Graftless sinus floor augmentation with an internal-port implant: long-term experience

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Objective: The objective was to assess the outcome of graftless sinus floor augmentation associated with dental implant placement performed with an implant system that has an internal port and screw, combined with the osteotome technique. **Method and materials:** Between 2012 and 2018, 722 titanium-aluminum-vanadium implants (Ti-6Al-4V ELI, diameter 3.75/4.20 mm) were placed in 331 patients. Implants 11.5 mm in length were inserted in maxillae with bone level ≤ 5 mm, and 13.0-mm-long implants were inserted in maxillae with bone level of > 5 to 8 mm. In all cases, no graft materials or bone substitutes were used for the sinus elevation. Implant condition was assessed at three different centers and the follow-up period ranged from 6 months to 7 years. **Results:** In total, 412 11.5-mm-long implants and 310 13-mm-long implants were inserted. Implantation was successful in 689 implants (95.4%), based on cone beam computed tomography and clinical evaluation as well as the patients' experience, with no statistically significant difference between the 11.5-mm and 13.0-mm implants. The complication rates were comparable between cases with bone levels from 3 to 5 mm and the > 5- to 8-mm bone level cases. **Conclusions:** The port and screw implant system may allow maxillary sinus augmentation without grafting or bony substitute. This can simplify relatively major surgery, such as a sinus augmentation procedure, to a less invasive procedure and potentially reduce the risk of complications.
(Quintessence Int 2019;50:560–567; doi: 10.3290/j.qi.a42656)

Key words: dental implant, graft, implant maintenance, maxillary sinus floor elevation

The use of bone grafts in respect to the maxillary sinus has been well documented since the 1960s.[1,2] From the 1980s, when modern titanium implants were introduced to dental implantology, both bone grafts and bone graft substitutes have been used for maxillary sinus augmentation procedures.[3,4] This technique is well developed and still in use.[5,6] Starting in 1997, but mainly during the last decade, however, the concept has emerged that graftless or "graft-free" sinus augmentation is possible and as effective as the bone graft/bone substitute approach.[7-9]

The present authors do not consider this controversial because with the proper selection of patients and implantation technique, both methods can coexist. Once patients are selected, the maxillary bone quality and the amount of available bony tissue below the sinus floor are assessed. In selecting the technique, the size and type of implant and the osteotome technique must be considered.

Recent improvements in dental implants and the introduction of implants with an internal sealing screw (eg Dynamic Implant Valve Approach [DIVA], Upheal Dental) in 2012 have been combined with the previously established use of endoscopy in endodontics.[10,11] Such improvements optimized both the implantation procedure and the maxillary sinus augmentation.[12,13] The question put by Kaman et al,[14] "Is it necessary to graft?" has not, however, been immediately answered.

The aim of the present study was to analyze the results of combined use of the DIVA implant with an internal sealing screw and the graftless sinus augmentation procedure. It was hypothesized that with the proper selection of patients, it is possible to apply graftless sinus floor elevation in the majority of cases, assuming that the correct osteotome technique is used.

Figs 1a to 1c The Dynamic Implant Valve Approach (DIVA) technology with internal port and two sealing screws.

Method and materials

Patients

In the current multicenter retrospective study, the implantation and sinus augmentation results obtained from 331 patients (average age 64 years; male 152, female 179) were analyzed. In total, 722 implants were inserted in the posterior maxilla. The inclusion criteria were:

- the presence of an edentulous posterior maxilla
- a need for maxillary sinus floor elevation/augmentation
- sinus wall thickness in the implantation area of at least 3 mm.

The exclusion criteria included thickness of the sinus walls less than 3 mm or more than 8 mm (no need for sinus elevation), the suspicion that primary stability of the implant could not be achieved, and evidence of unhealthy sinus.[15]

For all patients, the bone quality was evaluated using cone beam computed tomography (CBCT) as a part of the patient selection procedure. The bone density (D1 to D4) was measured on CBCT scans according to a previously established technique.[16] Sinus membrane thickness was evaluated on CBCT scans following previously published guidelines.[17,18] All selected patients had at least 6 months of follow-up; maximum follow-up was 7 years; 159 patients had at least 4 years of follow-up. The data were collected from two major medical centers (Barzilai University Medical Center, Ashkelon, Israel, and Galilee Medical Center, Nahariya, Israel) and in a private medical center (Andy Dental Center, Holon, Israel).

