Where technology meets dentistry

PALTOP

DIVA

By PALTOP

Innovative Sinus Lift Technology

With The Paltop Cutting Edge Manufacturing Technology

Innovative Sinus Lift Technology

- Innovative Sinus Lift Technology
- Patented technology around the world
- Simple and easy to use
- Uses the implant itself to elevate the sinus membrane and reduces the risk of perforation
- Enables the detection of sinus membrane movement through the implant
- “Smart” configuration allows injection of bone substitute directly through the implant
- Unique inner valve screw enables absolute sealing of the implant against oral flora

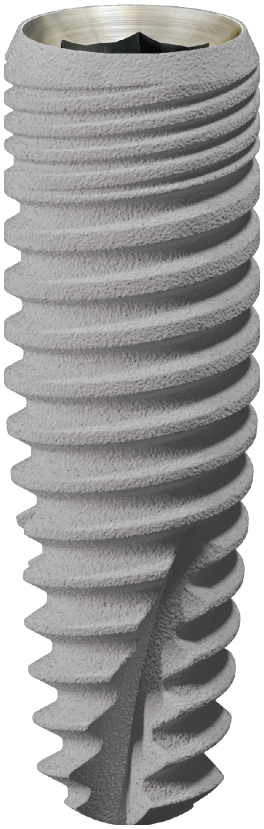
INTERNAL HEX

DIVA		
Ø 4.2 mm	L 11.5 mm	23-70003
Ø 4.2 mm	L 13 mm	23-70004
Ø 5.0 mm	L 11.5 mm	23-70005
Ø 5.0 mm	L 13 mm	23-70006

Advanced Prosthetic Components may be used with the DIVA Implants

*This product is not available in all markets where PALTOP operates
In several countries PALTOP has the marketing rights for this product although not exclusively

ABOUT PALTOP



Paltop is a premium manufacturer of dental implants that strives to provide highest quality products in the dental arena.

Leveraging decades of collective experience and industry leadership, the company established a cutting edge, fully automated manufacturing facility and has become one of the world's leading companies in the world in terms of products quality.

Paltop implemented manufacturing technologies that was taken originally from the semiconductors industry and the result is that in a comprehensive surface analyses study that conducted by Cologne University, comparing 120 implant systems, Paltop implants founded to have a superior implant surface with only pure raw material and without any contaminations.

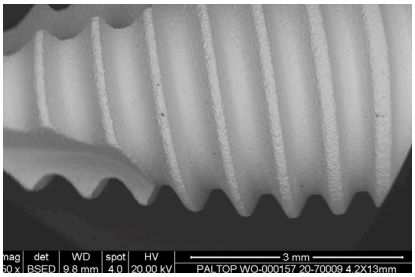
Paltop system main strengths are as follow:

- Better esthetic results due to fully concave emergence profile and one abutment - one time solutions for reduced tissue trauma
- Prevents bone loss due to combination of extremely clean surface and protective titanium package
- Immediate placement and loading due to unique implant design that combines the advantages of the traditional passive implants with the advantages of active implants, along with tailor made step drills and final drills creating an accurate implant-shaped osteotomy
- User friendly surgical kits provides simplicity and comfortability during the surgical treatment.
- Paltop developed comprehensive solution in digital dentistry and today Paltop serves dentist worldwide in digital individual treatment workflows via its unique platform

Ultra-Clean Surface Technology

The Ultra High Purity Cleaning Process is a comprehensive approach to producing a high purity surface for dental implants.

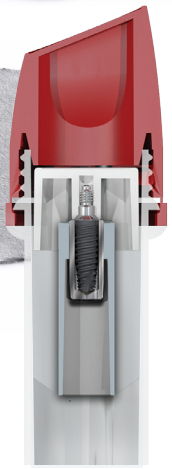
PALTOP's ultra clean surface technology is based on decades of experience of the company's founders in industrial manufacturing of highly sensitive components for advanced industries: semiconductors, oil & energy, chemical and pharmaceutical, food, etc.



From the Final report of the BDIZ EDI implant study 2014/15

> An Israeli manufacturer (PALTOP) has decided to consistently clean their products with ultra-pure water (UPW), which is rather expensive to produce compared to regular demineralized water and is otherwise mostly employed by the semiconductor industry.

> The illustration shows a complex packaging design where the implant is inserted in a separate sleeve made of the same material (grade 5 titanium) as the implant itself to reduce the influence of other materials to a minimum.



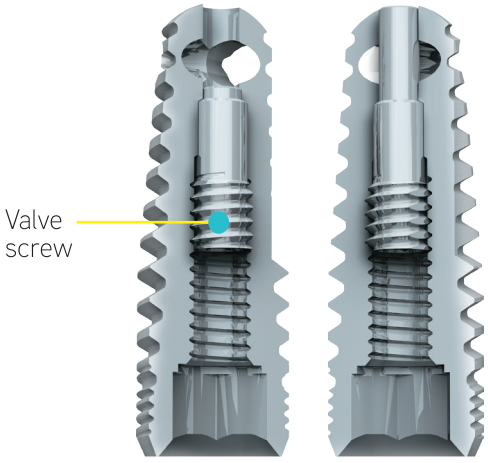
All Paltop's Components are Delivered Sterile

DIVA Sinus Lift Technology is here

Until recently, most of the sinus lift (or sinus elevation) implant procedures performed by dental surgeons were cumbersome and carried a high risk of possible complications including infection, bleeding and other post-op patient side effects.

