

The use of hyaluronic acid for crestal sinus lift: a randomized controlled clinical trial

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Abstract

The primary objective of this randomized clinical study was to radiologically assess the net bone gain and the reduction of graft volume achieved with the combination of mixed autologous and heterologous bone grafting (BG) alongside hyaluronic acid (HA), providing a comprehensive evaluation of the procedure's efficacy and safety.

Materials and Methods: Participants were selected from patients seeking implant treatment at the university hospital between February 2022 and January 2024. The procedure involved sinus elevation using techniques such as physiological water jet pressure (CaskIT), mechanical lifting tips (M.I.S.E.), and the Summers osteotomy method. Bone graft biomaterials were introduced after sinus membrane elevation, followed by simultaneous implant placement. Radiological imaging included pre- and postoperative CBCT scans, orthopantomography (OPG), and intraoral periapical radiographs.

Results: The study initially involved 16 maxillary sinuses from 8 patients. There was a significant increase in bone height in the Bone Graft (BG) and Hyaluronic acid (HA) groups from the initial measurement (T0) to the first (T1) and second follow-ups (T2). However, there was a significant decrease in bone height between the first and second follow-ups.

Conclusion: Both types of grafts are appropriate for maxillary sinus elevation with immediate implant placement. The HA contributed to graft augmentation and stabilization, fostering blood clot formation and preserving its stability.

Keywords: Hyaluronic acid, sinus lift, oral surgery, implantology, bone reconstruction, crestal lift.

Introduction

The sinus floor elevation technique, first introduced by Boyne and James in 1980, aims to encourage bone regeneration within the atrophic maxillary alveolar ridge, thereby rendering it suitable for dental implant placement¹. This procedure involves performing an osteotomy of the lateral wall of the maxillary sinus, elevating the Schneiderian membrane, and inserting autogenous particulate bone graft material between the membrane and the alveolar ridge². Bone augmentation typically utilizes autogenous bone, bone substitutes, or a combination of both. The transcrestal sinus floor elevation (tSFE) was initially described by Tatum and was subsequently modified



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by Summers, who, in 1994, pioneered the minimally invasive osteotome technique³. This method permits implant placement during the same surgical session or prepares the site for future implant placement. The osteotome, inserted at the edentulous alveolar crest, fractures the cortical bone of the sinus floor while preserving the integrity of the Schneiderian membrane.⁴ The compaction of the bone graft material then exerts lateral and apical pressure, elevating the membrane from the sinus floor, thereby creating space for grafting and allowing the placement of an appropriately long implant^{3,4}. The crestal approach is recognized for its high implant and prosthetic survival rates, low intraoperative complication rates, and reduced morbidity compared to the lateral approach. However, tSFE is considered to be safe only when an elevation threshold of 5 mm without bone grafting and implant placement is maintained. The technique has evolved to include the use of drills with depth stops to prevent perforation of the sinus floor and to facilitate subsequent placement of biomaterial grafts. In 2002, Fugazzotto introduced a method employing a trephine bur to drill up to the sinus floor, followed by hydraulic fracturing through osteotomes, a technique that has gained widespread acceptance. Techniques utilizing hydraulic pressure to elevate the Schneiderian membrane, based on Pascal's principle, have been reported to detach the membrane uniformly without perforations, even in cases of reduced alveolar ridge height. This method is followed by the insertion of a bone substitute biomaterial graft within the sinus and the immediate placement of an implant. Autogenous bone grafts continue to be regarded as the gold standard in bone regeneration. Initially utilized in sinus floor elevation by Boyne, James, and Tatum to minimize the volume of bone harvested and decrease donor site morbidity, bone substitutes—including xenogenic, allogenic, and synthetic materials—have been developed^{5,8}. These materials are favored for their low immunogenicity and capacity for high-volume bone augmentation, despite carrying a higher risk of infection compared to other materials. Xenogenic grafts are particularly notable for their low inflammatory response and durability, while synthetic biomaterials, such as bioactive glasses, demonstrate promise due to their ability to facilitate extensive bone neoformation and produce minimal residual graft material^{9,10}. Nonetheless, the use of these biomaterials is not without complications. For instance, if the grafting material is packed into a site with a significantly perforated membrane, there is a risk of the material migrating into the sinus cavity, potentially leading to sinus blockage, postoperative sinusitis, or infection. Surgical site infections may spread within the grafted biomaterial in the sinus cavities, necessitating complete removal of all infected material, as documented in studies examining bacterial proliferation within grafted tissues. The application of hyaluronic acid in gel form is increasingly employed to mitigate these risks due to its properties that significantly reduce the likelihood of perforation during membrane elevation and prevent sinus blockage in case of graft displacement, owing to its fluidity and solubility. Insufficient crestal bone in the edentulous posterior

