ISSN: 2472-3703 DOI: 10.6911/WSRJ.202601_12(1).0002

Study on the Osteogenic Effects of Yuliang Collagen Implantation Without Bone Grafting at 6–9 mm from the Maxillary Sinus Floor: A Prospective Cohort Study

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Abstract

Objective: To evaluate the osteogenic effect and implant survival rate in the peri-implant region following simultaneous maxillary sinus floor elevation via the crestal approach and Yuliang collagen (a high-purity type I collagen matrix) implantation, without additional bone grafting, in patients with residual alveolar bone height (RBH) of 6–9 mm in the maxillary posterior region. Methods: A prospective cohort study design was employed, enrolling 42 patients (50 implants) requiring maxillary posterior implant restoration with RBH of 6–9 mm. All patients underwent bone-free transalveolar sinus floor elevation, with Yuli'an collagen implanted in the elevated space during surgery. Immediate postoperative and 6-month/12-month postoperative cone-beam computed tomography (CBCT) scans were performed to measure new bone height (NBH) above the implant apex and bone density changes (gray-scale analysis). Surgical complications and implant survival were recorded. Results: We followed up on 50 implants in 42 patients for an average of 14.3 months. One case involved minor periosteal perforation during the maxillary sinus lift, which did not affect final healing. No implant infections or failures occurred. The implant survival rate was 98% (49/50). At 12 months postoperatively, CBCT measurements revealed new bone formation above the implant apexes. Compared to the preoperative RBH (7.2 ± 0.8) mm, the mean height of newly formed bone was (3.8 ± 0.9) mm, with an average increase of approximately 3.4 mm in sinus floor bone height. For assessing the density of newly formed bone, we used the density of the contralateral normal maxillary bone as a reference. The mean bone density in the newly formed bone area reached (65.2 ± 7.1)% and (88.7 ± 5.3)% of the contralateral normal maxillary bone density at 6 and 12 months postoperatively, respectively, indicating good maturity of the newly formed bone. Conclusion: For maxillary posterior regions with a ridge height (RBH) of 6–9 mm, sinus floor elevation via the crestal approach using Yuliang collagen protein alone (without bone grafting) can guide the formation of sufficient quantities of high-quality new bone. This approach achieves clinical osteogenic outcomes and high implant survival rates comparable to traditional bone grafting methods. YuLiAn collagen, serving as a space-maintaining and guiding matrix, demonstrated excellent biocompatibility and osteogenic potential in this procedure, offering a reliable option for simplifying surgical steps, reducing patient costs, and minimizing trauma.

Keywords

Maxillary sinus floor elevation; Bone graft-free; YuLiAn Collagen; Residual bone height; Bone regeneration; Implant.

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1. INTRODUCTION

Posterior maxillary teeth are frequently lost due to caries and periodontal disease. The alveolar bone in the edentulous posterior maxillary region undergoes progressive maxillary sinus pneumatization, resulting in insufficient residual bone height (RBH)—a common challenge in clinical implantology [1]. Sinus lift surgery addresses insufficient sinus floor height by elevating the sinus floor mucosa. Traditional approaches require additional bone grafting material (such as autogenous bone or allograft substitutes) to be placed submucosally beneath the elevated sinus floor after mucosal elevation. This supports the created space and promotes new bone formation. However, this increases surgical time and cost, while also introducing risks of infection, resorption, and rejection associated with the implanted materials.

In recent years, many scholars have proposed "bone graft-free" or "membrane/collagen-only" approaches for maxillary sinus floor elevation. The theoretical basis lies in the osteogenic potential of intact sinus floor mucosa itself, with the elevated submucosal space facilitating further organization of blood clots and subsequent bone formation [2]. Furthermore, relevant clinical studies indicate that when the retracted sinus height (RBH) is ≥ 5 mm, sinus floor elevation without bone grafting can achieve predictable osteogenic outcomes. However, a blood clot alone lacks stable spatial support and is prone to collapse, which may further compromise osteogenesis. Therefore, the use of biomaterials with space-maintaining capabilities, biodegradability, and tissue regeneration-promoting properties as a "scaffold" for the blood clot is particularly crucial [3].

YuLiAn Collagen is a high-purity type I collagen derived from bovine Achilles tendons. It undergoes deantigenation treatment, exhibiting excellent biocompatibility, degradability, and low immunogenicity. Its three-dimensional porous structure provides a scaffold for cell migration, vascular ingrowth, and bone tissue deposition while stabilizing the blood clot and preventing premature soft tissue invasion ([4]).

Currently, systematic clinical data supporting the osteogenic efficacy of Yuli'an Collagen alone without bone grafting for maxillary sinus elevation within specific RBH ranges (particularly the "intermediate" height of 6–9 mm) remains limited. A 6–9 mm RBH provides good initial implant stability, but the osteogenic effect of sinus elevation alone is limited. Whether Yuliang collagen protein implantation under these conditions can further guide new bone formation and enhance implant stability holds significant implications for clinical decision-making.