DIVA, a new sinus lift technology, delivers an innovative solution that enables sinus lift implants to be carried out using a simple, easy to learn and relatively short procedure, with significantly lower risk of complications and patient discomfort.

DIVA's technology is gentle and minimally invasive, significantly reducing the risk of membrane damage. DIVA is straightforward and easy to master, and is intended for use by specialized dental surgeons and general dental practitioners alike. The procedure's simplicity also carries additional benefits – a shorter chair time than other methods, fewer post-op complications and shorter overall treatment times. The unique technology enables sinus lift procedures to be performed even in cases of minimal residual bone. In addition, DIVA is suitable for patients with complex medical backgrounds who avoided these operations in the past due to the high level of possible risks. Finally, DIVA requires no additional specialized tools and/or accessories, resulting in lower procedure costs compared with other sinus lift procedures.



DIVA's Unique Innovations

DIVA Sinus Lift Technology possesses three unique innovations, including use of the implant itself to elevate the sinus membrane without risk of perforation; Its ability to detect sinus membrane movement through the implant; and a configuration that allows injection of bone substitute directly through the implant.

Two further innovations of the DIVA technique are the absolute sealing of the implant against oral flora, and its strength, which is greater than that of regular dental implants.

Great News for Patients

DIVA Sinus Lift Technology is great news for patients! Patients will benefit from shorter recovery times, including those of the prosthetic stage, and fewer post-op issues such that they can return to their normal routines faster.

All of the characteristics above make DIVA the obvious choice for expert dental surgeons and general practitioners alike, who wish to offer their patients an innovative, lower risk and less invasive option for their sinus lift implant procedures without compromising quality.

Main advantages of DIVA

DIVA Sinus Lift Technology is simple and easy-to-use, enabling not only specialized dental surgeons to perform sinus elevation implants, but also general practitioners, which greatly expands the range of procedures they can offer patients.

The less invasive technology significantly lowers the risk of membrane rupture.

The DIVA device is specially designed to make sinus lift procedures possible even in cases of minimal residual bone (3 mm).

The technology, unlike other sinus lift procedures, enables selective elevation of the sinus.

DIVA's minimally invasive sinus lift procedure leads to far lower risk of infection and other post-op complications, both during and after the procedure.

DIVA, which carries fewer associated risks than other sinus lift procedures, may be suitable for patients with complex clinical backgrounds.

Post-op side effects such as swelling, pain and bruising are significantly reduced, as well as patient recovery periods, including those of the prosthetic stage.

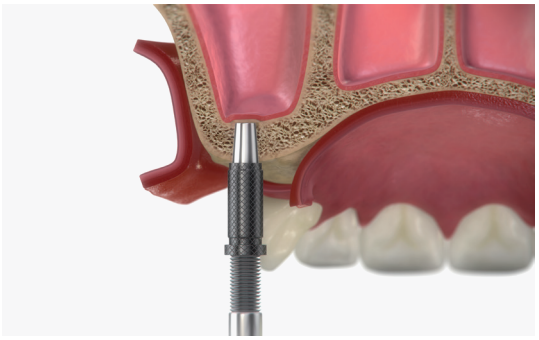
DIVA's shorter, more efficient procedure compared to other sinus lift operations results in significantly decreased chair time.

DIVA does not require additional special tools or accessories, which lowers procedure costs.

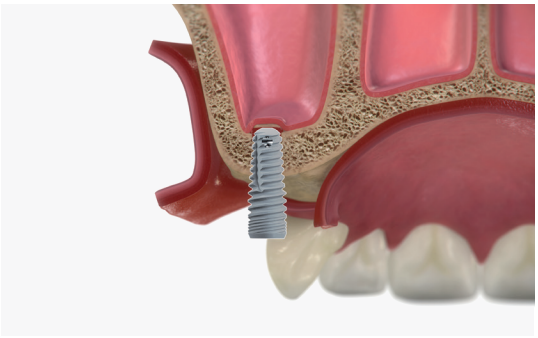
DIVA implant failure does not generally involve the sinus – failure behavior is similar to that of other implants.

Main steps

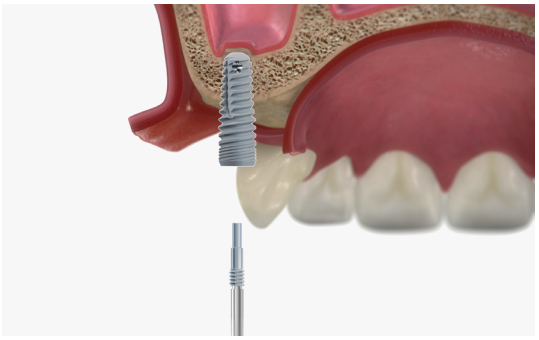
1. After review of the CT scan, use a round bur to indicate the implant's exact location. Start initial drilling beneath the sinus floor with a standard2 mm pilot drill until a depth of 1 mm beneath the sinus floor. Use a drill stopper to achieve the correct depth.



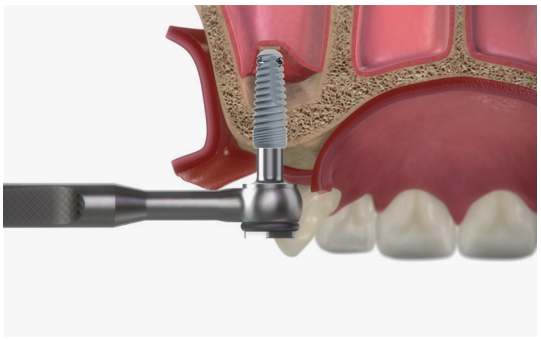
2. Insert the special concave Osteotom (tapered 2.2 mm - 2.7mm) with a stopper into the space created by the pilot drill. Gently apply pressure until the first crack of the sinus floor cortical bone is detected.



