 | Other postoperative symptoms

Overall, participants in the LW group significantly experienced more edema ($p < 0.001$; mean average days with edema = 7.0 in LW and 0.5 in OD), as described in Table 5. In the OD group, 50% ($n = 5$) of the patients did not report any swelling on any of the seven postoperative days while all patients (100%) in the LW group reported some degree of swelling from Day 0 to Day 4. Moreover, the LW group also experienced significantly more hematoma/bruising ($p < 0.001$) and epistaxis were only reported by patients (40%; $n = 4$) in the LW group (Table 5).

3.3 | Surgery duration

The mean duration of the surgical procedure was significantly shorter ($p < 0.001$) in the OD group compared to the LW group (32.9 ± 5.3 vs. 71.1 ± 10.4 min) (Table 5).

3.4 | Clinical outcomes and complications

There was no significant difference between the groups in terms of IT ($p = 0.062$) and ISQ T_0 ($p = 0.184$), although mean values were higher in the OD group for both parameters. ISQ T_6 was significantly higher ($p < 0.05$) in the OD group (74.4 ± 4.0) compared to LW (69.8 ± 5.1) (Table 5).

Regarding surgical intraoperative complications, there were significantly more Schneiderian membrane perforations in LW ($p < 0.001$) (Table 5). No other types of intraoperative complications were observed in both groups.

Early exposure of cover screw was detected in two implants (one in OD and one in LW) 3 weeks after surgery. All the remaining implants healed uneventfully, with an overall osseointegration success

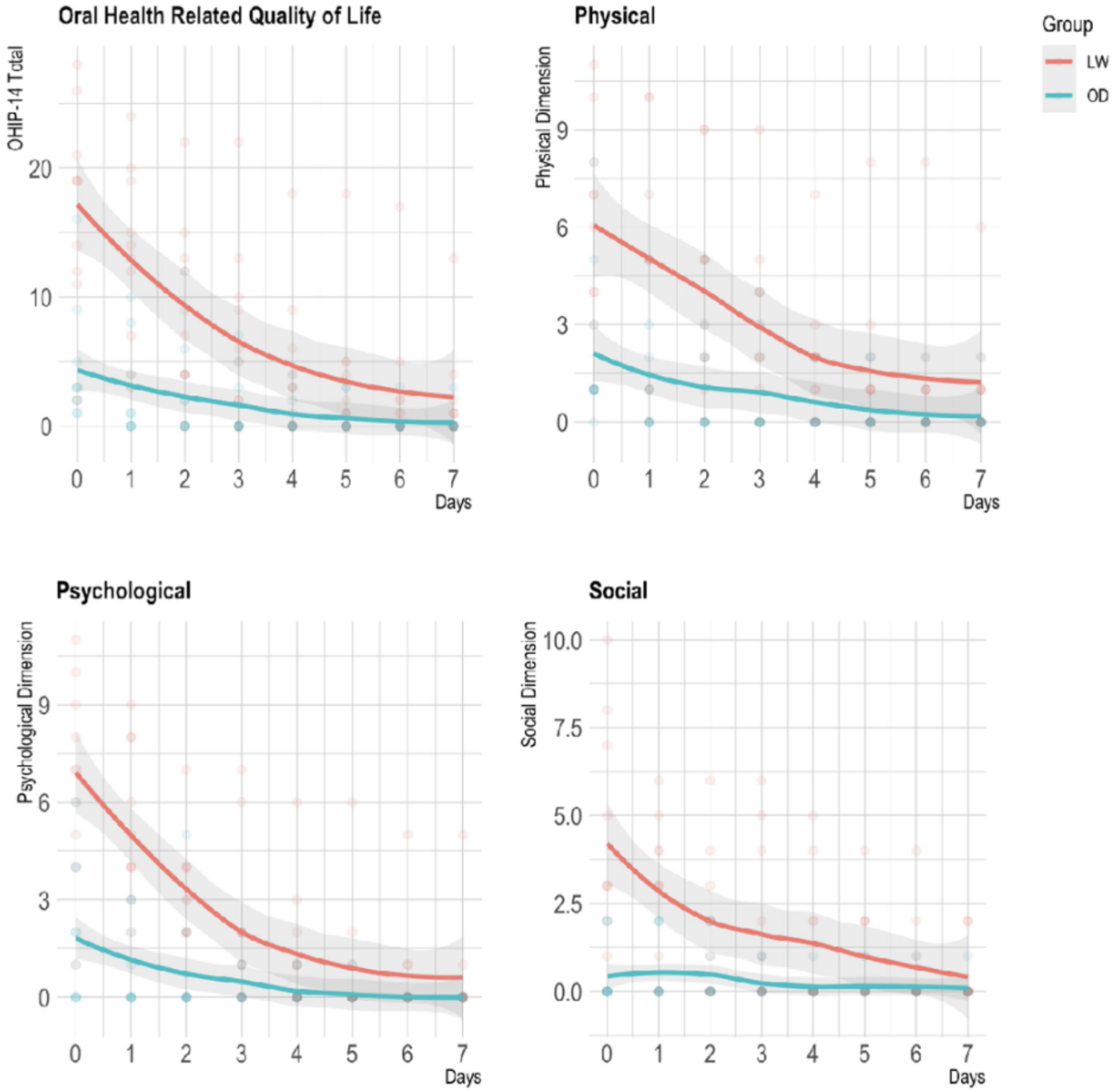

FIGURE 4 Scatterplots comparing the evolution of the overall score and each super-domain of OHIP outcomes between OD and LW groups. Values are presented as the absolute mean and 95% confidence interval values. LW, lateral window; OD, osseodensification; OHIP, Oral Health Impact Profile.

rate of 100%. All implants were successfully restored with screw-retained zirconia crowns.