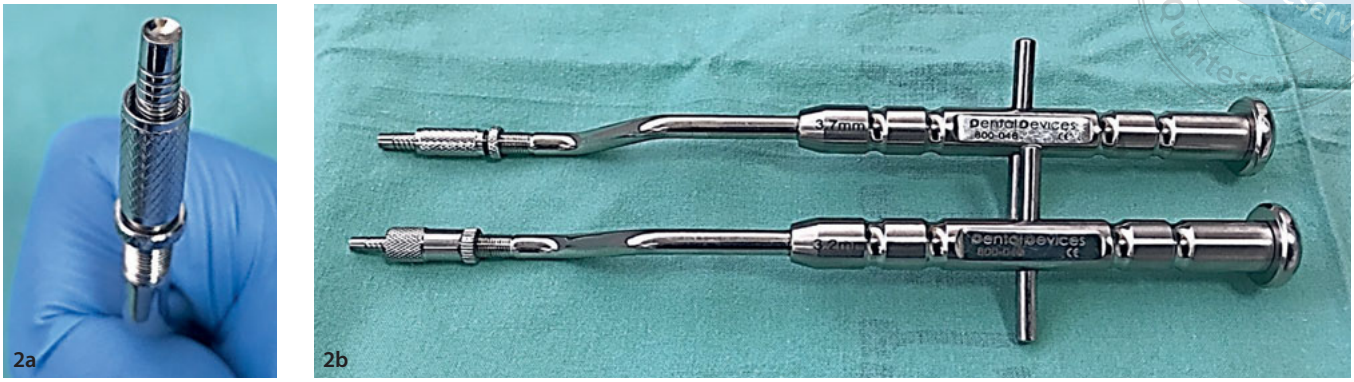
Responsible institutional review boards of the centers that were involved in the current research approved the study in accord with the ethical guidelines of the 1975 Declaration of Helsinki (amended 2013) protocol 0015-17 at Galil Medical Center, Nahryia, Israel, and 0063-16 at Barzilai Medical Center, Ashkelon, Israel.

The implant

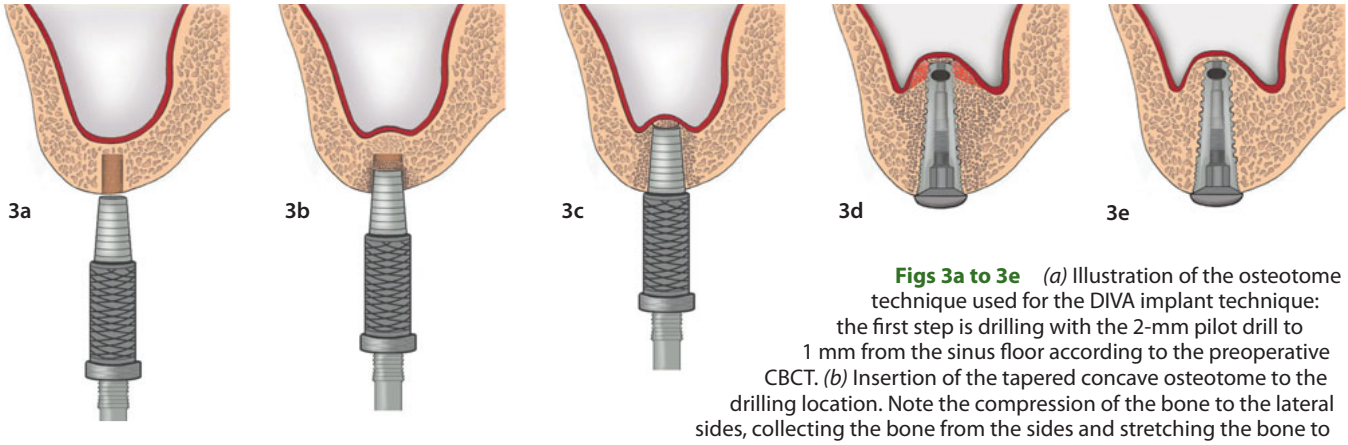
The titanium-aluminum-vanadium implant (Ti-6Al-4V ELI, diameter: 3.75 or 4.2 mm) has been in use since 2012, when the results of the dynamic fatigue test and the leakage sealing test confirmed its reliability.[10-13] The presence of an internal port and a sealing screw permitted a variety of procedures such as an irrigation for sinus membrane separation, bony substitute injection, and delivery of medications. The intra implant port allows the provider visual evaluation of the membrane status, and in cases of complications it also allows drug delivery as well as sinus irrigation (Fig 1). In the current study, DIVA implants were either 11.5 mm or 13.0 mm long and 3.75/4.20 mm in diameter. In the investigated cohort, the 11.5-mm implant was used when the thickness of the sinus walls in the implantation area was between 3 and 5 mm, while the 13-mm implants were used when the thickness of the sinus walls exceeded 5 mm.