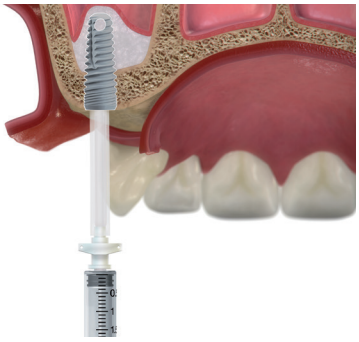
3. Insert the DIVA device using controlled rotation until initial primary stability is obtained.



4. With the attached special driver, unscrew and remove the first valve screw (the long one) located within the device. The bleeding that is observed from the DIVA channel indicates the sinus floor fracture.

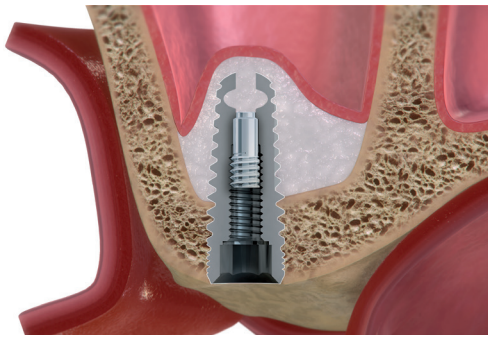


5. Attach a filled saline syringe to the IV Cannula. Use this apparatus to gently introduce 1cc of saline via the implant to rinse the sinus membrane. Remove the syringe and cannula, attach the ratchet to the implant, and carefully screw it in by 1mm. Repeat this rinse and ratcheting procedure until a counter sink for the DIVA device is attained. With this procedure, the membrane elevates, yet remains intact.



6. Detach the saline syringe from the IV Cannula, and then attach the CERASORB PASTE TCP syringe. Use this apparatus to inject TCP via the implant (approximately 0.5cc per implant) until the excess TCP overflows the implant.

6a. Use the attached driver and screw in the first valve screw to expel the remaining TCP from the inner tunnel of the implant, and then rinse the implant with saline and remove the valve screw.



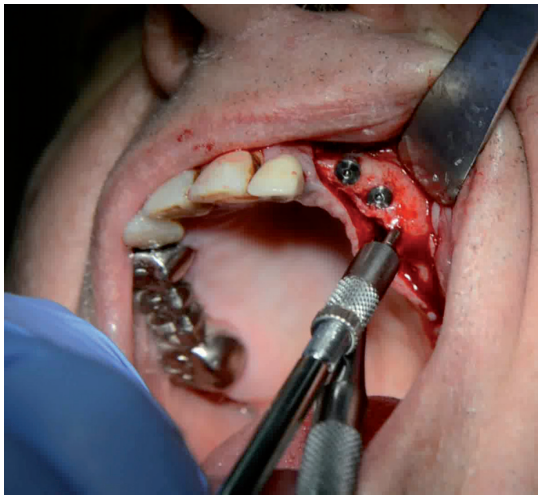
7. Screw in the secondary valve screw (the shorter one) to achieve absolute sealing, and cap the DIVA device with a cover screw.

8. After a 6-8 month osseointegration period, remove the cover screw to expose the implant and confirm that the inner valve screw has remained tight. Then, cap the DIVA device with the healing screw. The implant is now ready for permanent prosthetic restoration.

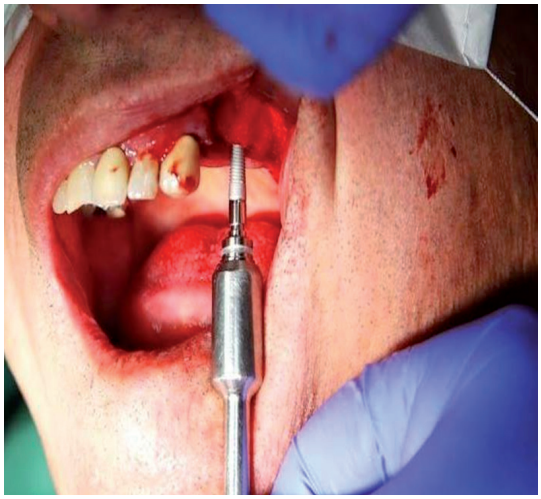
Main characteristics of DIVA sinus lift technology compared to other sinus elevation techniques

Criterion / Technology	Minimally invasive	Fewer Post-op side effects	Membrane safety	Shorter osseeointegration period	Minimal Residual bone
Open sinus elevation	X	X	X	X	X
Closed sinus elevation	V	V	X	V	X
Diva sinus lift technology	V	V	V	V	V