4 | DISCUSSION

Although the OD technique has demonstrated promising results for SFE with reduced RBH,[25,33] the LW technique has still been considered the gold standard approach when the RBH is less than 5 mm despite the associated patient morbidity.[11–13] Therefore, the purpose of this randomized clinical trial was to compare PROMs and clinical parameters after SFE by crestal approach with OD versus LW technique, both with simultaneous implant placement in similar local conditions (RBH ≤ 4 mm).

According to a systematic review on PROMs after SFE, moderate patients' discomfort mainly expressed by pain and edema should be expected.[34] In this study, the overall impact of SFE on patients' QoL was significantly lower in the OD group. Crestal approach with OD also resulted in significantly lower VAS scores for pain experience from Day 0 to Day 3 and significantly less need for analgesics intake

TABLE 3 Oral health-related quality of life for total OHIP-14 and each superdomain, according to the day of follow-up.

Day	Group	OHIP-14 total, mean (SD)	*p*-value	OHIP-14 physical, mean (SD)	*p*-value	OHIP-14 psychological, mean (SD)	*p*-value	OHIP-14 social, mean (SD)	*p*-value
0	LW	17.1 (7.6)	0.0023	6.1 (3.1)	0.0085	6.8 (3)	0.0018	4.2 (3.2)	0.0011
	OD	4.5 (4.7)		2.2 (2.5)		1.9 (2.1)		0.4 (0.8)	
1	LW	13.1 (6.9)	0.0014	4.9 (3.5)	0.0117	5.3 (2.4)	0.0003	2.9 (2.0)	0.0068
	OD	2.7 (3.6)		1.2 (1.7)		0.9 (1.3)		0.6 (1.0)	
2	LW	9.0 (6.6)	0.01237	4.1 (3.1)	0.01942	3.1 (1.9)	0.01034	1.8 (2.0)	0.1049
	OD	2.6 (3.9)		1.2 (1.8)		0.9 (1.7)		0.5 (0.8)	
3	LW	6.9 (6.9)	0.02379	3.0 (2.7)	0.03503	2.1 (2.5)	0.04167	1.8 (2.3)	0.09126
	OD	1.5 (2.6)		0.9 (1.5)		0.4 (0.7)		0.2 (0.4)	
4	LW	4.4 (5.6)	0.02345	1.8 (2.1)	0.00789	1.3 (1.9)	0.04321	1.3 (1.9)	0.06543
	OD	0.9 (1.5)		0.6 (1.0)		0.2 (0.4)		0.1 (0.3)	
5	LW	3.6 (5.4)	0.05704	1.7 (2.4)	0.05546	0.9 (1.9)	0.2339	1.0 (1.4)	0.1907
	OD	0.7 (1.3)		0.4 (0.8)		0.1 (0.3)		0.2 (0.4)	
6	LW	2.8 (5.2)	0.03309	1.4 (2.4)	0.03605	0.7 (1.6)	0.06789	0.7 (1.3)	0.2339
	OD	0.3 (0.9)		0.2 (0.6)		0.0 (0.0)		0.1 (0.3)	
7	LW	2.2 (4.0)	0.03291	1.2 (1.8)	0.03605	0.6 (1.6)	0.1468	0.4 (0.8)	0.4652
	OD	0.3 (0.9)		0.2 (0.6)		0.0 (0.0)		0.1 (0.3)	

Abbreviations: LW, lateral window; OD, osseodensification; OHIP-14, Oral Health Impact Profile-14.

compared to the LW technique. On Day 4, the mean VAS score for pain experience in the LW group was still greater than the overall highest mean score in the OD group, registered on Day 0.

Regarding postoperative symptoms (edema, hematoma, and epistaxis) self-reported by patients, all were significantly more prevalent in the LW group; in fact, epistaxis was only referred by patients ($n = 4$) in this group, presumably due to the higher incidence of membrane perforation observed. The difference in postoperative edema may be explained by the flap design which included a vertical releasing incision in the LW group but also by the duration of the surgical procedure which was on average more than twice as compared to the OD group ($p < 0.001$). In the LW group, all patients (100%) reported some degree of swelling from Day 0 to Day 4 while 50% ($n = 5$) of the patients did not report any edema on any of the seven postoperative days. These results are in accordance with another randomized clinical trial[16] that also reported a significantly lower incidence of swelling, bruising, and nasal discharge/bleeding with transcrestal SFE compared to the lateral approach.

