A Multicenter Retrospective Clinical Study with Up-to-5-Year Follow-up Utilizing a Method that Enhances Bone Density and Allows for Transcrestal Sinus Augmentation Through Compaction Grafting

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Purpose: *To evaluate the effectiveness and predictability of a novel biomechanical, minimally invasive bone instrumentation technique that enhances bone density through compaction grafting, called osseous densification, and allows for transcrestal sinus membrane elevation and augmentation with simultaneous implant placement.* ***Materials and Methods:*** *Patients who were consecutively treated with the bone densification and transcrestal sinus augmentation technique and were followed up in three treatment centers between May 2012 and September 2017 were included in this retrospective study. The summary statistics are presented as means for continuous variables and percentages for categorical variables.* ***Results:*** *In total, 222 patients with 261 implants were included in the final clinical analysis. The included follow-up period ranged from 6 to 64 months with a mean of 35 months. The subsinus residual bone height at baseline was 5.4 mm (SD: 1.9). Following the sinus augmentation, a significant vertical increase of 7 mm (SD: 2.49) was observed. No sinus membrane perforations and no late implant failures were observed from 6 up to 64 months follow-up, yielding a cumulative implant survival rate of 97%.* ***Conclusion:*** *This osseous densification technique for maxillary implant site preparation with transcrestal sinus augmentation and simultaneous implant placement led to favorable clinical outcomes with up to 64 months of follow-up.* Int J Oral Maxillofac Implants 2018;33:1305–1311. doi: 10.11607/jomi.6770

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Dental implant therapy is considered the "gold standard" for the rehabilitation of edentulous sites and has revolutionized the way dentistry is currently practiced.[1] Patients seek minimally invasive procedures and the timely delivery of implant-supported restorations.

Following tooth extraction in the maxillary posterior region, significant atrophy of the alveolar ridge and maxillary sinus pneumatization may occur. In such cases, sinus augmentation is required to create sufficient vertical bone volume for implant placement with adequate stability. Furthermore, implant placement in the posterior maxilla is additionally challenging due to poor bone quality and potentially narrow ridges. Osteotomy underpreparation is a commonly used method to enhance the implant primary stability.[2–4] However, this method may negatively impact osseointegration and lead to inadequate healing. According to Campos and coworkers, although osteotomy underpreparation may increase implant primary stability, a greater amount of necrotic dieback and interfacial remodeling may occur at the implant surface, potentially decreasing the implant secondary stability during healing.[5]

Numerous methods have been proposed to treat a vertically deficient, edentulous, posterior maxillary

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ridge of poor bone quality.[6] Traditionally, two techniques are employed, namely, the direct sinus elevation procedure using a lateral window approach and the indirect sinus elevation procedure using a crestal approach.[7] The lateral window approach has been reported to yield predictably favorable clinical results.[8] Nonetheless, the degree of invasiveness and patient morbidity, risk of severing the alveolar antral artery, risk of perforating the sinus membrane, delay in healing, and increased risk of postsurgical infection are major drawbacks of this procedure.[9] Conversely, the crestal indirect sinus elevation techniques are less invasive, less time-consuming, and reduce patient morbidity. However, the risk of membrane perforation may be as high as 24% due to lack of direct visibility and access.[10]

The Summers osteotomes as a crestal indirect sinus elevation technique has been reported to achieve vertical bone gain of approximately 4 to 5 mm.[11] This technique also is not without its drawbacks, namely, explosive force to the maxilla with poor control, unintentional displacement or fracture, membrane perforation, and even benign paroxysmal positional vertigo.[12]

The main prerequisite for osseointegration is a ridge with bone of sufficient volume for implant insertion.[13] Implant primary stability is also a key factor for achieving osseointegration. This mechanical stability is dictated by the amount of bone contacting the implant. The biologic secondary stability that is developed over time eventually results in osseointegration.[14] The implant primary stability is measured by several indicators. Insertion torque as a rotational force during implant placement is dictated by the physical interaction between the bone and the implant and is directly related to the initial bone quality and quantity.[15] Insufficient initial bone-to-implant contact (BIC) may contribute to the higher failure of an implant to osseointegrate and maintain its function,[16] especially in the posterior edentulous maxilla. Bone removal during osteotomy preparation increases bone microfractures that are associated with delayed healing and is directly related to reduced BIC.[17,18]