This prospective cohort study evaluates the clinical efficacy, osteogenic outcomes, and implant survival rate of sinus floor elevation with 6–9 mm RBH using Yuli'an collagen alone without bone grafting, to validate its clinical feasibility and effectiveness.

2. MATERIALS AND METHODS

2.1. Study Population

This study enrolled patients from January 2021 to December 2022 who underwent implant restoration at our hospital due to unilateral or bilateral maxillary posterior tooth loss, with CBCT-measured RBH of 6–9 mm. Inclusion criteria: age 18–70 years; no severe systemic diseases (except well-controlled hypertension and diabetes); thorough oral hygiene education with maintained good oral hygiene; No uncontrolled periodontitis; non-smokers or light smokers (<10 cigarettes/day); healthy maxillary sinus mucosa without acute/chronic inflammation; no patients with cold or flu; Class III alveolar bone; normal coagulation function without hematological disorders; keratinized mucosal width ≥3mm.Exclusion criteria: History of maxillary sinus disease or surgery; RBH < 6mm or > 9mm; Heavy smokers (>10 cigarettes/day); Pregnant or lactating women; Patients with severe periodontitis; Poor oral hygiene; Patients with uncontrolled blood glucose; Inability to attend scheduled follow-up

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appointments. A total of 42 patients (19 males, 23 females) aged 28–65 years (mean 51.4 years) were ultimately enrolled. Fifty implants (Straumann®, SLA surface, diameter 4.1 mm, length 8–10 mm) were placed. All patients provided informed consent, and the study was approved by the hospital ethics committee.

2.2. Surgical Approach

Preoperative Preparation: Comprehensive oral examination and oral hygiene education. Completion of relevant periodontal and dental treatments prior to surgery. CBCT assessment of maxillary sinus anatomy, RBH, and mucosal thickness. Prophylactic antibiotics administered 30 minutes before surgery.

Surgical Procedure: Under 4% articaine local anesthesia, make an incision at the crest of the alveolar ridge and elevate a full-thickness flap. After positioning the pilot drill, sequentially use osteotomes (Summers osteotomes) or specialized sinus floor elevation instruments (e.g., CAS-KIT) to gently tap and progressively elevate the maxillary sinus floor bone plate along with the mucosa inward and upward. Hydraulically elevate the maxillary sinus membrane by approximately 4–6 mm until sufficient implant space is achieved. Perform stepwise drilling, taking care to avoid mucosal perforation during the procedure [5].

Material Implantation: After the patient inflates their cheeks and the integrity of the sinus floor mucosa is confirmed, trim the pre-hydrated YuLiAn collagen (specification: 10mm × 10mm × 2mm, Beijing Yierkang Bioengineering Co., Ltd.) to a suitable size and shape. Gently push it under the elevated sinus floor mucosa using instruments to cover the entire elevated area, stabilizing the blood clot and maintaining space.No other osteogenic materials are implanted during this phase.

Implant Placement: Based on alveolar bone conditions, insert implants of appropriate length to ensure initial stability (insertion torque > 20 N·cm). Place healing abutments or cover screws, then meticulously suture the wound [6].

Postoperative Management: Prescribe oral antibiotics for 5–7 days and mouthwash for 2 weeks. Instruct patients to avoid strenuous activities such as forceful nose blowing, sneezing, or swimming. Sutures are removed at 2 weeks postoperatively.

2.3. Imaging Evaluation

Imaging was performed using the same CBCT unit (KaVo 3D eXam) at preoperative, immediate postoperative, 6-month postoperative, and 12-month postoperative time points. Two radiologists, blinded to clinical outcomes, independently measured:

RBH: The shortest distance from the alveolar crest at the implant site to the maxillary sinus floor bone wall at baseline.

New bone height (NBH): Vertical distance from the apical margin of the implant to the uppermost margin of newly formed cortical bone at the maxillary sinus floor at each postoperative time point. NBH at 12 months postoperatively served as the primary outcome measure.

Bone Density Analysis: Under standardized conditions, software (OnDemand3D) measured the mean gray value (HU) of the newly formed bone region (ROI, 3mm diameter circular area) above the implant apex. This value was compared to the gray value of normal cancellous bone in the non-elevated maxillary region on the same side to calculate the relative bone density percentage.

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2.4. Clinical Evaluation

Recorded: surgical duration, intraoperative complications (e.g., mucosal perforation), postoperative complications (e.g., infection, swelling, pain), implant survival status (no mobility, no infection, no persistent pain or numbness), and prosthetic completion time.

2.5. Statistical Analysis

SPSS 25.0 software was used. Quantitative data are expressed as mean ± standard deviation. Repeated measures analysis of variance was used to compare NBH and bone density at different time points. Implant survival rate was calculated using the Kaplan-Meier method. $P < 0.05$ was considered statistically significant.

3. RESULTS

3.1. Clinical Outcomes

All 50 implants were successfully placed and restored. The mean surgical time per implant was (35.2 ± 6.5) minutes. One case (2%) of minor maxillary sinus membrane perforation (<2 mm) occurred intraoperatively; no specific intervention was required, and postoperative healing was satisfactory. No postoperative infections, early implant loosening/failure, or maxillary sinusitis occurred.With an average postoperative follow-up of 14.3 months (range: 12–24 months), one implant became loose and failed 3 months after restoration loading due to the patient's non-compliance with medical advice regarding prolonged chewing of hard foods and delayed consultation. The cumulative implant survival rate was 98% (49/50). All retained implants functioned well with healthy surrounding soft tissues.