Among the potential intraoperative complications during SFE reported in the literature, sinus membrane perforation is the most common.[35] In fact, it was the only intraoperative complication observed in both groups of this study, with a higher incidence in the LW (40%; $n = 4$) than in the OD group (10%; $n = 1$) ($p < 0.001$). This is in accordance with previous clinical trials that also showed a higher prevalence of this complication in LW compared to transcrestal approach.[18,36] The detection of sinus membrane perforations may be difficult in the crestal approach due to limited visibility.[40] In our study, only one perforation was reported in the OD group since all the remaining cases had the grafting material fully contained in the immediate postoperative periapical radiograph. In the LW group, all perforations occurred during the elevation phase with manual curettes and not during antrostomy with the piezo device which was demonstrated to be extremely safe as reported in the literature.[22,37] A resorbable collagen membrane was used for perforation repair during surgery and its occurrence did not affect implant osseointegration. According to several authors,[38,39] sinus membrane perforations, if properly managed and repaired, do not appear to influence vital bone formation and implant survival. On the other hand, the single membrane perforation in the OD group was only detected in the postoperative periapical radiograph and therefore could not be repaired. However, the patient was followed during the healing period and it did not result in any type of complication. Six months after the surgery, before implant exposure, a CBCT was taken which did not reveal extruded grafting material into the sinus cavity.[40]

Regarding the bone grafting material in SFE, there seems to be no difference in the literature on implant treatment outcome with synthetic bone substitutes compared with other materials such as xenografts.[41–43] In this study, a synthetic calcium phosphosilicate bone substitute was used in two different delivery options: putty for the transcrestal approach with OD and particulate for the LW approach. The putty delivery option is extremely user-friendly and particularly indicated for transcrestal approach since it is applied directly into the osteotomy site with a cartridge system, minimizing the potential contamination of the graft. A major possible cause for graft contamination is the use of the same instruments for flap reflection and for graft placement in the sinus. Regarding the application of the particulate grafting material in the LW technique, the surgeon (J.G.) used separate sterile instruments for that particular step of the

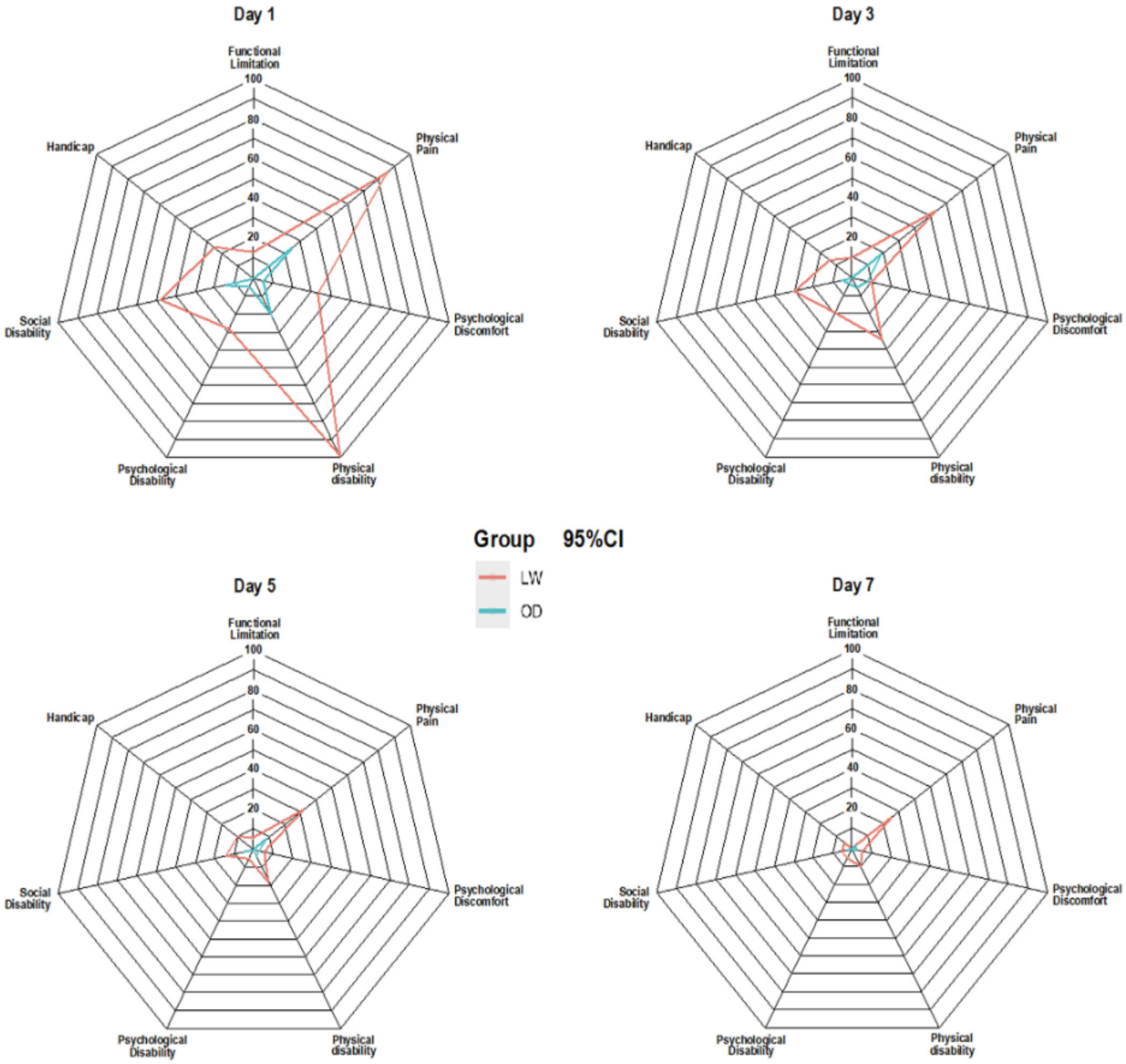

FIGURE 5 Radar plots comparing OD with LW self-reported outcomes for each of the seven domains of OHIP-14. Representing four follows-up periods of 1, 3, 5, and 7 days, the values were converted as percentages and are displayed with mean and 95% confidence interval values. LW, lateral window; OD, osseodensification; OHIP-14, Oral Health Impact Profile-14.

surgical procedure to prevent graft contamination. Furthermore, the antibiotic medication protocol followed proved to be effective in preventing postoperative infections in this study.