An additional novel technique of bone instrumentation called osseous densification was introduced.[19] It increases bone density through compaction autografting, which may overcome these disadvantages. It is a novel, biomechanical osteotomy preparation technique that preserves bone through a nonexcavating drilling process utilizing specially designed burs with a tapered geometry and specially designed flutes to progressively expand the osteotomy while compacting bone into its walls and apex.[19] In this manner, this bone densification method enhances implant primary stability due to an elastic "spring-back" effect created in the prepared osteotomy by the compaction autografting.[19] Additionally, the site preparation method may accelerate new bone formation as a product of the residual bone chips that act as a nucleation for new bone formation.[20–22] The capacity of the osseous densification drilling process to elevate the sinus floor without sinus membrane perforation is based on the fact that the densifying burs are capable of bone instrumentation in a counterclockwise motion. Hence, irrigation is optimized throughout the osteotomy site, and irrigation solution is constantly present at the apical end of the osteotomy. Therefore, once the sinus floor is penetrated by the nonexcavating bone compaction drilling process, irrigation solution and autogenous bone chips perform a hydraulic detachment of the sinus membrane and subsequent elevation.

The aim of the present multicenter retrospective case series is to evaluate the effectiveness and predictability of the osseous densification instrumentation method and its ability to facilitate transcrestal sinus elevation with simultaneous implant placement.

MATERIALS AND METHODS

Patients who were consecutively treated and followed up at three different periodontal centers for an atrophic, edentulous, or partially edentulous posterior maxilla requiring dental implant placement between May 2012 and September 2017 were included. All patients had a crestal sinus augmentation procedure utilizing the osseous densification instrumentation method and implant placement. Routine exclusion criteria included sinus pathology that precludes routine sinus augmentation, such as acute sinusitis, history of previous sinus surgery, and bisphosphonate or chronic steroid medications. Inclusion criteria stipulated a minimum subsinus vertical bone height of 2 mm. Patients with a minimum of 6 months follow-up from time of augmentation and implant placement were included in the final analysis. Yearly follow-up assessment comprised clinical evaluation with a minimum periapical radiograph or cone beam computed tomography (CBCT) and clinical photograph. The routinely collected clinical data included age, sex, implant location, intraoperative or postoperative complications, smoking habits, presence of systemic disease, implant diameter and length, and radiographic changes. The primary outcome variable was implant survival rate. This retrospective analysis was observed in full accordance with the World Medical Association Declaration of Helsinki. All patients signed a consent form. The patients' specific files and data were kept confidential. The extracted data were assigned a random case number. The patients' initials were not used as case identifiers.

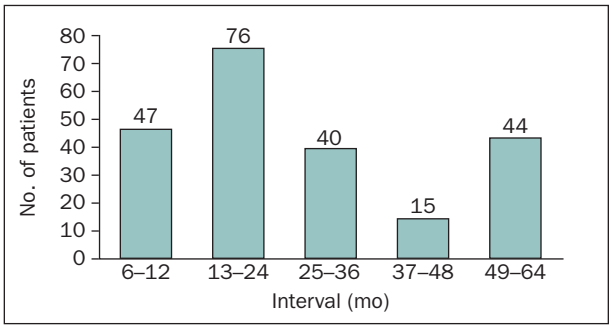

Fig 1 Number of patients followed per interval.

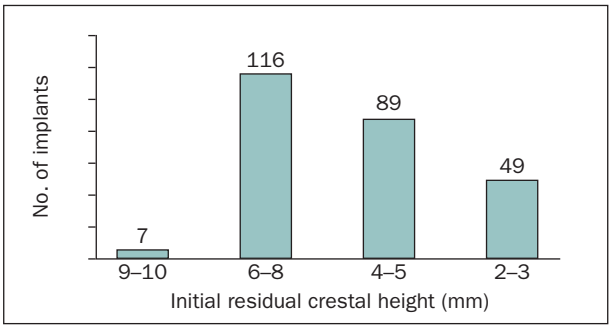

Fig 2 Number of implants placed in 222 patients according to the initial residual crestal height prior to sinus augmentation.

