Fourteen maxillary sinuses were reconstructed in 12 patients who presented with a previous sinus elevation failure. In all cases, large perforations of the sinus membrane occurred during removal of the failed graft from the sinus; the perforations were sealed with fibrin glue, then the site was grafted using homologous fibrin glue (HFG) mixed with a calcium phosphate scaffold (CPS). Histologic analyses revealed that the CPS-HFG graft was followed by an ossification process, with the formation of spongy bone similar to that of the normal skeleton. Twenty-four endosseous implants were successfully placed into the newly regenerated bone. All implants were successfully restored with ceramic crowns 6 months after placement. At the 3-year follow-up, no infections or implant failures were reported. The described technique offers several clinical advantages, as the removal of the failed graft, the sinus perforation repair, and the sinus elevation can be achieved in the same surgery without needing to postpone the regenerative surgery phase.

Implant rehabilitation of the posterior edentulous maxilla could be a challenging procedure, especially when residual bone height is reduced due to bone atrophy. Sufficient bone volume and quality have been regarded as the major predictors in rehabilitation with osseointegrated implants. The first sinus augmentation technique was presented by Tatum in 1977, and the first publication was made by Boyne and James in 1980. To date, two main sinus floor elevation techniques for implant placement are in use: a two-stage technique with a lateral window approach followed by implant placement during second-stage surgery, and a single-stage technique using either a transalveolar or lateral approach.

Although the sinus elevation procedure is relatively safe, some potential complications could occur. The most prevalent intraoperative complication is perforation of the sinus membrane, which can lead to graft infection, bone resorption, and early failure. Nose bleeding can occur after sinus membrane perforation and following the detachment of the membrane from the widely vascularized sinus walls. Postsurgical infection, as well as the surgical procedure itself, may often cause swelling and hematoma, which can have a severe impact on the patient’s quality of life. Postoperative

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infection and sinusitis after sinus augmentation have been explained by obliteration of the ostium owing to hematoma, swelling, or graft dislocation; impaired sinus production; and impaired ciliary function. If medical therapy alone fails to control the sinus infection, the guidelines for the treatment of transient rhinosinusitis suggest a transnasal endoscopy to establish maxillary drains for sinus irrigation. If this fails to achieve complete recovery within 3 weeks (or in the presence of exposed and sequestered endosinusal grafts), surgical curettage by means of functional endoscopic sinus surgery should be taken into consideration. In cases with surgical reentry after a failed sinus elevation, a successful procedure requires the removal of the failed graft, infection control, and accurate antrum cleaning, because eliminating the source of infection will avoid recurrences of rhinosinusitis and future grafting failures. The aim of the present study is to present a minimally invasive technique to perform the sinus elevation procedure in previously failed cases.

Materials and Methods

Patients

Fourteen maxillary sinuses were reconstructed in 12 patients (6 women, 6 men) aged between 45 and 72 years (median: 59.7 years). All patients were partially edentulous in the posterior maxilla and presented with a history of a previous major sinus elevation failure. All patients were treated at a private clinic in Rome, Italy. All surgical procedures were performed by two of the present authors (E.M. and A.M.M.). Local institutional review board approval was obtained for this study, and the study followed the Declaration of Helsinki guidelines. Patients were informed about the study protocol, and their signed and informed consent was collected. The patients who were enrolled in the study required bone regeneration to achieve the necessary bone volume for future implant placement in the posterior maxilla. The preoperative radiographic assessment included careful evaluation of any pathologic conditions of the sinus using orthopantomography and computed tomography. The patients were required to have good oral hygiene before treatment. The exclusion criteria were as follows: smoking habit, alcohol consumption, uncontrolled systemic conditions, uncontrolled periodontal disease, and current acute sinusitis.