Simultaneous implant placement during SFE is a predictable treatment modality even in cases with 1–3 mm of RBH provided meticulous surgical techniques are applied.[44–47] In this study, SFE with concomitant implant placement was performed in all 20 patients (overall mean RBH of 2.7 ± 0.69 mm) and no implants were lost.

Implant site preparation with OD drilling has been shown to present higher IT and ISQ compared to conventional drilling.[28,48–50] In this study, although the mean IT and ISQ T_0 values were higher in the OD group than in the LW group in which traditional osteotomy was used, the difference was not statistically significant. This may be explained by the very reduced RBH until the sinus floor for the OD technique to make a significant difference. On the other hand, ISQ T_6 was significantly higher ($p < 0.05$) in OD group compared to LW. In fact, after the second-stage surgery, 3 implants in the LW group had ISQ $T_6 < 68$ and therefore were not immediately restored. These patients were recalled for a new ISQ measurement after 3 weeks and two of them already had a value above the minimum established for the final impression and loading. However, 9 weeks after implant exposure, the remaining implant in the LW group persisted with an

TABLE 4 Oral health-related quality of life for each OHIP-14 domain, according to the day of follow-up.

T	Group	Functional limitation, mean (SD)	*p*-value	Physical pain, mean (SD)	*p*-value	Psychological discomfort, mean (SD)	*p*-value	Physical disability, mean (SD)	*p*-value	Psychological disability, mean (SD)	*p*-value	Social disability, mean (SD)	*p*-value	Handicap, mean (SD)	*p*-value
0	LW	1.0 (1.2)	0.0198	4.0 (1.6)	0.0083	2.2 (1.8)	0.0346	4.4 (2.4)	0.0031	1.3 (1.3)	0.0877	2.6 (1.5)	0.0011	1.6 (2.0)	0.0181
	OD	0.1 (0.3)		1.6 (1.5)		0.8 (1.6)		1.2 (1.1)		0.4 (0.7)		0.3 (0.7)		0.1 (0.3)	
1	LW	0.5 (1.1)	0.1468	3.4 (2.3)	0.0152	1.3 (1.3)	0.0322	3.9 (1.8)	0.0003	1.1 (1.2)	0.0474	1.9 (1.2)	0.0172	1.0 (0.9)	0.0017
	OD	0.0 (0.0)		1.0 (1.3)		0.2 (0.4)		0.7 (0.9)		0.2 (0.4)		0.6 (1.0)		0.0 (0.0)	
2	LW	0.7 (1.1)	0.0304	2.7 (1.7)	0.0279	0.6 (0.8)	0.4002	2.2 (1.5)	0.0075	1.0 (1.1)	0.0783	1.2 (1.2)	0.1567	0.6 (1.1)	0.0682
	OD	0.0 (0.0)		1.0 (1.4)		0.4 (1.0)		0.4 (0.7)		0.3 (0.7)		0.5 (0.8)		0.0 (0.0)	
3	LW	0.4 (1.0)	0.1468	2.1 (1.4)	0.0306	0.4 (0.7)	0.6538	1.4 (1.3)	0.0154	0.8 (1.2)	0.1108	1.2 (1.7)	0.1085	0.6 (1.1)	0.0682
	OD	0.0 (0.0)		0.7 (1.2)		0.3 (0.7)		0.2 (0.4)		0.1 (0.3)		0.2 (0.4)		0.0 (0.0)	
4	LW	0.3 (0.7)	0.0012	1.3 (1.2)	0.0457	0.2 (0.6)	0.0123	1.0 (1.4)	0.0346	0.3 (0.7)	0.0099	0.9 (1.4)	0.0568	0.4 (0.7)	0.0023
	OD	0.0 (0.0)		0.4 (0.7)		0.2 (0.4)		0.2 (0.4)		0.0 (0.0)		0.1 (0.3)		0.0 (0.0)	
5	LW	0.2 (0.6)	0.3173	1.3 (1.3)	0.0332	0.2 (0.6)	0.9422	0.7 (1.3)	0.2339	0.2 (0.6)	0.3173	0.6 (0.8)	0.2604	0.4 (0.7)	0.0679
	OD	0.0 (0.0)		0.3 (0.7)		0.1 (0.3)		0.1 (0.3)		0.0 (0.0)		0.2 (0.4)		0.0 (0.0)	
6	LW	0.2 (0.6)	0.3173	1.0 (1.2)	0.0198	0.2 (0.6)	0.9422	0.5 (1.0)	0.0679	0.2 (0.6)	0.3173	0.4 (0.7)	0.2548	0.3 (0.7)	0.1468
	OD	0.0 (0.0)		0.1 (0.3)		0.1 (0.3)		0.0 (0.0)		0.0 (0.0)		0.1 (0.3)		0.0 (0.0)	
7	LW	0.0 (0.0)	NA	1.0 (1.2)	0.0198	0.2 (0.6)	0.9422	0.4 (1.0)	0.1468	0.2 (0.6)	0.3173	0.2 (0.4)	0.5416	0.2 (0.4)	0.1462
	OD	0.0 (0.0)		0.1 (0.3)		0.1 (0.3)		0.0 (0.0)		0.0 (0.0)		0.1 (0.3)		0.0 (0.0)	