Surgical technique and follow-up

Initially the CBCT data were analyzed thoroughly by the provider, to identify the sinus floor thickness and any potential



Figs 2a and 2b A special tapered concave osteotome was used in combination with the DIVA implant.



Figs 3a to 3e *(a)* Illustration of the osteotome technique used for the DIVA implant technique: the first step is drilling with the 2-mm pilot drill to 1 mm from the sinus floor according to the preoperative CBCT. *(b)* Insertion of the tapered concave osteotome to the drilling location. Note the compression of the bone to the lateral sides, collecting the bone from the sides and stretching the bone to the apical part. *(c)* The osteotome fractured the sinus floor. Note that the sinus floor bone disk is connected to the sinus membrane and the bone being collected by the osteotome is compressed to the sinus area. *(d)* The DIVA implant elevates the bone disk and the sinus membrane. Note the bone being collected by the osteotome and the implant compressed to the tent performed by the elevation technique. The blood from the sinus floor fracturing fills the tent space. *(e)* After healing, bone forms around the implant.

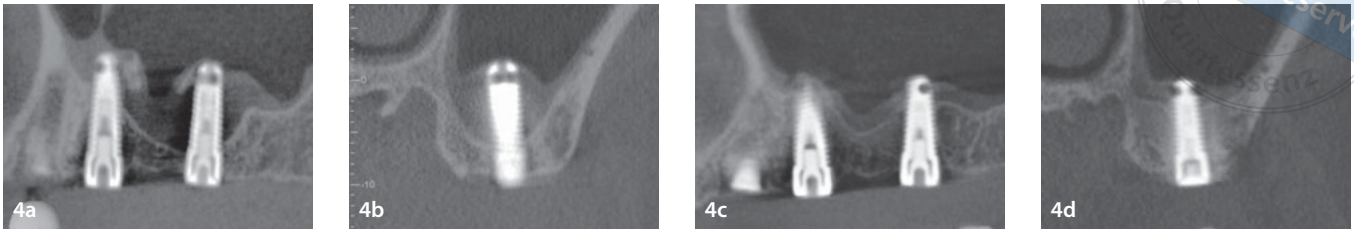
pathology. As described previously,[11-13] initial drilling was performed with a 2-mm-diameter drill up to 1 mm from the sinus membrane. This allowed insertion and manipulation with the tapered 2.2- to 2.7-mm curved osteotome, compressing the bone to preparation walls and towards the sinus floor (Fig 2).

In summary, the surgical procedure consisted of four maneuvers:

- Condensing the bone to the lateral walls and increasing its density and stability
- Stretching and increasing the bone height to 30% or more
- Collecting the bone and condensing it to the apical part (especially when the bone quality was D3 or D4)
- Fracturing the sinus floor, creating a bone disk connected to the sinus membrane (Fig 3).