Sinus Elevation Procedure

The osteotomy and sinus membrane elevation were performed using an ultrasonic device with dedicated inserts (Piezosurgery, Mectron Medical). Removal of the failed graft from the sinus (Fig 1a) was performed by means of manual instruments (excavators and spoons) and ultrasonic dedicated inserts for bone debridement (OT5, OT4, OP1, OP3; Mectron Medical). All necrotic and inflamed portions of both hard and soft tissues were carefully removed from the sinus cavity. The surgical field was then washed and cooled with a sterile saline solution. During the debridement, several lavages were performed with 10% hydrogen peroxide (H₂O₂). H₂O₂ provides a chemical effect as well as a mechanical cleansing effect, and it has broad-spectrum efficacy against viruses, bacteria, yeasts, and bacterial spores. The effervescent effect of H₂O₂ assisted in the removal of smaller portions of infiltrated inflammatory tissue. After each lavage with H₂O₂, the site was rewashed with saline solution so that the bone and soft tissue were not overly exposed to the caustic action of the H₂O₂. Infection control and accurate cleaning of the antrum were achieved in order to eliminate the source of infection, avoiding recurrences of rhinosinusitis and future grafting failure. A step-by-step procedure for preparation of the bone recipient site was followed according to a previously published protocol by the present authors. Large perforations (> 10 mm) of the sinus mucosal lining were encountered in all selected cases during removal of the failed graft material (Fig 1b), and attempts were made to repair them using homologous fibrin glue (HFG; Tisseel Duploject Kit, Baxter Healthcare).

The Tisseel Duploject needle was inserted 2 to 3 cm through the membrane laceration, then the antrum was filled with HFG (Fig 1c). Typically, 15 to 20 mL of thrombin-activated Tisseel is necessary to fill
the lower portion of the maxillary antrum. After 2 to 3 minutes, the HFG finished setting and had become a tight clot attached to the lacerated membrane (Fig 1d). The newly repaired sinus membrane was elevated to create space for the sinus graft. Bone regeneration was performed using porous calcium phosphate scaffold (CPS) granules with a mean pore size of approximately 200 µm (Pro-Osteon 200, Zimmer Biomet). Before placement, the CPS granules were rapidly molded with the HFG (Fig 1e).

Postoperative medications included 1 g Augmentin twice daily for 7 days (patients allergic to Augmentin received 1 g levofloxacin once daily for 7 days) and 550 mg naproxen twice daily for 3 days, unless medically contraindicated. Patients were instructed not to blow their noses for 14 days postoperatively.

Radiology and Histology

Radiographic analysis was performed before graft placement. After graft placement, both a physical examination and radiographic analysis (Giano, NewTom) were performed (Figs 2a and 2b). Second-stage surgery was performed after 7 to 9 months of healing, and 24 endosseous implants were placed at the first and second molar positions (Fig 2c): 14 NobelActive implants (diameter: 4.3 mm, length: 10 to 13 mm; Nobel Biocare) and 10 Brånemark System MkIII implants (diameter: 4.0 mm, length: 10 to 13 mm; Nobel Biocare).

During each of these procedures, a cylinder of the regenerated bone tissue was harvested using a 3.2-mm trephine bur, and the sample was prepared for histologic examination (Fig 2d). Trepanation of the graft removed a small

Fig 1  Clinical case example 1. (a) Removal of the failed, infected graft using a hand instrument. (b) A large sinus membrane perforation (> 10 mm) was seen during removal of the failed graft. (c) The needle of a Tisseel Duploject syringe (20 mL; Baxter Healthcare) was inserted about 2 to 3 cm through the membrane laceration, then the antrum was filled with the fibrin glue. (d) After 2 to 3 minutes, the fibrin glue finished setting and became a tight, attached clot to the lacerated membrane. (e) After elevating the repaired membrane, the sinus cavity was partially filled using a mixture of calcium phosphate scaffold granules and fibrin glue.
osseous cylindrical core, leaving an extremely small cavity with a sharp outline (Fig 2e). The specimens were fixed with 4% formalin for 24 hours, washed with distilled water, decalcified with formic acid for 24 hours, washed again in distilled water, and embedded in paraffin. The sections were stained with hematoxylin-eosin, and a histologic examination was conducted by an anatomo-pathologist.