Surgical Technique

All surgeons followed standardized surgical techniques. After administering a local anesthetic, a full flap reflection was raised utilizing common instrumentation and reflection techniques. For ridges with residual vertical height of ≥ 5 to 6 mm, a pilot osteotomy was prepared with a 1.7-mm-diameter pilot drill to the depth determined within approximately 1 to 2 mm from the sinus floor. Following radiograph confirmation, osseous densification drilling was performed utilizing Densah Burs (Versah) as per the manufacturer's protocols (www.Versah.com).

Depending on the implant type and diameter selected for the site, the narrowest densifying bur was selected and run in counterclockwise rotation with 1,200 rpm and irrigation (densifying mode) in a modulating "bouncing" application into the osteotomy until the dense sinus floor was reached. Thereafter, a wider densifying bur (3.0 mm) was utilized in the same modulating movement to gently interrupt the sinus floor and advance up to 3 mm beyond the sinus floor, in 1-mm increments. Bur depth was periodically verified by periapical radiograph. The radiograph also confirmed that autogenous bone derived from the osteotomy was by virtue of the bur's design, pushed apically and elevating the sinus membrane. Sequentially wider densifying burs were used in a similar manner, to continue the process, elevating the sinus membrane, and augmenting additional autogenous bone shaving into the sinus, never extending the burs further than 3 mm into the sinus. Following completion of the osteotomy and sinus augmentation, the selected implant was inserted.

In cases requiring greater than 3 mm of vertical sinus augmentation having a residual alveolar ridge height < 5 mm, the steps above were repeated with the exception of the initial pilot drill. After achieving the desired osteotomy width as described earlier, the established osteotomy was filled with particulate bone graft substitute; then, the final densifying bur previously used to prepare the osteotomy was used in counterclockwise rotation at 100 to 200 rpm without irrigation to propel the allograft apically in one gentle apical motion toward the sinus facilitating additional vertical and lateral membrane elevation. This was repeated until the desired vertical augmentation was achieved, also with radiographic verification, and the implant was placed. At all times, osteotomy steep underpreparation was avoided; the osteotomy major diameter was smaller than the implant diameter by no greater than 0.5 to 0.7 mm.

Statistics

All included cases were reviewed, and the summary statistics were analyzed as means (standard deviations) for continuous variables and percentages for categorical variables.

RESULTS

Two hundred forty-five patients in total were treated by the osseous densification technique at implant insertion. Following loss to follow-up (n = 23), 222 patients, 115 women and 107 men with a mean age of 58.4 years who received 261 implants, were evaluated in this retrospective study. Results reported no confounding systemic illness, and 18% of the patients were smokers. The range of the follow-up of the evaluated patients was between 6 and 64 months with a mean of 35 months. The number of patients and period of follow-up are demonstrated in Fig 1. The mean baseline subsinus residual bone height was 5.4 mm (range: 2 to 10 mm). The majority of patients (75%) had a baseline height ≥ 4 mm (Fig 2). Though not qualified as an outcome measure of this study, all sinuses were successfully augmented, with as much as 7-mm vertical augmentation (Figs 3 and 4). Representative clinical cases with follow-up radiographs are depicted in Figs 5 and 6. The implant widths ranged from 3.7 to 6 mm, and lengths ranged from 10 to 13 mm, depending on the system. Implants were inserted simultaneously with sinus augmentation in the majority of cases (94%). No sinus membrane perforations were observed. A total

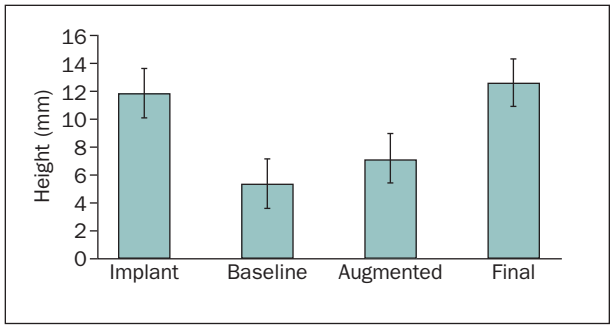

Fig 3 A significant augmentation of 7 mm ($P < .05$) was observed following the osseous densification technique, allowing for the placement of implants at a median height of 11.5 mm.

