Crestal sinus lift approach by injectable porcine collagenated bone with and without immediate implant placement

Gary Itkin[1]

Introduction

The maxillary double direction reabsorption, due to centripetal loss of the alveolar bone and sinus pneumatization, together with thin cortex and low trabecular density, poses a challenge for oral rehabilitation with dental implants.[1,2] This resorptive process is dependent on the number of lost teeth[3] and may lead to a remaining bone height of less than 1 mm.[4] A limited amount of alveolar bone available may result in a lack of primary stability and difficulty in achieving osteointegration. In this context, additional surgical procedures are mandatory to recover bone volume.[5-7]

Previously or simultaneously to implant placement, maxillary sinus elevations can be performed by lateral osteotomy or maxillary sinus floor elevation with osteotomes.[8,9] Depending on the risks of morbidity, time and costs of these types of treatments, other options, such as the use of short implants and/or zygomatic implants can be considered.[10] Maxillary sinus floor elevation by lateral window technique with bone graft is the preferred treatment when the available bone is <5 mm.[5,11-14] Additionally, when bone height varies between 3 and 5 mm, simultaneous placement of the implant is an option.[7,11] The choice of the treatment should be primarily based on anatomy, sinus health, desired bone augmentation, bone dimensions, general health status, smoking, oral hygiene, and preferences.[5,13,15]

The ideal bone graft should be biocompatible, osteoinductive, osteoconductive, completely replaced by new bone, capable of maintaining stable grafted volume, with good mechanical properties, derivative from a patient-friendly source, and it should also possess good handling characteristics.[10,13,16-19]

Despite being regarded as the gold standard, autologous bone[20-27] presents some limitations such as increased morbidity and limited availability.[21] In this context, several experimental studies on animals and humans have shown that porcine xenografts with 10% collagen exhibit excellent properties in terms of handling, biocompatibility and osteoconductivity, high absorption rate of the xenograft granules and major remodelling by autologous bone after 6 months.[28-31]

A limited number of randomised studies have reported the properties of xenografts based on collagenated cortico-cancellous porcine bone,[32] porcine bone-derived biomaterial[33] and particulate bone substitute of equine origin.[34] The literature shows that substitutes and autologous bone exhibit comparable clinical performance, providing for the successful use of bone substitutes in bone regenerative procedures. Furthermore, several studies demonstrated excellent xenograft biocompatibility with newly formed bone in maxillary sinus augmentation procedures and no evidence of inflammatory response to the graft,[32-34] but the physical shape of the grafting material also plays an important role, There is evidence in literature, that even after lateral or

[1] Dr Gary Itkin, DDS, MOI
Postgraduate programme, Endodontics- Specialisation, Riga Stradins University, Latvia
Diploma, Master of Oral Implantology, Rome Unicamillus University, Italy.
Private Practice, Riga, Latvia

crestal sinus lift approach, there is a high risk of Schneiderian membrane perforation due to sharp edges of the graft and a high pressure in the sinus. The shape of the graft should therefore be taken into consideration.

Schneiderian membrane perforation represents the most frequently described intra- operative complication during maxillary sinus floor elevation. The incidence of this adverse event has been reported to vary between 11% and 20% for the lateral technique and from 0% to 20% for the trans crestal approach.[35-37] Proper management of perforation is mandatory to complete membrane elevation and graft placement. Many approaches have been proposed in literature to overcome this problem, including suturing techniques, or the use of resorbable membranes, demineralized lamellar bone, biological glues, and buccal fat pad flap.[38-42] Nevertheless, particulate grafting material displacement into the sinus cavity remains a possible adverse event in case of Schneiderian membrane perforation, even after attempting to seal it during surgery.[43]

Both autologous bone and various bone substitutes have been studied in the last decades as grafting materials for maxillary sinus floor elevation. A recent meta-analysis including more than 130 studies with histomorphometric data showed that autologous bone resulted in the highest amount of newly formed bone but its use is associated to significant drawbacks (high resorption rate, limited availability, and patient morbidity).[44] Bone substitutes (allografts, xenografts, and alloplastic materials) appear to be good alternatives to autologous bone both in terms of osteoconductive properties and long-term survival rate.