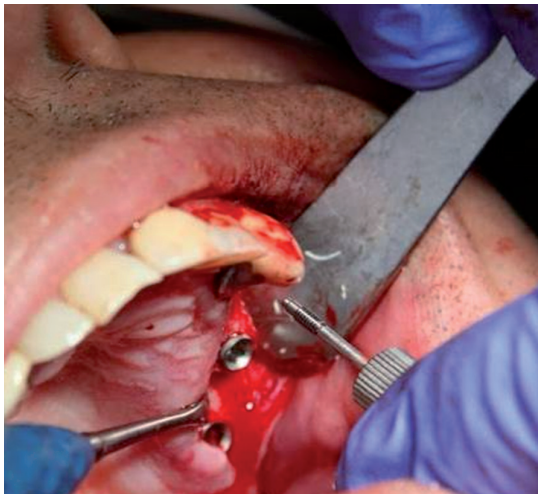
DIVA's sinus lift procedure



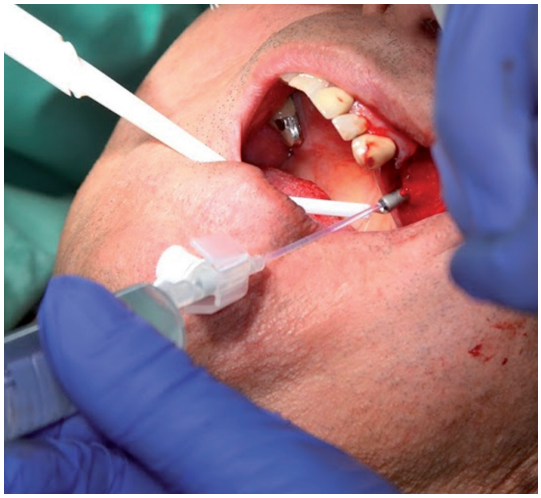
Ostiotom use



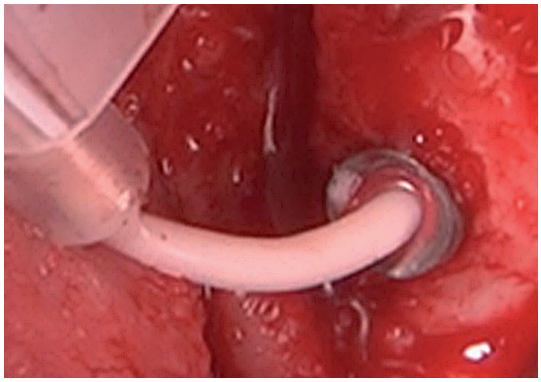
Insert DIVA device



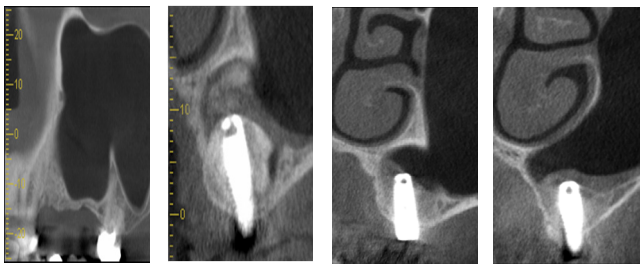
Unscrew primary valve screw



Membrane lifting



CT Scan



Before the procedure | Immediate-implant A | 12W post-op implant A | 12W post-op implant B

Oded Nahlieli

Four-years' experience with dynamic implants with internal port for minimally invasive sinus elevation

Oded Nahlieli, DMD[1]/Ami Zagury, DMD[2]/Eli Michaeli, DMD[3]/Noam Bruck, DMD[4]/Dorit Dil Nahlieli, Pharm. D[5]/Nardy Casap, MD, DMD[6]

Objective: The purpose of this article is to describe long-term results of the dynamic implant valve approach (DIVA) for the dental implant procedures when the implant system with internal ports was used. **Method and Materials:** During 2012 to 2015, 378 titanium-aluminum-vanadium implants (Ti_6Al_4V ELI; diameter 3.75 mm; length 11.5 and 13 mm) were implanted in 172 patients (one to nine implants per patient) using the DIVA technique. The DIVA implants were used in cases when sinus membrane and/or nasal floor elevation procedures were needed. The condition of the implants was assessed during the follow-up period up to 60 months. **Results:** Out of 378 inserted implants, 257 implants were inserted in the maxilla with the bone level < 5 mm, and 121 implants were inserted in the maxilla with the bone level > 5 mm. In 357 cases (94.5%), the implantation was totally successful both from objective CBCT clinical and subjective patients' viewpoints. The comparison of complication rates between the cases with the bone level < 5 mm and the cases with the bone level > 5 mm indicated no significant difference ($P = .32$). **Conclusion:** Preliminary results that the DIVA simplifies the dental implantation procedure and augmentation treatment were confirmed. The implant with an inner sealing screw can be used in cases with elevation of the maxillary sinus membrane, and simplifies the surgery and secures optimal dental implant placement. This new type of implant simplifies the maintenance phase of implant dentistry and helps to overcome possible complications. *(Quintessence Int 2016;47: 669–675; doi: 10.3290/j.qi.a36328)*

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

During the 2000s, endoscopy was successfully introduced in endodontics and root canal treatment.[1-3] It was inevitably followed by the introduction of endoscopy in dental implantology.[4,5] The next logical step was to find means of using endoscopic observations after an implant was placed. The necessity of such an approach was obvious because implant failure, implant fracture, peri-implantitis, complications due to nerve perforation, sinus augmentation complications, and other implant complications remained unsolved problems, despite recent improvements in implantology.

For this purpose, and based on the authors' endoscopic maxillary sinus experience, a dental implant system with an internal port was developed. It was successfully tested in an animal model, and was introduced into implantology practice.[6-8] In short, the new

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Figs 1a and 1b The DIVA implant is stabilized after the drilling and the osteotomy procedure. Note the separation of the sinus floor.

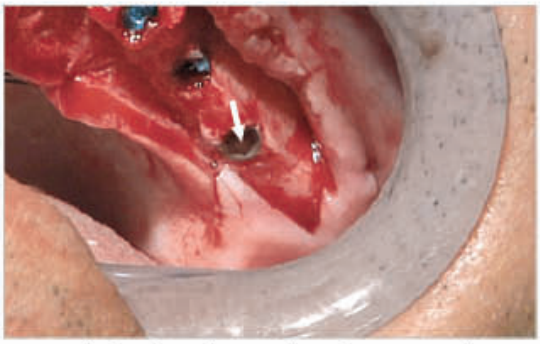


Fig 1c Bleeding from the internal port demonstrates the sinus floor fracture.