Abbreviations: LW, lateral window; OD, osseodensification; OHIP-14, Oral Health Impact Profile-14; SD, standard deviation.

TABLE 5 Clinical parameters: insertion torque, ISQ at baseline and after 6 months, medication usage, and complications (edema, hematoma, and epistaxis).

	OD	LW	*p*-value
Implant insertion torque (Ncm), mean (SD)	48.0 (17.8)	31.8 (16.0)	0.062
ISQ, mean (SD)			
T_0 (baseline)	65.5 (11.1)	61.5 (10.9)	0.184
T_6 (6 months)	74.4 (4.0)	69.8 (5.1)	0.046
$\Delta[T_6-T_0]$	9.2 (11.5)	8.6 (8.0)	0.818
Surgery time (min), mean (SD)	32.9 (5.3)	71.1 (10.4)	<0.001
Medication usage in 7 days, median (IQR)	2.0 (1.0)	7.5 (6.5)	<0.001
Average days using pain medication, median (IQR)	1.0 (0.8)	4.5 (2.0)	<0.001
Surgical complications			
Schneiderian membrane rupture, % (*n*)	10.0 (1)	40.0 (4)	<0.001
Postoperative symptoms			
Edema, % (*n*)	50.0 (5)	100.0 (10)	<0.001
Average days (*n*), mean (SD)	0.5 (2.8)	7.0 (2.0)	<0.001
Hematoma, % (*n*)	10.0 (1)	30.0 (3)	<0.001
Average days (*n*), mean (SD)	0.0 (0.0)	0.0 (0.5)	<0.001
Epistaxis, % (*n*)	0.0 (0)	40.0 (4)	<0.001
Average days (*n*), mean (SD)	0.0 (0.0)	0.0 (2.0)	<0.001

Note: Mann–Whitney test.
Abbreviations: IQR, interquartile range; ISQ, implant stability quotient; LW, lateral window; OD, osseodensification; SD, standard deviation.

ISQ value below the threshold so our decision was to initiate a progressive loading protocol with a provisional crown out of occlusion in attempt to stimulate bone remodeling and increase ISQ. After 3 weeks, ISQ value was 73 so final impression was made and the implant was restored with a screw-retained zirconia crown. One possible reason for this apparent faster osseointegration in the OD group may be the full maintenance of the buccal wall of the sinus, contrary to the LW technique. Although we can infer that healing and graft maturation in SFE seems to be faster with OD compared to LW, these results should be further studied in future preclinical and clinical research.

A resorbable collagen membrane was used to cover the window in the LW group. Although implant survival rate seems not to be significantly influenced by the use of a barrier membrane for antrostomy coverage,[51] it may reduce the postoperative displacement of the grafting material and increase the percentage of newly formed bone by reducing the proliferation of nonmineralized tissue.[52,53]

Unintentional early exposure of cover screw occurred in two implants (one in each group) and were detected 3 weeks after surgery. Patients were instructed to perform meticulous plaque control, apply 0.2% chlorhexidine gel twice a day and were examined every 2 weeks for the first 2 months followed by a monthly check-up to assess the need of intervention. As described in the literature,[54,55] these implants ended up having slightly more marginal bone loss; however, the prompt diagnosis and the regular recalls allowed to prevent further severe complications. All the remaining implants healed uneventfully. After the second-stage surgery, all implants were clinically stable resulting in an overall osseointegration success rate of 100%.

Pain can be defined as a subjective experience which is dependent on several factors and on each individual. The subjectivity of PROMs in general along with the relatively small sample size can be considered the main limitations of this study. Furthermore, the experience of the surgeon may have played a role in the results since both procedures are technique-sensitive. In order to reduce as much as possible the presence of biases, the study was designed as a randomized clinical trial so participants were blinded and randomly allocated into either test or control group. In addition to the main purpose of this study, it will be interesting to follow these patients and evaluate the long-term stability of the implants.

5 | CONCLUSION

Within the limitations of this study, it can be concluded that OD and LW techniques were similarly effective in SFE with simultaneous implant placement when RBH ≤ 4 mm. However, OD significantly outperformed LW in pain experience, impact on self-perceived QoL, surgery duration, postoperative edema, and analgesics intake.