maxilla, often resulting from alveolar bone atrophy and sinus pneumatization, has been extensively studied over recent decades. Various surgical techniques and grafting materials for sinus augmentation, particularly via lateral access, have demonstrated safety and predictable results, making them preferred methods for supporting implants in severely atrophic maxillary posterior ridges. Nevertheless, when a more conservative and less invasive approach is desirable for bone regeneration prior to implant placement, the crestal approach is favored. Originally developed by Summers using osteotomes, this technique has undergone modifications incorporating biocompatible grafts and techniques that expand and compress the alveolar ridge. While autogenous bone grafts remain the gold standard due to their osteogenic properties, the morbidity associated with harvesting has led to increased use of bone substitutes such as tricalcium phosphate, as well as allografts, alloplasts, and xenografts, which are valued for their osteogenic, osteoconductive, and osteoinductive properties. Despite some controversies regarding the use of bone materials to maintain space and elevate the membrane for new bone formation, biomaterials have been shown to effectively enhance ossification around implants¹⁶. A primary risk of the transalveolar technique remains membrane perforation, although sinus lifts performed without grafting have been successfully conducted¹⁴. This study aimed to evaluate and compare the beneficial effects of utilizing bone grafts and hyaluronic acid (HA) as grafting materials during sinus lift procedures, followed by implant placement, through radiological analysis of bone gain and reduction.

Materials and Methods

Study Design

This investigation was conducted as a randomized clinical trial (RCT) to compare the efficacy of bone graft alone for crestal sinus lift with the combination of bone graft and hydroxyapatite (HA) for another dental implant. The research adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The trial was performed at the Department of Maxillofacial Surgery and Implantology, Faculty of Dentistry, University of Rome Tor Vergata, Italy. Informed consent was obtained from all participants, and the study received ethical approval from the Faculty of Dentistry's ethics committee at the University of Rome Tor Vergata.

Participants, sample size calculation, randomization

The sample was obtained from patients seeking implant treatment at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Ospedale San Pietro Fatebenefratelli, Rome, Italy. Data collection took place between February 2022 and January 2024. The sample size was calculated using G*Power 3.1.3, with an 80% study power, a significance level of $p = 0.05$, and an effect size of 0.83 derived from a study by Kang. To account for potential attrition, two additional maxillary sinuses were included per group, resulting in a total sample size of 16 maxillary sinuses. Each group comprised 16 maxillary sinuses (8 patients).

The maxillary sinuses were randomly allocated to one of two cohorts: the Bone Grafting group (intervention cohort) or the Hyaluronic Acid group (control cohort), with 8 maxillary sinuses in each group.

Inclusion criteria comprised satisfactory oral health, bilateral edentulism in the maxilla, an age range of 30 to 70 years, and an alveolar ridge bone height (measured from the alveolar crest to the floor of the maxillary sinus) spanning from 0.5 to 5 mm. Exclusion criteria encompassed metabolic diseases affecting bone metabolism (such as hyperparathyroidism and osteoporosis), use of medications that influence bone metabolism (including corticosteroids, oral contraceptives, and hormonal or chemical therapies), history of head and neck radiotherapy, and systemic conditions such as diabetes, cardiovascular diseases, leukemia, hypertension, coagulation disorders, and autoimmune diseases.