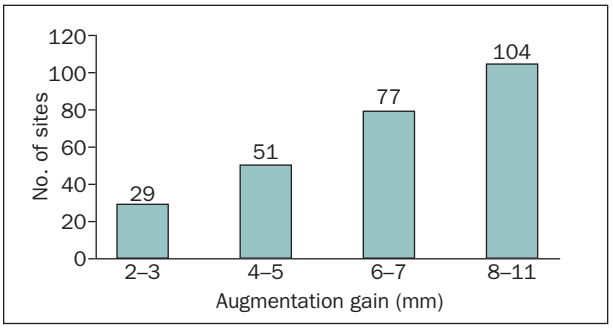

Fig 4 Number of sites according to augmentation gain.

of eight implants failed: five at osseointegration evaluation 3 months postplacement, and three at 6 months postplacement. No late failures were observed in cases over 6 months and up to 64 months of follow-up, resulting in a survival rate of 97% (Figs 7 and 8).

DISCUSSION

Sinus membrane elevation and augmentation procedures are widely reported in the literature with predictability.[23,24] Among these, the indirect crestal approach described by Summers[25] has been widely used, due to its lower morbidity and its invasiveness, with simultaneous implant placement as a predictable procedure with implant survival rates reported to range from 95.2% to 100% during 6 to 18 months follow-up,[23] and with a survival rate of 90.4% with long-term follow-up (up to 12 years).[26] Huynh-Ba et al has observed no difference in the implant survival between direct or indirect sinus elevation procedures.[27]

The residual bone height was defined as a predictor of the implant survival rate using the Summers osteotome technique.[28–30] Toffler reported a 73.3% implant survival in a ridge crestal height of ≤ 4 mm.[28] Rosen et al reported similar results with a global implant survival rate of 85.7% in the presence of residual crestal height of ≤ 4 mm.[29] Del Fabbro and coworkers reported, in a systematic review, a similar reduced implant survival rate at sites with < 5 mm.[30] Therefore, the literature widely supports the indirect subcrestal sinus elevation technique for use in sites with a minimum of 6 mm residual crestal height.[23,26]

In this retrospective study, a simplified, minimally invasive transcrestal sinus augmentation approach utilizing the osseous densification method was performed to simultaneously augment the sinus and prepare the osteotomy, by compacting autogenous bone tissue along its walls and apex.[19] This was achieved exclusively by the unique novel design of the densifying burs. This method enhances bone plasticity by introducing the densifying bur into the osteotomy in a modulating "bouncing" motion, in and out of the osteotomy. Therefore, when coupled with copious irrigation, it induces a hydrodynamic compression wave ahead of the point of contact. The irrigating fluid that is forced into the osteotomy facilitates the autografting of bone particles, which are derived from the osteotomy walls to be re-grafted back as compacted autograft into both the lateral and apical directions.[19]

The present retrospective study demonstrated that osseous densification as a transcrestal sinus elevation approach successfully augments sinuses with various residual bone height as low as 2 mm and ridge width ≥ 4 mm. Eight implants failed in five patients; five implants in three patients failed at the 3-month evaluation, and three implants in two patients failed at 6 months postplacement. Three out of the five patients with failed implants were smokers. Ninety-seven percent of the implants placed and followed over 5 years have survived and were adequately restored. At a residual bone height of 2 to 5 mm, the osseous densification method is comparable to the gain resulting following augmentation by the lateral window approach, yet with the added benefit of reduced invasiveness. At sites presenting with advanced ridge atrophy (residual height < 5 mm), bone substitute material was effectively propelled into the sinus further elevating the membrane, with a demonstrated low risk of perforation.