3.2. Imaging Findings

New bone height (NBH): Immediately postoperatively, the elevated space was filled with blood clots and Yuliang collagen. CBCT showed no distinct bone shadow, as Yuliang collagen itself is non-radiopaque. At 6 months postoperatively, hazy bone shadows were visible, indicating new bone formation, with an average NBH of (2.9 ± 0.8) mm.At 12 months postoperatively, the newly formed bone had further matured, with clear trabecular structures visible on imaging. The mean NBH reached (3.8 ± 0.9) mm. When superimposed on the preoperative mean RBH (7.2 ± 0.8) mm, the mean total available bone height around the implant at 12 months postoperatively reached (11.0 ± 1.2) mm, meeting the requirements for bone coverage around the vast majority of implants.Differences in NBH at each time point were statistically significant ($P < 0.01$).

Bone density changes: The relative bone density percentage in the new bone area significantly increased from (65.2 ± 7.1)% at 6 months post-surgery to (88.7 ± 5.3)% at 12 months post-surgery ($P < 0.01$), indicating that the quality of new bone approached that of normal maxillary cancellous bone by 12 months.

Table 1. Changes in new bone height (NBH) and bone density at different postoperative time points (n=49)

Time Point	New bone height (mm, mean ± SD)	Relative Bone Density (%) (Mean ± SD)
6 months post-op	2.9 ± 0.8	65.2 ± 7.1
12 months postoperatively	3.8 ± 0.9	88.7 ± 5.3

Note: Repeated measures ANOVA was used for intra-group comparisons at different time points, $P < 0.01$.

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4. DISCUSSION

The results of this study indicate that in cases with a maxillary sinus floor height (RBH) of 6–9 mm, performing a transalveolar maxillary sinus floor elevation using only Yuliang collagen without bone grafting can successfully guide the formation of approximately 3.8 mm of new bone. This new bone achieves near-normal density within 12 months, with a high implant survival rate (98%), demonstrating reliable clinical outcomes.

These findings validate the concept that "the submucosal space beneath the maxillary sinus floor possesses intrinsic osteogenic potential." Implant placement under conditions of RBH ≥ 6 mm achieves favorable initial stability, with the sinus floor mucosal space providing a foundation for blood clot stabilization and transformation. The key to osteogenesis lies in maintaining spatial stability, as consistent space maintenance ensures blood clot organization and subsequent bone formation [6]. As an absorbable collagen matrix, Yueliyan collagen served as an ideal "space maintainer" and "guide" in this study. Its three-dimensional structure provided an anchoring framework for the blood clot, while its slow degradation profile (approximately 3–6 months) aligned with the rate of new bone formation, ensuring sustained maintenance of the osteogenic space.

Compared to traditional bone grafting, this method offers significant advantages: 1) Reduced technical sensitivity: Eliminates the need for bone harvesting or processing of graft materials, shortening surgical duration; 2) Lower costs: Most commercially available bone graft materials are imported and expensive; 3) Reduced risks: Avoids complications associated with graft materials, including infection, rejection, and uneven resorption;4) Reduced trauma: Eliminates the need for autogenous bone grafting and avoids a second surgical site. Furthermore, the 98% retention rate observed in this study is comparable to the success rates (95%–99%) reported in most maxillary sinus elevation procedures [7].

This study also has certain limitations. The selection criteria for indications were relatively stringent, focusing only on patients with RBH ≥ 6 mm. An RBH ≥ 6 mm ensures initial implant stability, which is a prerequisite for performing the non-bone grafting technique. The implant surgeons were experienced practitioners with over five years of implantology experience. During surgery, it was crucial for the surgeon to avoid mucosal perforation when performing sinus elevation. If significant perforation occurred, it might necessitate switching to bone grafting or using a barrier membrane for repair. Although only one case of microperforation did not affect outcomes in this study, it highlights the technical sensitivity involved. The study sample size was limited, and the follow-up period was relatively short (mean 14.3 months). Longer observation and follow-up are needed to confirm bone stability and implant survival rates. Furthermore, this single-arm observational study lacked direct randomized comparison with a bone grafting group. Future well-designed randomized controlled trials (RCTs) with larger samples and extended follow-up periods are required to provide higher-level evidence.

5. CONCLUSION

In the maxillary posterior region with residual alveolar bone height of 6–9 mm, sinus elevation surgery using Yuliang collagen protein alone (without bone grafting) effectively guided the formation of high-quality new bone. This approach yielded clinical and radiographic osteogenic outcomes comparable to traditional bone grafting methods, accompanied by a high implant survival rate.This technique simplifies the surgical procedure, reduces treatment costs and risks, and represents a reliable, biologically principled treatment option. YuLiAn collagen demonstrated favorable clinical performance in this application.

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