The implant was inserted until stable with the inner screw, which was removed afterwards. Delicate irrigation with the isotonic saline via the screw hole separated the membrane. Bleeding from the hole represented a fracture of the sinus floor. Slow ratcheting of 1 mm, accompanied by equally slow injection of 1 mL of the saline, helped to elevate collected bone particles and to stretch the sinus membrane. To rule out a possible perforation, the integrity of the membrane was evaluated by observing the respiratory movement of the injected saline.

For each case a CBCT scan was taken immediately after the surgery. Bimonthly follow-ups were set starting from the first month up to 18 months postoperatively, with subsequent visits at 2, 3, and 4 years after the intervention when possible. Follow-up CBCT investigations were performed at 6 and 12 months



Figs 4a to 4d *(a)* Immediate postoperative sagittal CBCT scan of a 56-year-old woman with two DIVA implants 3.75 mm in diameter and 11.5 mm in length. The posterior crestal bone level was 3 mm. *(b)* Coronal CBCT scan of the same patient. *(c)* Six-month sagittal CBCT of the same patient. Note the almost complete formation of bone around the two DIVA implants. *(d)* Six-month coronal CBCT of the same patient.

after surgery to evaluate the crestal bone levels and morphology, the bone-to-implant interface, and implant-sinus connections (Fig 4). The patients' reports of pain or discomfort were documented. Extraoral and intraoral examinations were performed that included oral hygiene evaluation and instructions. During follow-ups, practitioners also examined peri-implant soft tissue, the restoration, and occlusal wear. The follow-up reports specifically indicated whether the connections were intact and if no fractures or chipping had occurred. All the patients included in the study underwent prosthetic restoration 6 months after the procedure.

Analysis

The stability and the implant survival results were compared for 11.5-mm (sinus wall thickness from 3 to 5 mm) and 13-mm-long implants (sinus wall thickness from > 5 to 8 mm). The rate of complications was assessed in correlation with the thickness of the sinus membrane.

Results

Out of 722 inserted implants, 412 implants were inserted in the maxilla with the bone level from 3 to 5 mm, and 310 implants were inserted in the maxilla with the bone level from > 5 to 8 mm. The mean bone density measured on the CT images was 0.35 ± 0.04 g/cm^2. The mean thickness of the sinus membrane was 1.6 ± 0.7 mm, but this variable presented a wide range from 0.5 mm to 4.2 mm. The number of implants per patient varied from one to eight.

The rate of complications is presented in Table 1. The implant failure consisted of 33 implants (4.6%) in 18 patients. In 689 implants (95.4%), implantation was successful from objective CBCT and clinical and subjective patients' judgments, with no statistical difference between 11.5-mm and 13-mm implants. The rates of complications for the cases with bone level of 3 to 5 mm and the cases with the bone level of > 5 to 8 mm were comparable ($P = .48$). Complications such as infection/peri-implantitis, loss of stability of restorative components, and peri-implant mucosal hyperplasia were equally distributed among both groups. Minor perforations of the sinus membrane occurred in eight cases, all with bone level less than 5 mm. The main cause for failure was failure to achieve osseointegration and local infection. The minimum follow-up period in this study was 6 months. The follow-up period for 518/722 (71.7%) implants was at least 18 months, and for 159/722 (22.0%) implants the follow-up period was 4 years. In total, 78.8% (26/33) of the complications occurred in the first 6 months.

Discussion

The main finding of the present study supports the viewpoint that proper insertion of implants in the posterior maxilla can be effectively achieved without grafts and/or bone substitutes. The initial stimulus to investigate the effectiveness of the above-described graft-free technique was an animal study performed in 2011.[19] The authors used rabbits to evaluate new bone formation in the maxillary sinuses with and without bone grafts. It was suggested that the grafting material slowed the healing process. The degree of new bone formation following maxillary sinus graft depends on the applied graft material.[20] Displacement of a graft, graft resorption, and/or infection of the graft materials are still possible even when the most advanced implantation technique is applied.[21-23] Rarely, dental implants may even migrate in the grafted maxillary sinus.[24]