Aim of the Study

This clinical trial aimed to analyse radiological changes in vertical dimensions of maxillary sinus after hydraulic injection of micronized heterologous xenograft simultaneously with and without implant placement.

Materials and Methods

Study Design

Twelve patients were included in this study. Eight women and four men. The youngest patient was 38, the oldest 65 years old. The average age of the patients was 50 years.

In total 15 closed sinus lifts were performed were performed to restore upper molar and premolar areas of maxillary sinus.

Before treatment computer tomography of the maxilla was performed with Gendex Kavo Kerr 3D CT or Kodak 3D CT. The height of the remaining bone height and width was measured in the centre of planned implant surgery in all the patients. Inclusion criteria comprised no inflammation within the sinus on the side of the implant surgery.

Exclusion criteria: Radiation therapy of the head and neck; immunosuppressed or immunocompromised; treated with or under intravenous treatment of bisphosphonates; untreated periodontitis, poor oral hygiene and low motivation; uncontrolled diabetes; pregnant or breast feeding; psychiatric problems or sinusitis.

Cases that had perforation of the Schneiderian membrane during surgery were excluded from the research. OsteoBiol® heterologous porcine xenograft Gel 40® was chosen because of its unique properties.

According to manufacturer the Gel 40 is made of a collagen matrix (type I and III) obtained using an exclusive Tecnoss® process, loaded for 60% of its volume with micronized heterologous bone (granulometry up to 300 µm).

The collagen component of the Gel 40 facilitates the formation of primary blood clot and the subsequent invasion of repairing and regenerative cells; whereas the cortico-cancellous component provides the necessary scaffold function for bone deposition. The collagen gel component contained in Gel 40 is rapidly and totally resorbed. It is also endowed with anti-inflammatory, eutrophic and cicatrizing properties. This lipophilia is due mainly to a percentage of polyunsaturated fatty acids of the oleic-linoleic series (to which Omega 3 also belongs) directly derived from the raw material. Such components possess a valuable antioxidant action on the free radicals and therefore aid tissue regeneration.

The distinctive characteristics of viscosity and density of Gel 40 facilitate the handling of the product providing a glue-like support.[45-48]

For an implant, the Transmucosal implants Prama RF with regular transmucosal neck 2,8mm (Sweden & Martina) with tapered morphology particularly suitable for poorly mineralized bone and able to obtain primary stability. Given the rounded apex, it is also optimal in cases of maxillary sinus floor elevation.[49-50]

Surgical Procedure

All the Surgeries were performed by one surgeon with the same techniques, materials and instruments.

- Stage one

The Surgical preparation included 1g of Antibiotic (Augmentin), and NSAID 100mg of Aponil (Nimesulidum) 30 minutes before the surgery, and 1 minute preceding the beginning of the sinus-lift procedure mouthwash with chlorhexidine 0,2%.

Fig 1

Fig 2

Infiltration (i.e posterior and middle superior alveolar nerve , greater palatine nerve) anesthesia with 4 % Ubistesin forte was used.

After the mucoperiosteal flap was detached normal bone tissue was exposed. The preparation of the implant site and Schneiderian membrane elevation was performed according to the manual of Sinus Flow Kit®.

With a spot drill the optimal place was marked for intraosseous implantation. Then, with a guide drill a preparation was made approximately 0,5 mm shallower than the height of the alveolar ridge within this area as calculated on CBCT. Stopper drills were used to ensure accurate control of depth during drilling. After completion of the preparation, a special hollow implant analogue of 3,5mm in diameter of the same length was screwed in. The sinus was filled with Gel 40® with a Sinus Flow® appliance through this hollow analogue.(Figs 1,2)

OsteoBiol Gel 40® porcine bone xenograft was used for all cases.

Gel 40® is made of collagen matrix (type I and III) obtained using an exclusive Tecnoss® process, loaded for 60% of its volume with micronized heterologous bone (granulometry up to 300 mM).