Fig 1d The irrigation via the internal port separates the sinus membrane from the sinus floor.

titanium-aluminum-vanadium implant (Ti_6Al_4V ELI) had an internal port and sealing screw that served mainly for drug delivery, and direct endoscopic observation via its channel. This invention permitted design of the dynamic implant valve approach (DIVA; Upheal Dental) for dental implant procedures, which uses an implant with an inner sealing screw. The main goal of the newly designed implant was to increase the longevity of oral implants and to manage implant complications in a rapid and convenient manner. The main application of the DIVA is for maxillary implants, and the main benefit is the increased safety and precision of the implantation procedure in cases of narrow and insufficient bone level for implant placement. The preliminary results of the implementation of the DIVA indicated reduced risk of complications and improved approach for the maxillary sinus floor augmentation.[7]

While the authors' previous research reported initial results of implementation of the implant with an internal port, there was no possibility to assess the implant survival rate up to 3 to 4 years, as well as the rate of long-term complications. The purpose of the current research was to evaluate the qualities of the DIVA and the implant by assessment of data taken from a significant number of patients during long-term follow-up.

METHOD AND MATERIALS

The implant

The properties of the titanium-aluminum-vanadium implant (Ti_6Al_4V ELI; diameter 3.75 mm; length 11.5 and 13 mm) were reported previously.[6-8] The results of the dynamic fatigue test and the leakage sealing test confirmed high reliability of the implant as a mechanical

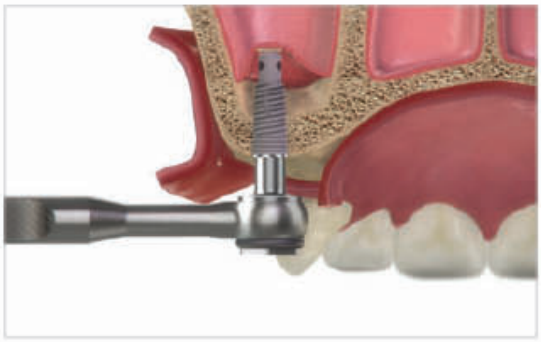


Fig 1e Slow ratcheting elevates the sinus membrane without perforation.

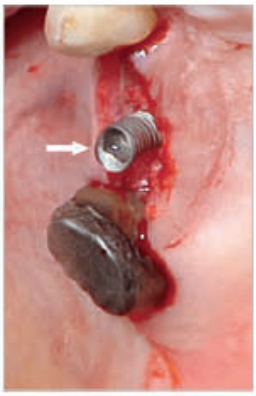
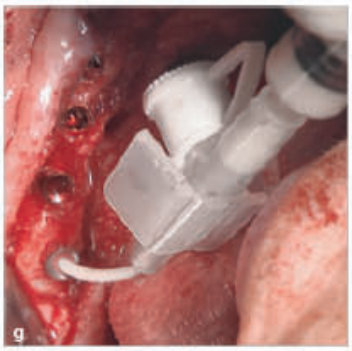
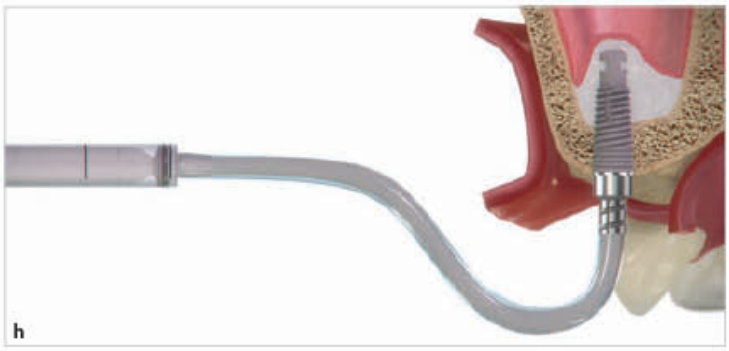


Fig 1f Saline movements in the implant coronal space during respiratory movements show the integrity of the sinus membrane.





Figs 1g and 1h Injection of the beta-tricalcium phosphate and hyaluronic acid via the internal port to the sinus elevation space.

device. The minimally invasive DIVA procedure was also described in detail in a previous publication.[7]

In short; the drilling should reach a 1-mm level from the sinus floor, followed by insertion and manipulation with the tapered 2.2- to 2.7-mm curved osteotome (Upheal Dental) until the exact length is reached according to the initial cone beam computed tomography (CBCT) data (Fig 1a). The implant should be inserted until it is stable and its internal screw is removed (Fig 1b). The sinus floor location can be observed endoscopically through the implant, and minor bleeding from the channel indicates that the sinus floor is fractured (Fig 1c). The separation of the sinus membrane should be achieved by careful irrigation with isotonic saline via the internal channel (Fig 1d). The elevation of the membrane is achieved by slow 1-mm ratcheting of the implant during slow introduction of 1 mL of saline (Fig 1e). The integrity of the membrane should be evaluated by the respiratory movement of the irrigated saline level via the implant coronal space (Fig 1f). Injection of Cerasorb (beta-tricalcium phosphate and hyaluronic acid; Curasan) via the inner channel is recommended. This approach has more significance in cases when the maxillary bone level at the implantation site is < 5 mm or when better stabilization is needed (Figs 1g and 1i). The injection of

Fig 1i Bony substitute penetration via the ports of the implant in the mushroom effect.