The osseous densification technique has been introduced and validated by biomechanical and preclinical histologic animal studies.[19,20–22] Huwais and Meyer demonstrated that osseous densification increases the bone mineral density around the periphery of the osteotomy and produces a compaction autografted bone along the entire depth of the osteotomy, particularly at the apical portion. Furthermore, due to the spring-back effect created by the elastic strain recovery of the compacted bone, a reverse compression of bone tissue

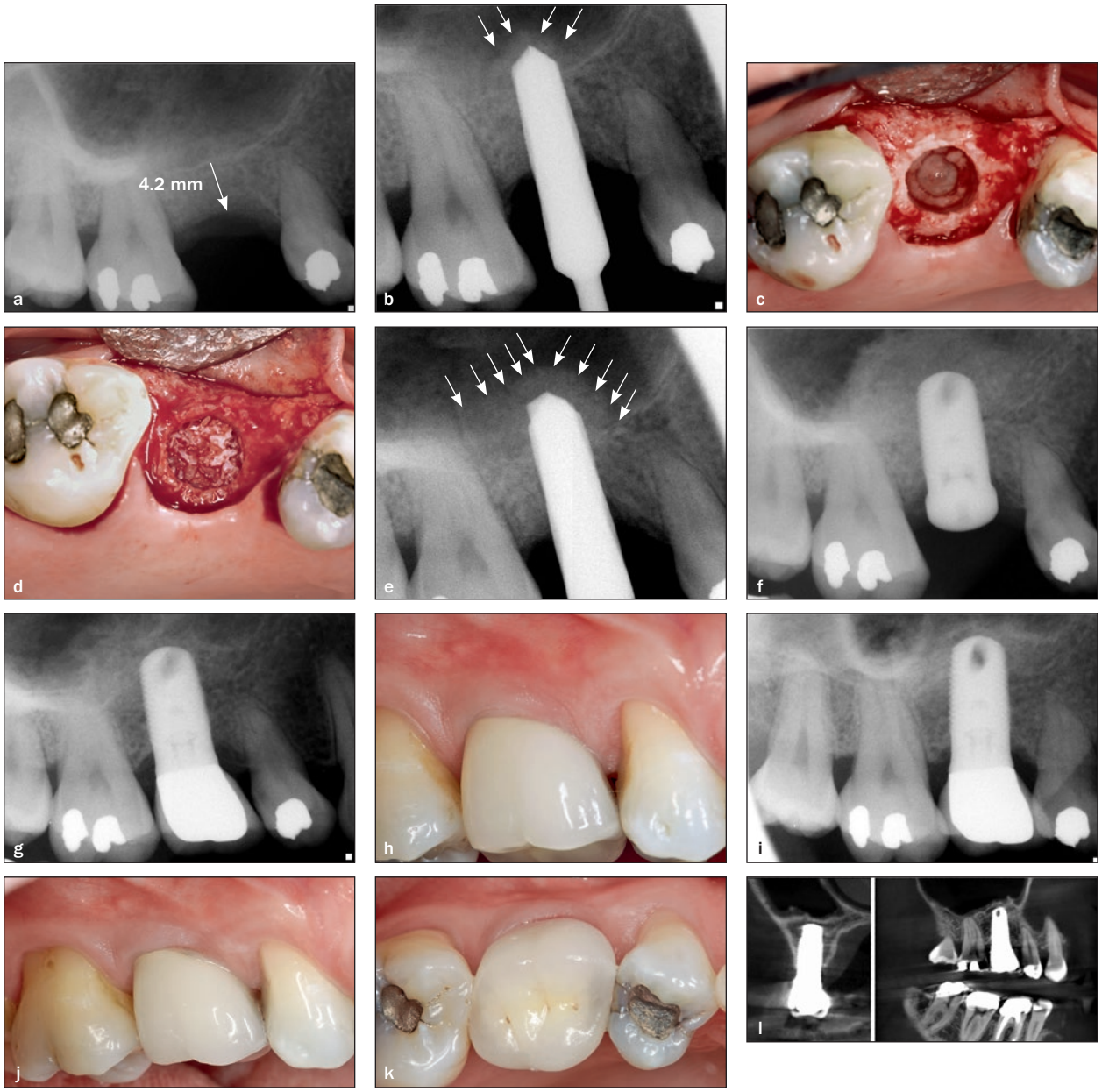

Fig 5 Representative clinical case with 5-year clinical and radiographic follow-up. *(a)* Initial radiograph with 4 mm of residual alveolar bone height. *(b)* Radiograph of densifying bur (3.0) entering the sinus cavity and facilitating autogenous bone grafting into the sinus and elevating the membrane up to 3 mm. *(c)* Occlusal view of the osteotomy created by densifying bur (4.0 mm) expanding the osteotomy and depositing autograft up to 3 mm into the sinus. *(d)* Occlusal view of the final osteotomy created, and filled with particulate allograft. *(e)* Radiograph of densifying bur (5.0) used in counterclockwise direction at 100 to 200 rpm propelling allograft into the sinus and elevating the membrane beyond the initial 3 mm. *(f)* Radiograph of the implant placed at the time of surgery. *(g)* Radiograph of the implant 3 years postplacement. *(h)* Clinical view of the implant 3 years postplacement. *(i)* Radiograph of the implant 5 years postplacement. *(j and k)* Buccal and occlusal clinical views of the implant 5 years postplacement. *(l)* CBCT cross-sectional and sagittal views of implant 5 years postplacement. The arrows depict the additional deposited allograft that had been propelled by the densifying bur lifting the membrane further.

against the implant body is created and consequently enhances the implant primary stability.[19] Histologically, the compacted autografted bone mechanically interlocks with the implant, resulting in a greater volume of woven bone and improved BIC.[20,21,22] A greater amount of autograft, derived as bone chips from the osteotomy preparation, acts as nucleating bridging surfaces for new bone formation, akin to autogenous bone graft that promotes bone formation around implants.[20,21]

The osseous densification as a transcrestal sinus augmentation technique presented here provided three distinct advantages. The first advantage is obviating the disadvantages of the lateral window approach, and the adequate minimal residual crestal