This property allows the material to be injected into the sinus through the implant analogue with a special syringe.

The injection of the material was performed very slowly to minimize the risk of membrane perforation. (Fig 3)

Where it was possible, the placement of Prama implant (Sweden & Martina) 3.8, 4.25 or 5.0mm in diameter was used depending on the width of the ridge.

Postoperative antibiotics and anti-inflammatory medication were prescribed (Amoxicillin 625mg every 12h for seven days and 100mg Aponil (NSAID) every 12h for 5 days.

Digital radiographs were done after the surgery to see the quantity and direction of injected material and to observe the quality of the surgery in total.

Chlorhexidine mouthwash was prescribed for 10 days.

- Stage two

6 months after the Surgery a follow up CBCT was performed to evaluate and measure the newly formed bone. In cases with no implant placement at the first stage an implant was placed (Prama RF, Sweden & Martina).

Results

The crestal sinus lift was performed in 13 patients, and 15 sites were augmented. Simultaneously with sinus lift,13 Prama RF Implants were installed (8 Females and 4 males). The youngest patient was 38 and the oldest 65 years old. The average age was 46 years. In one patient the Schneiderian membrane perforated, so this patient was excluded from the study. All other patients had a good healing result, with no complications. No one reported any adverse incidents. All the measurements (Fig 4) were performed, using Kodak or

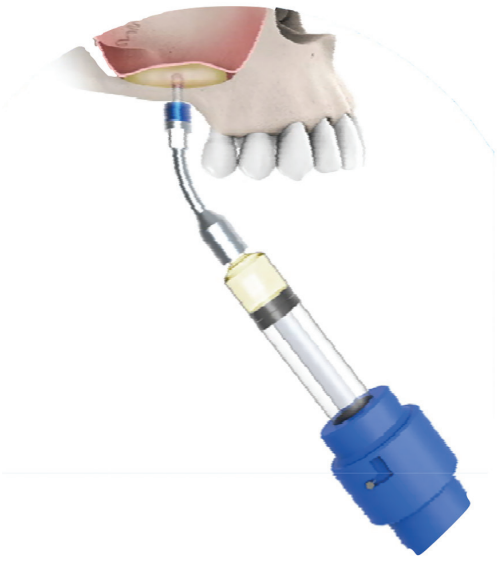

Fig 3

Table 1

Name of patient	Age	Sex	Tooth nr	Initial bone height (mm)	Final bone height (mm)	Gain of new bone
1	65	F	17	4,18	11,32	7,14
		F	27	4,57	9,14	4,57
2	52	M	16	3,37	9,53	6,16
3	52	F	14	4,9	8,49	3,59
		F	25	4,7	11,92	7,22
4	38	F	17	3,21	10,35	7,14
5	57	M	17	3,13	9,61	6,48
6	39	M	26	1,59	5,95	4,36
7	39	F	16	5,77	10,39	4,62
		F	17	3,41	9,88	6,47
8	58	F	26	4,1	11,32	7,22
9	43	F	26	6,57		
10	58	M	27	1,4	7,8	6,4
11	58	F	14	5,6	11,2	5,6
			15	3,8	9,7	5,9
12	47	F				

Average gain: 6,435 mm

Kavo WixWinx software. To improve accuracy, the distance from the adjacent tooth until the point of the centre of sinus lift was measured on both CT Scans. The vertical height of the bone was measured on the primary CT scan and the same procedure performed on the final CT scan, made 6 months after the primary examination. Everything was inserted into the data chart (Table 1), and the gain of new bone was measured. The minimum gain of new bone was 3,59mm and the maximum 7,22 mm. The average gain in vertical dimension was 6,435 mm.

Discussion

In the early 1970s, Tatum began to augment the posterior maxilla with autogenous rib bone to produce adequate vertical bone for implant support. He found that on-lay grafts below the existing alveolar crest would decrease the posterior intra-dental height significantly. In 1974, Tatum developed a modified Caldwell-Luc procedure for sinus grafting. The crest of maxilla was in-fractured to elevate the maxillary sinus membrane. Autogenous bone was then added in the area previously occupied by the inferior third of the sinus and dental implants were placed 6 months after the surgery.