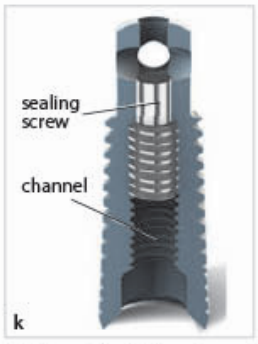


Fig 1j and 1k The sealing screw totally obstructs the channel due to friction and titanium features.

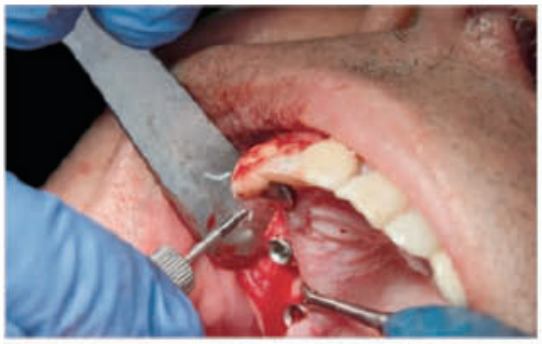


Fig 1l The sealing screw is inserted into the implant channel after completion of the bony substitute gel injection.

the bony substitute gel via the implant port performs a "mushroom" effect, helping to elevate and stabilize the membrane. Following the injection of Cerasorb, the sealing screw is inserted back and secured (Figs 1j to 1l).

The patients

During 2012 to 2015, 172 patients (89 women, 83 men, age range 31 to 85, mean age 50) were treated with DIVA, and 378 new type implants were inserted. The main inclusion criterion was a need for maxillary sinus floor elevation/augmentation to be performed for successful implant insertion. In one case, three implants were used for nasal floor elevation. The exclusion criteria were: unhealthy sinuses, thickness of the sinus walls less than 3 mm, and calculated suspicion that primary stability of the implant could not be achieved. The bone quality of the patients was initially assessed using CBCT and CT images. The bone density was measured on the CT images.[9]

The analysis of the outcome was performed separately for the patients with a follow-up period from 4 months to 2 years (main group, n = 172, 378 implants) and for the patients with a follow-up of between 2 and 4 years (subgroup A, n = 84, 180 implants). Another subgroup, B, consisted of 33 patients (age > 60, 68 implants) with age-related osteoporosis. In addition, a comparison of outcomes between cases with bone level < 5 mm and cases with bone level > 5 mm was also performed. The possible failure cases were planned to be tested for correlation with the bone quality and the bone density. For this purpose, chi-square analysis and Fisher exact test were used, with the level of significance set at $P < .05$.

Follow-up intervals were set at 1, 4, 6, 12, and 18 months postoperatively, with follow-up visits at 2, 3, and 4 years after the implantation. In addition to these scheduled visits, 22 patients referred to the clinic on an as-needed basis. CBCT was taken immediately after the procedure and after 4 and 12 months. The follow-up period lasted from 4 to 60 months. The follow-up assessment included evaluation of patients' reports of pain or discomfort, an extraoral and intraoral examination with calculation of the plaque score, checks for calculus presence and location, peri-implant soft tissue examination, examination of the restoration with assessment of occlusal wear, checking that connections were intact, and checks for fracture or chipping. The radiographic examination included the assessment of crestal bone levels and morphology, the assessment of the bone-to-implant interface, and checking that connections were intact.

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki (amended 2000) as reflected a priori after approval by the institution's ethics committee.

Table 1 Complications of implantation procedures and implant maintenance

Type of complication		Number (%)
0 to 2 years' follow-up (n = 378)	Complications associated with implant planning	0
	Implant fractures	0
	Infection/peri-implantitis	4 (1.05%)
	Complications due to implant malposition	0
	Complications related to non-optimal dental implant placement	0
	Intraoperative sinus membrane perforation	0
	Complications in the sinus elevation surgery	0
	Open sinus surgery because of complications	0
	Complications after immediate implant placement into extraction sites	1 (0.3%)
	Failure to achieve osseointegration	6 (1.6%)
	Loss of stability of restorative components	3 (0.8%)
	Peri-implant mucosal hyperplasia	2 (0.5%)
	Complications associated with systemic disorders (diabetes)	6 (1.6%)
	Implant failure (cumulative)	16 (4.2%)
2 to 4 years' follow-up (n = 180)	Implant fractures	0
	Infection/peri-implantitis	4 (2.2%)
	Peri-implant mucosal hyperplasia	1 (0.5%)
	Loss of stability of restorative components	2 (1.1%)
	Complications associated with systemic disorders (diabetes)	3 (1.6%)
	Implant failure (cumulative)	5 (2.8%)

RESULTS

Out of 378 inserted implants, 257 implants were inserted in the maxilla with the bone level < 5 mm, and 121 implants were inserted in the maxilla with the bone level > 5 mm. The mean bone density measured from the CT images was 0.33 g/cm². The number of implants per patients varied from one to nine.

The rate of complications is presented in Table 1. Esthetic complications were not assessed. The implant failure consisted of 21 implants (5.5%) in nine patients. Table 1 also shows that the first 2 years after implantation were more crucial for implant survival than the subsequent years. The comparison of complication rates between the cases with the bone level < 5 mm and the cases with the bone level > 5 mm indicated no significant difference ($P = .32$). Osteoporosis did not affect the rate of complications (subgroup B vs main group, $P = .45$). The correlation was also negative in tests for the bone quality and the bone density (failure vs D3 or D4 bone quality: $r \leq 0.22$, $P < .01$; failure vs density in HU: $r \leq 0.19$, $P < .01$).