AUTHOR CONTRIBUTIONS

João Gaspar: Conceptualization (lead); investigation (lead); methodology (lead); project administration (supporting); writing—original draft (supporting). **Luís Proença:** Formal analysis (supporting); writing—original draft (supporting). **João Botelho:** Formal analysis (lead); investigation (supporting); methodology (supporting); conceptualization (supporting); writing-original draft (lead). **Vanessa Machado:** Investigation (supporting); methodology (supporting); writing—original draft (supporting). **Leandro Chambrone:** Conceptualization (supporting); investigation (supporting); methodology (supporting); writing—original draft (supporting). **Rodrigo Neiva:** Conceptualization (supporting); investigation (supporting); methodology (supporting); writing—original draft (supporting). **José João Mendes**: Project administration (lead); writing—original draft (supporting).

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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CHAPTER 6

GENERAL DISCUSSION, CONCLUDING REMARKS AND FUTURE DIRECTIONS

6.1. General Discussion

The introduction of OD in 2015 marked a paradigm shift in implantology. As a non-subtractive drilling technique, OD preserves bone integrity and promotes bone compaction, thus offering unique advantages over conventional methods (63–68). The dual-mode action of OD drills, operating in both counterclockwise (CCW) and clockwise (CW) directions, enhances its versatility and allows its use in various clinical contexts (64,69–71).

The overall purpose of this thesis was to explore the potential of OD as a novel surgical technique for implant site preparation in comparison with the traditional osteotomy protocol. In addition, our aim was also to validate its application in different clinical scenarios and to confirm its efficiency and positive impact in patients' experience after SFE.

This research project was therefore structured into three stages. Initially, we performed a systematic review to appraise the available evidence on the clinical characteristics produced by OD drilling compared with the conventional drilling technique. Until that moment, several systematic reviews have provided important insights about OD concept; however, they have either considered only animal studies or combined data from animal preclinical and human clinical studies (63,72–74). In contrast, our review was the first to analyze data exclusively from human subjects which enhances its clinical relevance. Clinicians often seek evidence that directly applies to patient care, and human-focused reviews provide the most relevant information for guiding clinical decisions. Our results demonstrated that osseodensification presented consistently higher ISQ at baseline and at 4-6 months after implant placement compared with conventional drilling. The biological rationale for this is that the bone densification along with the presence of residual bone chips at the osteotomy walls results in an enhanced contact between the implant and the surrounding bone due to compaction auto-grafting and the associated spring-back effect (64,75), increasing bone-to-implant contact (BIC) upon insertion (63,65,66). These autografted bone particles in the trabecular spaces act as nucleation sites for faster bone formation around the implant, potentially accelerating healing (65,76,77). However, these findings should be cautiously interpreted since only three studies fulfilled the inclusion criteria for the meta-analysis, which demonstrates the need for further research. Still, none of the included studies reported inferiority of clinical outcomes of OD compared with conventional drilling. Besides this, our study was only able to provide estimates in terms of ISQ values so it would be interesting to broaden to other clinical parameters in the future. A more recent multicenter controlled clinical trial (78) showed that, regardless of the jaw and area operated, OD demonstrated not only significantly higher implant primary stability values but also significantly higher insertion torque compared with standard subtractive drilling.

Secondly, we had the opportunity to participate in an international multicenter retrospective clinical study with colleagues from five nationalities, which confirmed the ability of OD to expand the interradicular septum for post-extraction implant placement in molars. Although retrospective studies have inherent limitations, they remain valuable especially when dealing with concrete and objective data obtained from routine clinical practice, which can offer insights into how treatments perform in everyday setting. Our primary outcome was interradicular septum width measurement pre-instrumentation and osteotomy diameter post expansion. According to several authors, the ideal implant positioning in molar extraction sockets will most often require the osteotomy to be in the septum, not only for optimal emergence profile of the restoration but also regarding implant survival (79,80). Historically, a minimum of 3 mm width of interradicular septal bone (ISB) was considered important to achieve initial stabilization of an immediate molar implant (81). In this retrospective study, twenty-three extraction sockets had ISB width of 2.5 mm and one had 2.8 mm. Still, adequate septum expansion was achieved in all these sites using OD, with osteotomy final diameter ranging from 3.5 to 4.5 mm which provided adequate implant stability upon insertion. Overall, the results were encouraging and allow to validate the use of OD in another clinical indication, positioning it as a reliable and predictable treatment modality. In addition, we introduced a novel molar socket classification system based on the width of the interradicular septum pre-instrumentation, which can be used by the scientific community and facilitate communication between peers. The typical classification of molar extraction sockets by Smith and Tarnow (82) is based on the surrounding bone around immediately placed implants. Thus, it does not consider the precise measurement of the septum width before osteotomy, and the socket type may be different depending on the diameter of the implant placed. Considering these limitations, we suggested a new diagnostic classification based on the ISB width before site preparation, aiming to facilitate more effective treatment planning. With a more detailed classification system, dental practitioners may be able to develop and implement more targeted and personalized treatment protocols for different types of molar extraction sockets. This may include selecting appropriate instrumentation, considering the need for ridge preservation techniques, or deciding if immediate implant placement is applicable, which may lead to improved patient outcomes and reduce the risk of complications. Regarding other parameters considered in this retrospective analysis such as IT or ISQ, it may be more challenging to draw accurate conclusions since different implant systems with singular macrogeometries were placed by the various clinicians which may have influenced the results.