The classical lateral sinus lift is a painful and uncomfortable treatment often resulting in postoperative pain. It also has a high risk of complications and this is why surgeons often choose the crestal approach to sinus floor elevation.

Modern dentistry aims to be minimally invasive. That is why there are many different biomaterials on the market, that can replace the autogenous bone grafting, thus minimizing a risk of complication of different donor sites and postoperative discomfort.

The different properties of biomaterials like xenografts, allografts, alloplastic materials composed of hydroxyapatites and other materials all have different resorption times.

The features of bone substitute are critical factors for the success of bone augmentation.[51] Gel 40 was chosen for this research due to its favourable properties as a bone grafting material. It is made of a collagen matrix (type I and III) obtained using an exclusive Tecnoss® process, loaded for 60% of its volume with micronized heterologous bone (granulometry up to 300 µm).

Thanks to its collagen component, Gel 40 facilitates the formation of the primary blood clot and the subsequent invasion of repairing and regenerative cells while the cortico-cancellous component provides the necessary scaffold

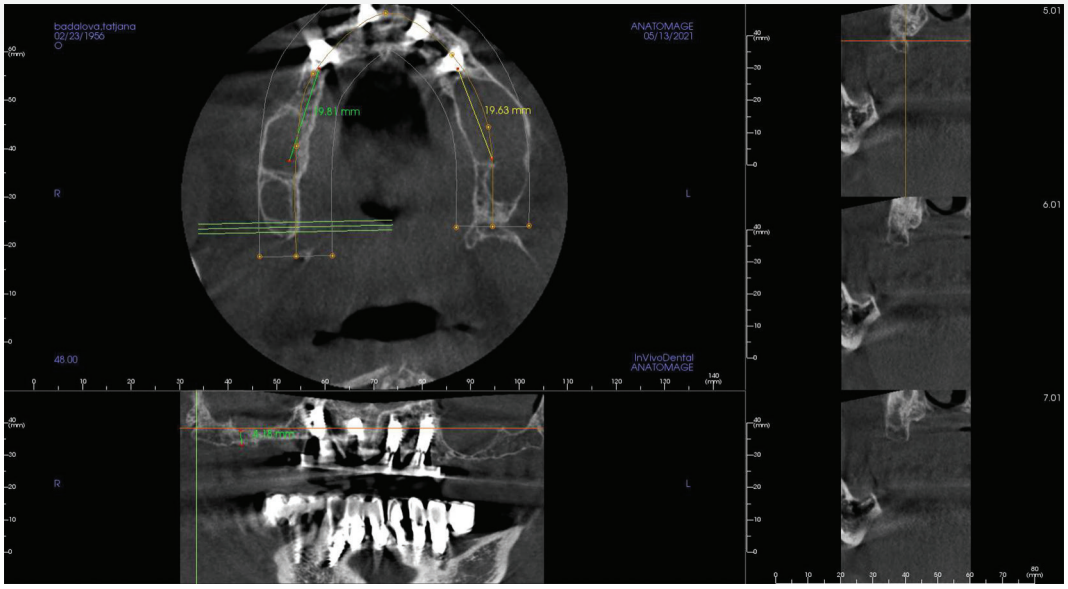

Fig 4

function. The collagen gel component contained in Gel 40 is rapidly and totally resorbed, thus does not leave any particles of the biomaterial in the maxillary sinus. It is also endowed with anti-inflammatory, eutrophic and cicatrizing properties. The lipophilia of the material is due mainly to a percentage of polyunsaturated fatty acids of the oleic-linoleic series (to which Omega 3 also belongs) directly derived from the raw material. Such components possess a valuable antioxidant action on the free radicals and therefore aid tissue regeneration. No additional antibiotic was used in the sinus.

The distinctive characteristics of viscosity and density of Gel 40 facilitate the handling of the product providing a glue-like material.