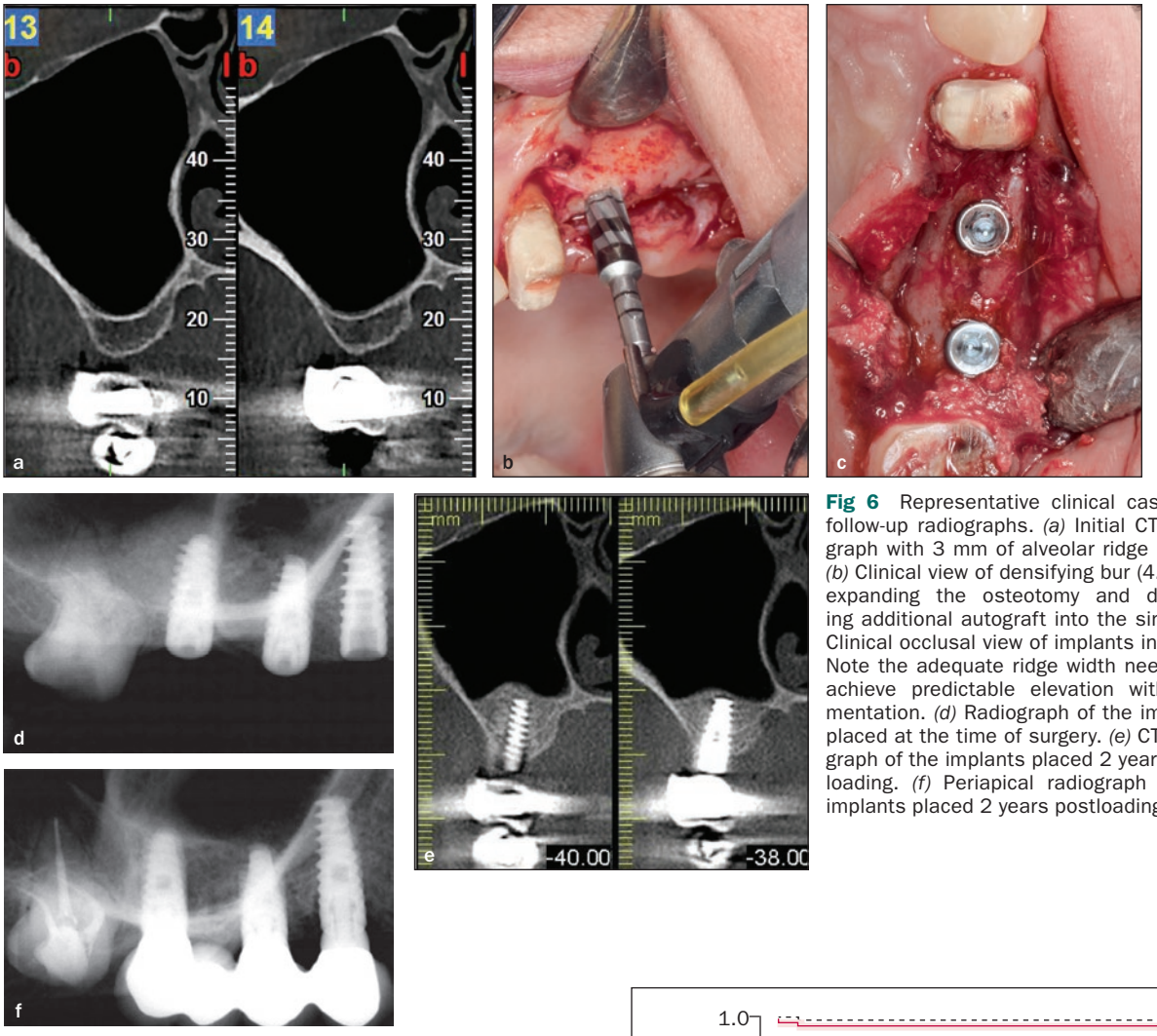

Fig 6 Representative clinical case with follow-up radiographs. *(a)* Initial CT radiograph with 3 mm of alveolar ridge height. *(b)* Clinical view of densifying bur (4.0 mm) expanding the osteotomy and depositing additional autograft into the sinus. *(c)* Clinical occlusal view of implants in place. Note the adequate ridge width needed to achieve predictable elevation with augmentation. *(d)* Radiograph of the implants placed at the time of surgery. *(e)* CT radiograph of the implants placed 2 years postloading. *(f)* Periapical radiograph of the implants placed 2 years postloading.

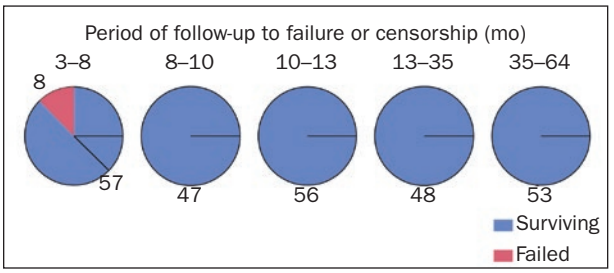

Fig 7 All failures occurred within the first 6 months following placement in this medium-term study (maximum follow-up time: 64 months).

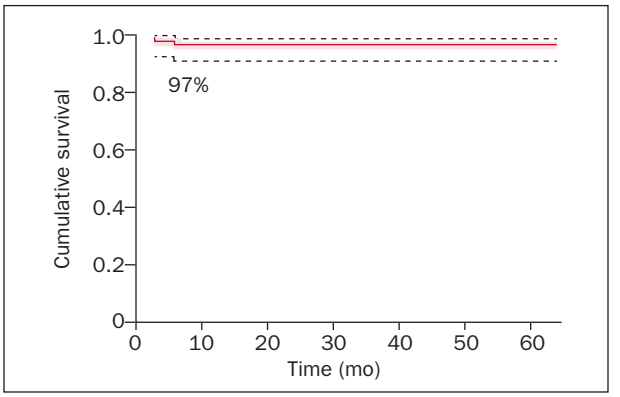

Fig 8 A 97% survival rate was observed during the follow-up period (95% confidence interval is depicted with a dotted line).

height needed for the predictable transcrestal Summers technique. Second, by compacting bone as an autograft into the osteotomy walls, the implant's primary stability is enhanced.[19,20,22] Third, the sinus is effectively augmented with low risk of membrane perforation. Additionally, it was generally observed that the procedure chairside time was reduced, as was treatment duration, trauma, and morbidity, with improved patient comfort.

By comparison, the clinician requires certain surgical acumen and needs to overcome a learning curve of this new technique. The extensive experience of the clinicians performing the technique likely added to the favorable results presented here.

CONCLUSIONS

This 5-year follow-up retrospective study has demonstrated that osseous densification as an instrumentation technique that enhances bone density through compaction grafting is an effective method that facilitates crestal sinus augmentation with a 97% implant survival rate in a wide range of residual crestal heights.

Controlled clinical studies are required to further assess the efficacy of this technique and evaluate its performance and patient-related outcome.

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