Lastly, we delved into the application of OD for SFE, in which it may have great impact. According to the literature, although the OD technique has demonstrated promising results for SFE in cases with reduced bone height (70,83), the lateral window technique (LW) has still been considered the gold standard approach when RBH is less than 5 mm, despite the associated patient morbidity (24,33,84). Direct comparative studies between OD and LW for SFE are limited and the available evidence is mostly based on case series and observational studies, making it challenging to draw definitive conclusions about the superiority of one technique over another. Further, the minimum bone height required for the safe use of OD is not yet well established in the literature. Therefore, we decided to conduct a randomized clinical trial (RCT) with the aim of comparing the effectiveness and patient-reported outcomes after SFE with OD versus LW, both with simultaneous implant placement in similar local conditions (RBH ≤ 4 mm). Studying the effectiveness of OD for SFE in this specific range of bone height addresses a clinically relevant question regarding the feasibility and success of this technique in challenging anatomical situations in which LW is typically the only alternative considered. Regarding the study design, RCTs are considered the gold standard for assessing both the safety and efficacy of medical interventions, as they offer several advantages that contribute to the robustness of scientific evidence. Considering previous studies (85–87) and our clinical experience in general, our expectations were that OD would have superior patient-reported outcome measures (PROMs) and improved overall patient experience compared with the LW group, which was confirmed in our RCT. However, PROMs rely on a subjective perception, and responses may be influenced by personal interpretation and experience. Different individuals may interpret and respond to questions differently, leading to variability in the reported outcomes. This subjectivity along with the relatively small sample size can be considered the main limitations of this study. To mitigate bias as much as possible, the study was designed as a RCT ensuring participant blinding and random allocation into either the test or the control group. Additionally, the experience of the surgeon may have played a role in the results since both procedures are technique sensitive.

As reported in our systematic review (88) and in previous studies (89–91), implant site preparation with OD drilling has been shown to present higher insertion torque and ISQ compared to conventional drilling. However, in our RCT, although the mean IT and immediate ISQ values were higher in the OD group than in the LW group in which conventional osteotomy was used, the difference was not statistically significant. This could be explained by the very reduced bone height available for the OD technique to make a significant difference. Conversely, ISQ at 6 months was significantly higher ($p < 0.05$) in the OD group compared to LW. One possible explanation for this apparently faster osseointegration in OD group may be the complete preservation of the buccal wall of the sinus, contrary to the LW technique. Although we may presume that healing and graft maturation in SFE seems to be faster with OD compared to LW, these findings should be further investigated and explored in future research.

6.2. Concluding Remarks

Paper I – This systematic review was the first to analyze data exclusively from human subjects. It demonstrated that OD presented consistently higher ISQ at baseline and at 4-6 months after implant placement when compared to conventional drilling. However, these results should be cautiously interpreted since only three studies fulfilled the inclusion criteria for the meta-analysis. Nevertheless, within the limitations of these findings, we may infer that implant site preparation with OD might be particularly useful in low-density bone and when immediate temporization is intended. It is also important to mention that none of studies reported inferiority of clinical outcomes of OD compared to traditional drilling protocol.

Paper II – This up-to-5-year follow-up retrospective multicenter study demonstrated that OD is a viable and predictable treatment modality for interradicular septum expansion and immediate implant placement in molar extraction sockets. Moreover, it allowed the introduction of a new molar socket classification system based on the available septum width prior to implant site preparation.

Paper III – Within the limitations of this RCT, OD and LW techniques were similarly effective in SFE with simultaneous implant placement when RBH ≤ 4 mm. However, OD significantly outperformed LW in terms of pain experience, impact on self-perceived quality of life, surgery duration, postoperative edema and analgesics intake.

In conclusion, this doctoral project allowed to obtain clinically relevant key findings, which we now summarize:

1. OD is an effective and versatile technique that can be predictably used in various clinical scenarios, ranging from routine implant site preparation to more complex procedures such as bone expansion and SFE.
2. ISQ and insertion torque tend to be higher when OD is used for implant site preparation, compared to conventional drilling protocol.
3. OD is a safe and effective technique for interradicular septum expansion and simultaneous site preparation for post-extraction implant placement in molar sockets.

4. OD is a real and predictable alternative to the classic LW approach for SFE in extreme cases with reduced RBH, with a significantly improved overall patient experience.

6.3. Future Directions

This thesis demonstrated the clinical potential of OD technique in implant dentistry; however, ongoing research is crucial to further enhance its understanding and optimize its application. While current evidence strongly supports the use of OD, further well-designed long-term randomized clinical trials are warranted to solidify its standing as a valid alternative to established techniques. Future research should focus on expanding the evidence base and refining methodologies to enhance even more the scientific community's confidence in OD. Furthermore, we consider extremely important to emphasize the importance of proper training in this technique, which is essential for its consistent and successful implementation in clinical practice.

CHAPTER 7

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CHAPTER 8

ANNEXES

Annex 1. Egas Moniz Ethics Committee Approval | Internal Process nº859

Comissão de Ética EGAS MONIZ

Proc. Interno nº 859

Ex.mo Senhor
João Rui Carvalho Gaspar

Monte de Caparica, 20 de fevereiro de 2020

Ex.mo Senhor,

Em resposta ao Pedido de Parecer que submeteu à apreciação da Comissão de Ética da Egas Moniz, com o tema denominado **"Elevação do seio maxilar por abordagem crestal com osseodensificação versus abordagem clássica com janela lateral"**, *foi aprovado* por unanimidade.