According to Table 1, signs of local infection and failure to achieve osseointegration were the main causes of failure, and the implants were removed 2 to 3 weeks after the insertion (on average).

During the follow-up period, the assessment was made by taking subjective information from the patient, intraoral clinical observation, and in few cases by endoscopic control via internal port (screw) of the implant. In 357 cases (94.5%), the implantation was totally successful both from objective CBCT, clinical, and subjective patients' viewpoints (Figs 2 and 3).

DISCUSSION

The aim of the present study was to report the results of DIVA implant usage in adults by assessing an

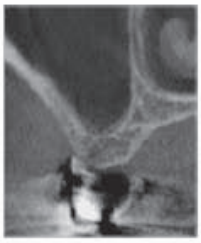


Fig 2a CBCT scan before implantation and the implant installation. Note the bone level of 4 mm.

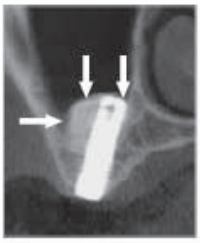


Fig 2b CBCT scan taken immediately after the DIVA implant procedure with sinus elevation and the injection of beta-tricalcium phosphate with hyaluronic acid. Note the perfect elevation of the membrane (arrows).

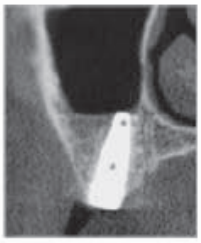


Fig 2c CBCT scan 4 months postoperatively. Note the good bony restoration around the implant.

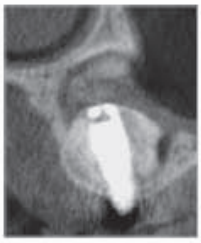


Fig 3a CBCT scan obtained immediately after DIVA implantation and the sinus elevation with the Cerasorb gel.

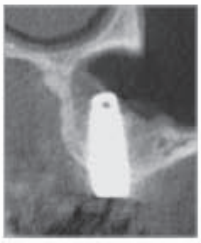


Fig 3b CBCT scan 6 months after the surgery. Note the bony regeneration around the implant.

extended follow-up period. The current implant survival rate with different implant systems varies from 90% to 100%.[10-15] The present results are within this range. However, the fact that the obtained results were taken from implants inserted in the posterior maxilla should be noted. Although the bone mineral density of the posterior maxilla is significantly lower than the density of the anterior maxilla and especially of the mandible, these results are satisfactory.

The importance of the DIVA approach is evident, not only in the simplification and increased precision of the implantation procedure itself, but also in the improvement of the maintenance phase of implant dentistry. The maintenance of an implant encompasses the preventive care necessary to preserve the health and integrity of both soft and hard tissues around the implant, and the procedures required to sustain the function of the restoration. For these purposes, the implant with an internal sealing screw might help to secure proper management of inflammatory diseases, bone loss, and low-density bone, thus reducing the risk of delayed complications. The data from Table 1 show that the rate of complications and the implant failure during the 2- to 4-year period after implantation was lower than during the first 2 years after surgery.

The implantation procedure reduced complications due to intraoperative sinus membrane perforation, and complications in the sinus elevation surgery. The maintenance of the implants during follow-up included the option of endoscopic observation of the bone condition, irrigation, drug delivery, and other therapeutic procedures above the implant that were performed via the internal port of the implant. Therefore 32 events of various complications (see Table 1) led to only 21 implant failures.

The lack of significant difference in the complication rate between the cases with the bone level < 5 mm and the cases with the bone level > 5 mm is mainly due to additional efforts during the implantation procedure. The injection of a bony substitute via the implant's inner channel, other measures in the sinus elevation procedure, and further stabilization of the tent formation equalized conditions between the cases with bone level < 5 mm and the cases with bone level > 5 mm. Osteoporosis did not affect the rate of complications, most probably because it does not affect jaw bones as seriously as other bones of the body. A recent study indicated that the trabecular bone structure of the maxilla is not affected by osteoporosis.[16] Perhaps this was the main reason that there were no differences between osteoporotic and nonosteoporotic patients.

At the same time, age-related changes of the facial skeleton might require more efforts in the maintenance phase of implant dentistry. For this purpose, the implant inner channel can serve for delivering drugs inside the bone in cases of inflammatory diseases, fur-

ther bone augmentation in ageing patients, delivering other agents when the bone quality is deteriorating with advanced age, and for endoscopic monitoring of the implant site. It can be hypothesized that the 5-year and 10-year survival rates of the new implants might be very impressive.

CONCLUSION

The preliminary results show that the DIVA simplifies the dental implantation procedure and augmentation procedure treatment. The implant with an inner sealing screw that is used in cases with elevation of the maxillary sinus membrane simplifies the surgery and secures the optimal dental implant placement. The new type of implant simplifies the maintenance phase of implant dentistry.

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Professor Nahlieli is a clinical advisor for Upheal Dental, Givatayim, Israel.