Postoperative CT scans showed no Gel 40 was left in the sinus, and there is no more than 1 mm gain of bone over the implant after a 6 months period. That means, that Gel 40 works as safe and effective material to safely lift the Schneiderian membrane and activate the osteo inductive and osteo conductive properties

On the control radiographs (Figs 5,6) immediately after the surgery, a large volume of Gel 40 can be seen in the sinus

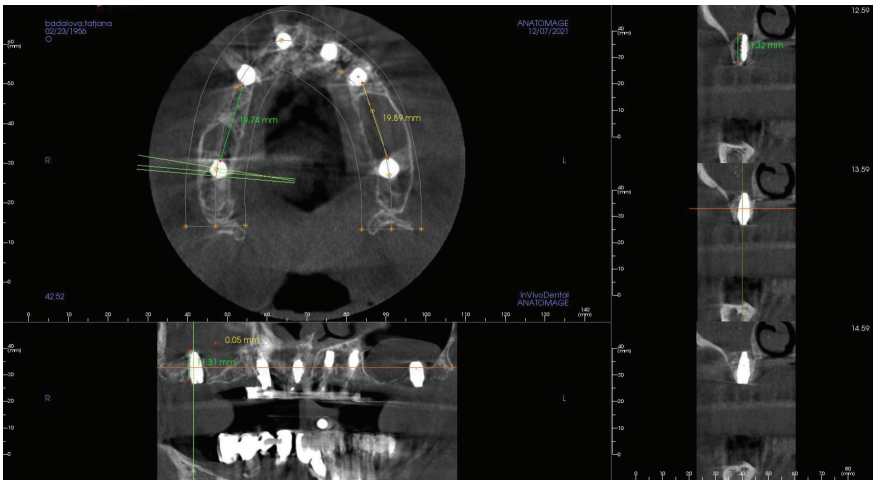

Fig 5

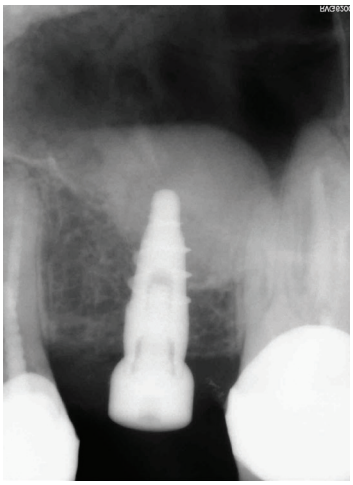

Fig 6

and after 6 months of healing there is a noticable shrinkage of the graft. According to Carl E. Misch[52] the crestal approach sinus lift with simultaneous implant placement should be performed when the residual bone height is at least 5 mm. This is to ensure implant primary stability. We were able to get a primary stability in 3,13 mm bone height.

The insertion of a Prama RF implant (Sweden & Martina) with a safe apex facilitated the support and stability of the Schneiderian membrane and helping to avoid shrinkage of the graft.

Conclusions

This research illustrates, that the use of xenograft, injected with sinus flow device facilitates a safe and effective way of lifting the Schneiderian membrane and facilitating space for new bone regeneration. There is almost no risk of membrane perforation as the material that was used is in a gel form. The slow hydraulic pressure helps to detach the membrane from the floor of the maxillary sinus. It was also clear that with only 3 mm of residual bone and correct dental implant geometry it is possible to achieve sinus floor elevation with simultaneous implant placement. The gain of average of 6,43 mm of new bone provides for the placement of an implant at least 6mm in length or longer.

There is no need of harvesting grafts from the patients. Doing the lateral window access sinus with more morbidity and higher risks of complications might be less necessary than we thought in the past. New biomaterials and less traumatic techniques create the possibility of treating more patients than before.

Disclosure:
The author declares that, while associated with Dentiks SIA, distributors of OsteoBiol and Sweden & Martina, the research work was performed without any commercial interest.

References

The full list of References 1-52 is available on request from: ursula@moderndentistrymedia.com

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