Table 1 Complications of the implantation procedures and implant maintenance

Implant	Type of complication	n (%)
11.5-mm-long implant: sinus wall thickness 3 to 5 mm (n = 412)	Complications associated with implant planning	0 (0.00)
	Implant fractures	0 (0.00)
	Infection/peri-implantitis	4 (0.97)
	Complications due to implant malposition	0 (0.00)
	Complications related to nonoptimal for rehabilitation of dental implant placement	0 (0.00)
	Intraoperative sinus membrane perforation	8 (1.94)
	Complications in the sinus elevation surgery	0 (0.00)
	Open sinus surgery because of complications	0 (0.00)
	Complications after immediate implant placement into extraction sites	1 (0.24)
	Failure to achieve osseointegration	8 (1.94)
	Loss of stability of restorative components	3 (0.73)
	Peri-implant mucosal hyperplasia	2 (0.48)
	Implant failure (cumulative)	21 (4.12)
13-mm-long implants: sinus wall thickness > 5 to 8 mm (n = 310)	Complications associated with implant planning	0 (0.00)
	Implant fractures	0 (0.00)
	Infection/peri-implantitis	4 (1.3)
	Peri-implant mucosal hyperplasia	1 (0.32)
	Complications due to implant malposition	0 (0.00)
	Complications related to nonoptimal for rehabilitation of dental implant placement	0 (0.00)
	Intraoperative sinus membrane perforation	0 (0.00)
	Complications in the sinus elevation surgery	0 (0.00)
	Open sinus surgery because of complications	0 (0.00)
	Loss of stability of restorative components	3 (0.97)
	Peri-implant mucosal hyperplasia	2 (0.65)
	Failure to achieve osseointegration	5 (1.61)
	Implant failure (cumulative)	12 (2.90)

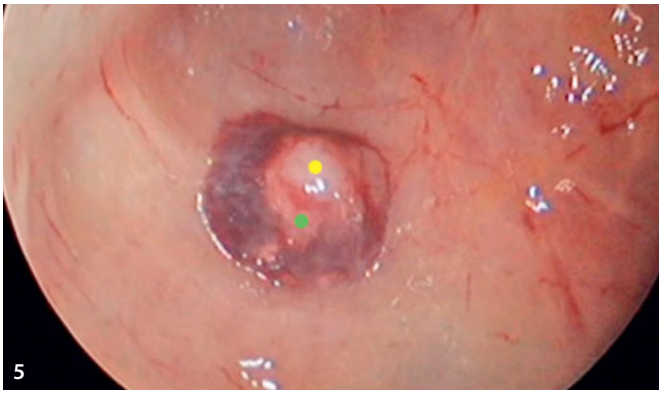
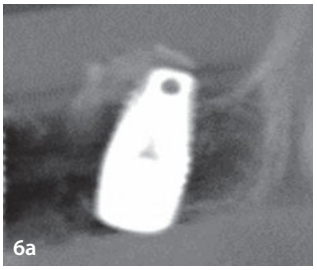
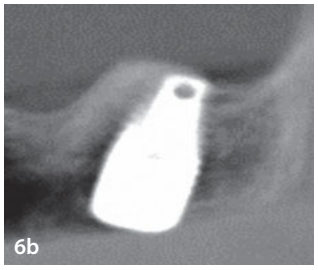


Fig 5 An endoscopic view from the sinus showing the tent formation immediately after the insertion of the DIVA implant. Note the bone disk connected to the sinus membrane (yellow point), the bone collected and compressed under the bone disk and around the implant (green point), and the blood that fills the tent.