Com os melhores cumprimentos,

A Presidente da Comissão de Ética da Egas Moniz

Profª. Doutora Maria Fernanda de Mesquita

EGAS MONIZ – COOPERATIVA DE ENSINO SUPERIOR, CRL
Campus Universitário – Quinta da Granja – Monte de Caparica
2829-511 Caparica

Annex 2. Informed Consent for clinical treatment in the Randomized Clinical Trial

EGAS MONIZ

COOPERATIVA DE ENSINO SUPERIOR, CRL

Consentimento Informado

Código | IMP:EM.PE.17_03

Por favor leia com atenção a seguinte informação. Se achar que algo está incorreto ou que não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita, queira assinar este documento.

No âmbito do Doutoramento em Ciências Biomédicas do Instituto Universitário Egas Moniz, sob a orientação do Professor Doutor José João Mendes, solicita-se autorização para a participação no estudo "Elevação do seio maxilar por abordagem crestal com osseodensificação *versus* abordagem clássica com janela lateral" com o objetivo de avaliar a performance clínica de implantes e o conforto pós-operatório após técnica de elevação do seio maxilar.

A reabilitação oral com implantes endósseos é uma excelente opção de tratamento para pacientes edêntulos, com elevadas taxas de sucesso. De modo a poder ser candidato à colocação de implantes, o paciente deverá ter quantidade óssea suficiente. Uma limitação frequente para a colocação de implantes na maxila posterior é a reduzida altura óssea residual até ao seio maxilar. Deste modo, é muito frequente a necessidade de se realizar um procedimento regenerativo denominado "elevação do seio maxilar", para aumento da altura óssea disponível e assim ser possível colocar implantes.

Este estudo clínico de investigação tem como objectivo comparar duas técnicas de elevação de seio maxilar - técnica de janela lateral e técnica de osseodensificação. Ambas as técnicas estão bem descritas na literatura científica, com excelentes resultados. A técnica clássica de janela lateral foi descrita em 1980, sendo por isso realizada há muitos anos com altas taxas de sucesso. Mais recentemente, em 2015, foi introduzida uma nova técnica, a osseodensificação, que demonstrou igualmente ter excelentes resultados, com a vantagem de ser menos invasiva do que a técnica de janela lateral. Deste modo, pode oferecer vantagens em termos de diminuição de dor e edema pós-operatório, com potencial impacto na melhoria da qualidade de vida do paciente. O estudo vai ser um Ensaio Clínico Randomizado – isto significa que a escolha da técnica a utilizar em cada caso será aleatória – em metade dos pacientes incluídos, será realizada a técnica de janela lateral e na outra metade será realizada a técnica de osseodensificação.

A sua não participação não lhe trará qualquer prejuízo. Este estudo pode trazer benefícios: 1) possibilidade de colocar implantes numa região sem dentes, onde não seria possível sem este tipo de procedimento regenerativo; 2) acompanhamento clínico após colocação do implante; 3) avaliação do conforto pós-operatório.

A sua participação neste estudo é voluntária. Tem o direito de recusar a sua participação no estudo a qualquer momento, sem prejuízos para si. O estudo mereceu parecer favorável da Comissão de Ética Egas Moniz. Os contactos serão feitos em ambiente de privacidade clínico, ao abrigo do Código Deontológico e de Conduta Ética da Ordem dos Médicos Dentistas. No caso de aceitar participar neste projeto de investigação, a Egas Moniz - Cooperativa de Ensino Superior, CRL possibilita de forma gratuita a técnica de elevação do seio maxilar.

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____

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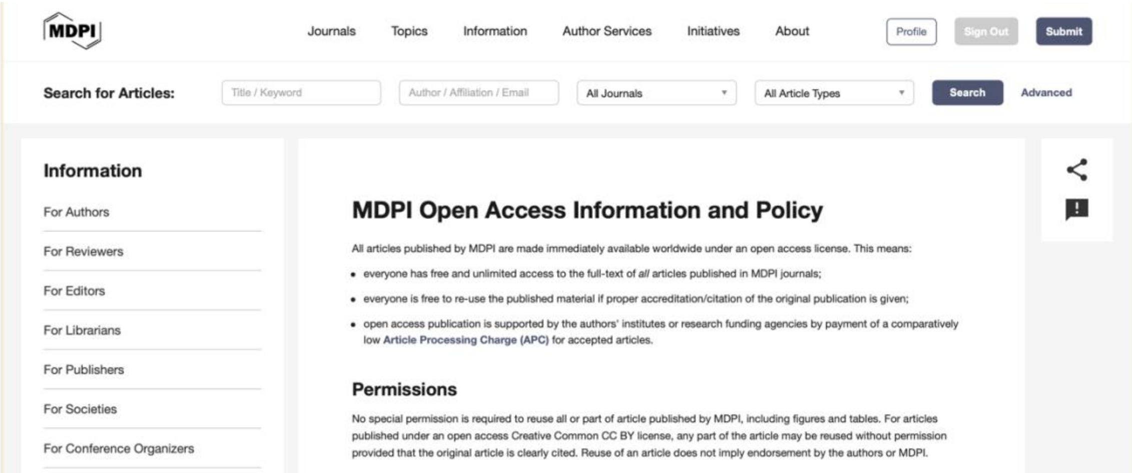
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