Methods

The primary indication for sinus graft surgery is the planned implant reconstruction of the edentulous posterior maxilla, which is often affected by post-extraction alveolar bone loss and sinus pneumatization, leading to bone that is too atrophic for implant placement. Sinus graft surgery is suitable for the reconstruction of single or multiple teeth as well as the completely edentulous posterior maxilla. Before initiating surgical treatment, a comprehensive patient history and physical examination are essential. Important aspects to note in the medical history include recent upper respiratory infections, chronic sinus conditions, persistent sinus or facial pain, otitis media, previous nasal or sinus surgeries, prior maxillary reconstruction attempts, and smoking habits. Research shows that while the complication rate for sinus lift grafts in smokers is similar to that of the general population, smokers with implants placed in sinus-grafted bone have a higher failure rate than nonsmokers. A preoperative CT scan is recommended to assess existing bone volume, rule out sinus disease, and detect bone septa. The sinus lift procedure was performed using implant osteotomy and various lifting techniques, including water-jet pressure, mechanical lifting tools, and the Summers technique. Bone biomaterial was inserted, and bone-level implants were placed simultaneously. Imaging included pre- and postoperative intraoral periapical radiographs, orthopantomography, and cone-beam computed tomography.

Surgery stage

The surgical procedure commenced with stringent aseptic protocols, beginning with a mucoperiosteal incision to expose the alveolar ridge. Using a pilot drill, the initial site for the implant osteotomy was identified, followed by the utilization of progressively larger drills, each paired with specific plugs, to delicately approach the sinus floor without perforation. This meticulous drilling was carried out employing the Crestal Approach Sinus kit, the Maxillary Sinus Elevation kit, and the technique developed by Summers, each intended to incrementally elevate the sinus floor in preparation for implant placement. The crestal approach kit, notably,

featured drills with an inverted conical design that efficiently produced a conical bone fragment during drilling. This distinctive shape not only facilitated a safe membrane elevation but also utilized bone particles generated during drilling to assist automatically in elevating the membrane. The system incorporated color-coded plugs to identify the requisite lengths for safe elevation, accommodating various sinus floor conditions, including flat, sloping, or septated anatomies. Moreover, a hydraulic lifting mechanism employing a water jet was introduced to elevate the membrane safely and effectively after completing the osteotomy. An adapter connected to a syringe filled with normal saline was attached to the osteotomy site. The controlled injection of saline exerted gentle pressure on the sinus membrane, causing it to lift softly, with a depth gauge fitted with a stopper used to confirm the successful separation and elevation of the sinus lining. Post-osteotomy and hydraulic elevation, a biomaterial, specifically MP3 Bioss, was introduced into the site. This material was then compacted utilizing a specialized plugger equipped with dedicated length stops to ensure precise implant placement. Subsequently, the site was sutured closed, and healing was allowed to proceed, with a second stage of prosthetic loading scheduled after six months. Cone beam computed tomography (CBCT) analysis was performed to evaluate bone formation within the peri-implant region, and implant survival was assessed at one year following the sinus lift procedure. Additionally, the Maxillary Indirect Sinus Elevation technique was employed as an alternative trans-alveolar sinus elevation approach. This method involved a drill and stop system to facilitate atraumatic, gradual elevation of the sinus membrane by 5 to 10 mm above its original position, thereby preserving the Schneiderian membrane and permitting the placement of filling materials. Following the elevation, an autologous bone graft was inserted into the prepared site. The implants utilized in this technique were Premium models by Sweden & Martina.