Results

Fourteen maxillary sinuses were reconstructed in 12 patients who presented with previous sinus elevation failure. With the

Fig 2 Clinical case example 1. (a) A preoperative panoramic radiograph shows the failed grafting of the maxillary left sinus. (b) A CBCT scan (Giano, NewTom) of the maxilla shows the failed graft and the chronic inflammation of the sinus membrane. (c) The first of two implants was inserted into the regenerated bone. (d) A trephine bur was used to collect bony biopsy samples of the regenerated bone. (e) A bone biopsy sample was collected 9 months after sinus elevation.
exception of 2 patients who experienced pain and swelling after 3 days of uneventful healing, the patients’ postoperative quality of life was generally good. The most common complication was hematoma (30% of cases), and all disappeared after 1 week. No acute sinusitis was encountered after surgery.

At the second-stage surgery, the grafted area had a hard consistency with a rather compact appearance that was resistant to trephine penetration.

The histologic appearance of the cores was uniform for all specimens except for the number and thickness of the osseous trabeculae, which were consistent with the presence of spongy bone (Fig 3a). These trabeculae ranged from thin to thick, with wide to very narrow intertrabecular spaces, respectively (Fig 3b). These spaces were occupied by a few fibrils and mononuclear cells and no visible inflammatory cells; moreover, osteoblast- and osteoclast-like cells were present.

All implants were successfully restored with ceramic crowns 6 months after placement (Fig 4a). All patients were treated for 3 years, and no infection or implant failures were recorded during the follow-up period (Fig 4b).

Discussion

The posterior maxillary region is difficult to rehabilitate with implants due to two main limiting factors: maxillary sinus pneumatization and low bone density (Fig 5a).2,8,9 Sinus

Fig 3 Clinical case example 1. (a) A low-magnification histologic cross-section of the specimen shows the relative proportion of bone trabeculae and fibrillar connective tissue. Note that the empty spaces correspond to decalcified hydroxyapatite granules. (b) Reconstituted bone tissue at ×100 magnification shows primary bone trabeculae that outline spaces of various sizes, each containing delicate connective tissue. Note the numerous osteocytes and the demineralized hydroxyapatite (H). Hematoxylin and eosin (h&e) stain.

Fig 4 Clinical case example 1. (a) The patient received the final fixed two-unit prosthesis. (b) A pantomograph taken at the 3-year follow-up shows the long-term success of the procedure.
Fig 5  Clinical case example 2. (a) A preoperative computerized tomography scan shows the marked bone atrophy of the maxilla and the failed grafting of both the left and right sinus. (b) The needle of a Tisseel Duploject syringe (20 mL; Baxter Healthcare) was inserted about 2 to 3 cm through the membrane laceration, then the antrum was filled with the fibrin glue. (c) After 2 to 3 minutes, the fibrin glue finished setting and became a tight, attached clot to the lacerated membrane. (d) After elevating the repaired membrane, the sinus cavity was partially filled using a mixture of calcium phosphate scaffold granules and fibrin glue. (e) At the second-stage surgery, two implants were placed in the regenerated bone. (f) The patient received the final fixed 12-unit prosthesis. (g) A pantomograph taken at the 3-year follow-up shows the long-term success of the procedure.
membrane perforation can present during different steps of the procedure: during the osteotomy access, after bony window removal or reflection, during the membrane elevation, or during sinus grafting (Fig 5b).10–12 A few studies have reported techniques for repairing large perforations, as this complication can be a real challenge for the surgeon and push the latter to abort and postpone the grafting procedure. Pikos proposed the use of a slow-resorbing type I collagen membrane for repairing large and complete sinus membrane perforations.13 Despite the semirigid structure and biocompatibility of the collagen membrane, the need for external fixation requires the surgeon to have more experience and more time. Kim et al reported the use of a pedicled buccal fat pad for the membrane closure; however, the procedure had several postoperative complications, including partial necrosis, shrinkage, fibrosis, distortion, and retraction of the wounds.14 Clementini et al sutured the large perforations to the bone directly lateral to the osteotomy lines with a resorbable suture.15 The literature indicates that membrane perforations larger than 10 mm render maxillary sinus elevation surgery unfeasible.16 According to the present authors’ previously published technique for bone regeneration before grafting, preparation of the recipient site is fundamental and allows access to the underlying healthy bone structure, which is critical for graft ossification.7