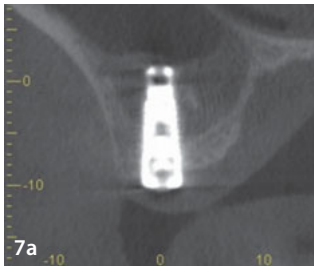
While simultaneous implant placement with sinus augmentation is possible, in some cases a 4-month period is required after grafting before dental implants can be placed.[23]

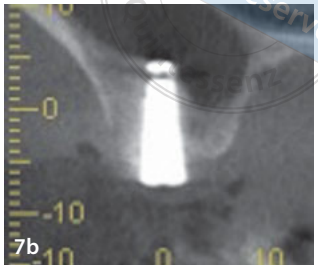
This in no way means that grafts are to be totally rejected. There are numerous cases when the morphology of the maxilla and the sinus may require grafting. This aim of the present study was to demonstrate that the implant system with port and screw may offer an alternative for graftless implantations. The osteotome technique first advocated by Tatum in 1986[25] combined with the implant system with port and screw technique can save, compress, stretch, and elevate the bone only in the target area. The internal hole of the implant permits irrigation, membrane separation, and monitoring, while slow ratcheting helps to avoid unnecessary damage of the membrane. The bone is slowly compressed by the ratcheting and together





Figs 6a and 6b *(a)* Immediate postoperative sagittal CBCT of a 40-year-old woman with a DIVA implant 4.2 mm in diameter and 13 mm in length. The bone level was 6 mm, with D4 bone quality. Note the bone compression and elevation. *(b)* Sagittal CBCT 6 months later in the same implant, with complete coverage of bone around the implant.





Figs 7a and 7b *(a)* CBCT (coronal view) of a 60-year-old man immediately after the procedure. *(b)* CBCT (coronal view) of the same patient 4 months later, demonstrating good bone quality around the DIVA implant.

with a small amount of saline produces a "cushion" that gently elevates the sinus membrane (Fig 5). Although relatively simple, the use of this system required training.

Moving to graftless procedures, it was suggested to replace the bone graft by a blood clot or the blood clot combined with collagen sponges.[26,27] The present authors' experience suggests that an additional blood clot is not needed. Penetrating the periosteum of the maxillary bone, an osteotome invades the submucosal capillary bed of the sinus wall, which produces sufficient bleeding for the further osteogenic process (Fig 6). Concerning this matter, the present findings are in concordance with the previous report by Falah et al,[8] who found that the blood clot from surrounding bleeding is sufficient to be considered an autologous osteogenic graft material (Figs 7 to 9).

The sinus membrane thickness evaluation varies in different studies from 0.2 to 4.4 mm.[17,18,28-31] As only eight cases of minor and self-healing membrane perforations were involved in the present series, no sound statistics were possible due to the small number. However, it is important to note that these perforations occurred only in cases with a membrane thickness of less than 1 mm.

The present study utilized the Ti-6Al-4V ELI 3.75/4.20-mm diameter 11.5/13.0-mm length DIVA implants and the results cannot be generalized for other types of dental implants. Further studies should evaluate the effect of additional cofounding factors such as systemic diseases, age, and sinus anatomy on the success rate and complications.

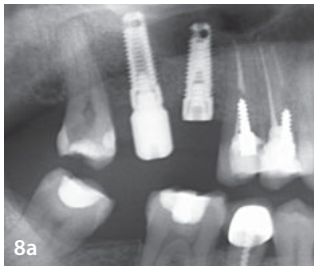


Fig 8a Panoramic radiograph immediately following implantation and sinus elevation of two DIVA implants at the maxillary right first and second molars.

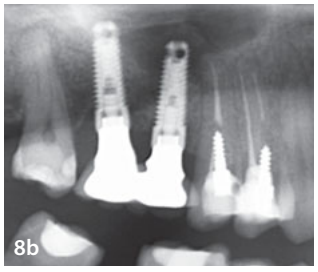


Fig 8b Panoramic radiograph 8 months post-implantation with crown rehabilitation. Note the bone in the sinus around the DIVA implant at the maxillary right first molar.

Conclusions

The port and screw implant system may allow dental implant insertion and maxillary sinus augmentation without grafting or bony substitute. Implants with an inner sealing screw and the proper ratcheting technique can simplify the surgery, reduce risk for complications, and may secure optimal placement of an implant without the addition of graft material.

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