The internal hex connection and the surface treated with zirconium oxide blasting and acid etching ensure their stability after insertion. The rationale behind utilizing autologous bone for sinus augmentation includes expediting the vascularization of the graft, enhancing soft tissue healing, reducing post-surgical morbidity, and bolstering bone formation. The benefits of employing an autologous blood product encompass eliminating the risk of cross-reactivity, immune reactions, or disease transmission. The improved handling characteristics may allow for the placement of a denser graft, thereby supporting space maintenance and bone regeneration. Additionally, a variation of the Summers technique, modified by Fugazzotto in 2002, was employed. This method involved elevating a full-thickness flap under local anesthesia to fully expose the bone ridge. A single trephine drill was utilized to carefully prepare the site, with modifications based on the initial bone height, ensuring that the preparation length was 1 mm shorter than the available bone height. The Straumann osteotome was subsequently used to fracture the sinus floor, with the Valsalva maneuver performed to verify the integrity of the Schneiderian

membrane. Implant placement proceeded regardless of the Valsalva maneuver outcome, with the implant inserted at a slow speed to ensure the rough surface was entirely buried. In this case, a hyaluronic acid graft was used. According to Pascal's Law, the expelled fluid exerts uniform pressure across the Schneiderian membrane. This facilitates a smooth elevation across various clinical situations, thereby circumventing the potential for membrane perforation often associated with sinus-lifting instruments. The deployed biomaterial elevates and maintains its position within the sinus cavity, thereby promoting the genesis of new bone tissue. To our knowledge, there is a paucity of studies directly evaluating hyaluronic acid as a substitute for bone-derived biomaterials in human subjects. However, extensive research has investigated the interactions of hyaluronic acid with other biomaterials. These studies underscore hyaluronic acid's capacity to facilitate bone regeneration, notably by accelerating mesenchymal cell differentiation and enhancing extracellular matrix mineralization. The findings presented herein demonstrate that a less invasive approach, when combined with a biomaterial that induces osteogenesis, can significantly reduce patient morbidity and minimize risks and complications during or after surgery. Throughout the procedure, parameters such as residual bone height at the time of implant placement, postoperative bone height at six months, the height gain achieved, average primary implant stability, and the length of the implants used were meticulously recorded. Furthermore, the incidence of drilling complications and the overall implant survival rate (100%) were documented. The criteria for implant survival included the absence of clinically detectable implant mobility, pain, or subjective sensations; recurrent peri-implant infection; or continuous radiolucency around the implant, ensuring a comprehensive assessment of the procedure's success over a one-year follow-up period.

Radiographic stage

Three CBCT scans were obtained for each patient using the 3D imaging system (Sirona, Verona, Italy). All scans were performed at the same radiology center to maintain consistent radiographic parameters, ensuring the same patient positioning at three time points: pre-operatively (T0), immediately post-operatively (T1), and six months post-operatively (T2), prior to the second surgical procedure (implant placement). Additionally, pre- and post-operative periapical and intraoral images were taken. The first scan (T0) was used to measure bone height before the maxillary sinus lift, utilizing specific points in the sagittal view. The third scan (T2) was used to evaluate the extent of the lift at the same locations.

Bone height was measured on the initial scan (T0) at five designated points in the coronal view, with each point in the coronal view corresponding to a matching point in the sagittal view, using the "ruler" tool. Similarly, bone height was assessed on the third scan (T2) at five points in the coronal view. Using the same procedure, bone height was also evaluated in both sagittal and coronal views on the second scan (T1).

Two equations (Table 1) were employed to determine

the subsequent parameters: bone height immediately post-surgery, bone gain at six months, and bone reduction at six months.

Table 1. Explication of equation for calculating bone loosed or gained

Bone gain	=	Bone height T2 – Bone height T0
Bone reduction	=	(Bone height T1 + Bone Height T0) – Bone Height T2

Results

The study initially involved 16 maxillary sinuses from 8 patients. Table 1 displays the descriptive statistics of bone height at different time intervals for both groups. There was a significant increase in bone height in the Bone Graft (BG) and Hyaluronic Acid (HA) groups from the initial measurement (T0) to the first (T1) and second follow-ups (T2). However, there was a significant decrease in bone height from the first to the second follow-up. All these changes were statistically significant, with a p-value of less than 0.05. Table 4 reveals that there were no statistically significant differences between the two groups in terms of bone gain or bone loss at the 95% confidence interval. The average amount of bone gained in the BG group was slightly higher by 0.43 mm compared to the HA group. Similarly, the average bone loss was marginally greater in the HA group than in the BG group, with a difference of 0.44 mm.