When a second maxillary sinus elevation is performed, residues of necrotic tissue, infected and/or non-integrated grafting material, fibrotic tissue, and cicatricial adhesions of the sinus membrane are often found. Removing these unhealthy tissues permits in situ plasmatic imbition for the first 24 to 48 hours, resulting in vascular ingrowth and cellular nutrition. There are anatomical variations and pathologic conditions, such as inflammatory-infective processes or sinus manifestations of systemic diseases, that represent contraindications and should be treated prior to maxillary sinus elevation.5,6 Complications can be easier managed if promptly diagnosed. Postoperative infections are relatively uncommon, with infection rates reported between 2% and 5.6%, with no distinction between sinus graft infection and true sinus infections.17 Most frequently, the infection is an infected sinus graft; according to Urban et al, patients who are promptly diagnosed can be successfully treated by removing the infected graft and cleansing the remaining graft.18 It should be considered that the graft is located below the elevated sinus membrane, hence the term subantral augmentation. True sinus infections are less common but may have more widespread consequences, such as a pansinusitis, which can occur as a result of the interconnectivity of the sinus network.19,20

Several advantages have been reported when using HFG to repair the sinus membrane perforation.21 First, the elasticity of the fibrin clot, as well as its tight adhesion to the sinus membrane, may allow a safer and less traumatic management of the membrane itself during the detachment phase. Then, the strong clot adhesion can reinforce the previously perforated sinus membrane and permit an easier membrane detachment due to the hydraulic pressure produced by the HFG clot. After the elevation procedure is completed, the HFG remains attached to the sinus membrane, further protecting the membrane itself during the filling of the cavity (Fig 5c). In the present study, HFG adhesive properties were used when preparing the bone graft by mixing the HFG liquid with the particulate bone graft according to the authors’ previously published protocol.7 With this approach, neither membranes nor fixation screws are needed to stabilize the graft, as the mixture of HFG-CPS complex hardens in situ in 2 to 3 minutes and perfectly adheres to the recipient site. This is because the CPS granules were amalgamated with the HFG, preventing their escape into the sinus in case of accidental perforation of the repaired membrane. In addition, HFG works as a space-maker among granules, accelerating the new fibrin formation, vascular ingrowth, and osteogenic cell migration into the graft and contemporarily avoiding excessive compression of bone graft material during placement. Furthermore, the mixture of HFG-CPS allows for a smoother graft surface and could reduce the risk of new perforations caused by the sharpness of the granules themselves (Fig 5d).
Biologic interactions of HFG with soft and hard tissues must also be considered to support its use in the sinus elevation procedure. First, HFG stimulates the release of, and entraps, a large number of cytokines and other elements involved in promoting tissue regeneration, such as fibrinogen, fibronectin, platelet-derived growth factor, transforming growth factor-beta, vascular endothelial growth factors, and others. Then, the concentrate has a marked anti-inflammatory action by the suppression of proinflammatory chemokines, and it also has an antimicrobial effect. The hemostatic properties of fibrin glue also could be involved in determining the absence of nose bleeding in patients, which may be caused by the lesion of posterior lateral nasal arteries perforating the nasal wall laterally, often occurring during membrane detachment from the mesial/nasal wall. These characteristics, together high biocompatibility, contributed to the observed reduction of postsurgical discomfort, improving patients’ quality of life (Figs 5e to 5g).

Conclusions

The aim of this pilot study was to present a novel technique for the management of the sinus elevation failures using HFG and CPS. Despite the limitations of this study concerning the sample size and study design, the use of fibrin glue may be helpful in reducing complications following sinus elevation. Furthermore, the accurate removal of the previous failed graft and inflamed tissues from the maxillary sinus enhances the healing phase and stimulates the new ossification process.

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