Discussion

Maxillary sinus lifting is a progressively advancing surgical technique aimed at increasing bone height to facilitate dental implant placement. A thorough understanding of the maxillary sinus anatomy and its variations is essential, as complications such as Schneiderian membrane perforation can occur during sinus window preparation. Pre-surgical evaluation with Cone Beam Computed Tomography (CBCT) is highly recommended to detect the presence of septa, which may add complexity to the procedure. Significant research has been dedicated to identifying the most effective bone graft materials for sinus lifting. Autogenous bone grafts are considered the gold standard, as they provide osteoconduction, osteoinduction, and osteogenesis—key factors for successful bone regeneration. However, harvesting bone from another site in the patient's body extends the surgical time and increases post-operative discomfort^{2,3}. This has led to growing interest in alternative grafting materials, either by combining autografts with other types of grafts or by completely substituting them with different materials⁹. The use of alloplastic grafts, such as Hydroxyapatite, has gained popularity for their ability to streamline surgical procedures¹⁷. However, in cases of significant bone loss, the large quantities of material required can make this approach costly. To address this, recent research has investigated combining alloplasts with Advanced Platelet-Rich Fibrin (A-PRF) to reduce

the amount of graft material needed while enhancing osteogenesis. A-PRF, being an autologous material, eliminates the risk of disease transmission. Additionally, its gelatinous consistency stabilizes the clot and graft, promoting faster ossification^{13,15}. The current research was designed to assess the effectiveness of these bone graft materials in the context of maxillary sinus lifting. Mixed bone grafts, which combine different types of graft materials, have shown to be easily accessible, cost-effective, and capable of providing satisfactory results. These grafts are also notable for their utility without the need for absorbable or non-absorbable membranes^{18,19}. In this study, the effectiveness of mixed bone grafts was compared to Hydroxyapatite (HA), another class of alloplastic material known for its reliability and frequent use in grafting procedures. The inclusion criteria for the study sample involved patients aged 35–50 with bilaterally edentulous posterior maxilla, bone height ranging from 0.5 mm to 5 mm according to the Misch classification, and no systemic diseases or nasal/sinus conditions that would contraindicate sinus lifting^{10,20}. The sample consisted of 16 maxillary sinuses from 8 patients; however, one patient was excluded due to non-attendance at the radiographic follow-up. Radiological assessments utilized CBCT and XCP scans for precise measurements at three time points: pre-operation (T0), immediately post-operation (T1), and six months post-operation (T2). The study demonstrated that both bone graft materials facilitated sufficient bone growth for immediate implant placement, with no significant differences in bone gain or reduction observed between the groups. Clinical and radiological complications were notably absent during the 6-month follow-up period. These findings concur with those of Guarnieri et al.²¹ and Tarnow et al.²², who reported favorable outcomes concerning implant stability and bone formation following the absorption of the grafts. However, a longer-term study indicated a greater reduction in bone height over 2.5 years compared to the current study's 6-month observation period. Advancements in the field, such as hydraulic lift techniques and the development of specialized drill systems and instruments, have enabled minimally invasive procedures that preserve sinus membrane integrity and ensure optimal implant stability^{23,24}.

Conclusions

Within the limitations of the present study, both types of grafts could be used for maxillary sinus lifting. The HA helped increase and stabilize the graft, enhancing blood clot formation and stability. In summary, the research highlights the effectiveness of mixed bone grafts and HA when used in maxillary sinus lifting, demonstrating promising results for bone regeneration. Further studies with longer follow-up periods are recommended to confirm these findings and to continue improving the techniques and materials used in sinus augmentation surgeries.

Abbreviations

HA: Hyaluronic Acid
BG: Bone Graft

CBCT: Cone Beam Computed Tomography
RCT: Randomized Controlled Trial
tSFE: Transcrestal Sinus Floor Elevation.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the Faculty of Dentistry, University of Rome Tor Vergata. All participants provided written informed consent prior to enrollment.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests.

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