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Dynamic Implant Valve Approach for Dental Implant Procedures

Oded NAHLIELI[1]

Objective: *To present the results of our current research involving the dynamic implant valve approach (DIVA) in cases with human patients.*
Methods: *The new kind of implant was designed with an internal sealing screw that might serve for drug delivery system and possible endoscopic direct observation via its channel. The DIVA was used in cases when the implant insertion should be combined with the maxillary sinus floor lifting and/or bone augmentation procedure. A total of 63 patients (female n = 31, male n = 32, age range 33–67 years old, mean age 49 years old) were treated with DIVA and 218 new type implants were inserted.*
Results: *Out of 218 inserted implants, 146 implants were inserted in the maxilla with bone level < 5 mm, and 72 implants were inserted in the maxilla with bone level > 5 mm. The number of implants per patients varied from one to eight. The failure consisted of seven implants (3.2%) in five patients. No correlation was found between failure cases and the bone density or quality. Follow up (4 to 18 months) showed that in 211 cases (96.8%), the implantation was totally successful both from objective clinical, imaging (cone beam computed tomography) and subjective patients' viewpoints.*
Conclusion: *The new dynamic implant valve approach simplified dental implantation procedure and postoperative treatment. The implant with an inner sealing screw could be considered for use in cases when elevation of the maxillary sinus membrane is needed, as well as in cases when bone augmentation procedures or future treatment might be suspected.*

Key words: *dental implant, maxillary sinus floor lifting, bone augmentation*

When dental restoration began to shift from fixed bridges to dental implants, contemporary dentistry appreciated the importance of anatomy of the maxillary sinus and the bone quality of the maxillary bone. The low position of the maxillary sinus could prevent effective dental implantology below the sinus. Fortunately, it soon became clear that maxillary sinus floor lifting procedure with bone augmentation might help to overcome this problem and dental implantology gained new stimulus. However, despite all recent improvements in dental implantology, complications are still unavoidable in this area of dentistry[1]. While blinded or endoscopically guided, an implant insertion procedure can damage of anatomical structures such as inferior alveolar nerve, other nerves the maxillary sinus, and to lingual perforation[2-4]. Loosening of implant or fracture of the implant head during insertion also can occur[3,5]. The sinus floor lifting/augmentation itself is not perfected yet and also can lead to further complications[6,7].

In the 1980s and '90s, several works of Tatum et al indicated possibilities to combine sinus floor augmentation with implant placement[8-10]. However, inflammatory diseases around the implant area presented a problem that has not yet been solved. This problem only appeared at the beginning of the 1990s[11,12] and was inevitably following the development of implantology. Researchers and clinicians are in need of finding predictable techniques to treat peri-implant bone loss and stop its progression, but up to now their results have

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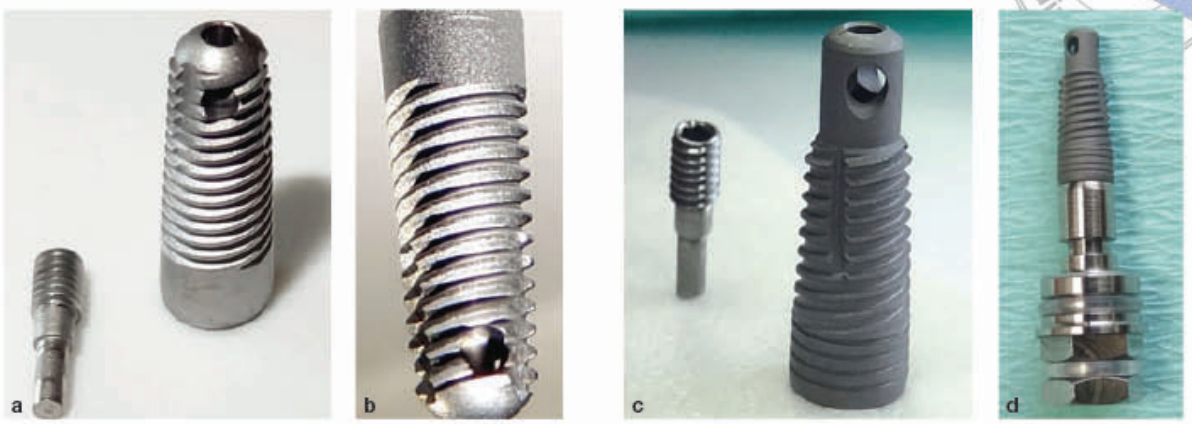

Fig 1a to d The DIVA implants with the internal sealing screw.

Fig 2 Injection of bony substitute via the implant channel.

not been satisfactory[13]. Inflammation due to implant insertion procedures or due to implant relocation can affect the maxillary sinus[14,15], which stresses the need to improve maxillary sinus augmentation.

High demand for minimally invasive procedures led us to invent the implant for a one-stage transcrestal augmentation of the sinus and implant placement. This dynamic implant valve approach (DIVA) (Uplagon Dental) consists of an implant with an inner sealing screw, which facilitates and expedites the closed sinus lift procedure, which further reduces the risk for inadvertently tearing the Schneiderian membrane. This system was tested *in vitro*, and later its feasibility was tested in a large animal model (swine)[16]. The testing revealed that the DIVA can be successfully used for augmentation procedures, especially of the maxillary sinus, in a standard fashion, as well as for intra- or postoperative delivery of therapeutic agents, and in combination with a dental endoscope for direct vision during the procedure. Our current research presents the first results of the DIVA usage in cases with human patients.

Materials and methods

The implant

The Titanium-Aluminum-Vanadium implant (Ti-6Al-4V ELI) was designed with an internal sealing screw that might serve for endoscopic direct observation and as a drug delivery system via its channel (Figs 1 and 2). The implants have external standard platform diameters of 3.25 and 3.75 and were tested in the ISRAC – Israel Laboratory Accreditation Authority for dynamic fatigue test as requested for endosseous dental implants (ISO 14801:2007). As it was said previously, they were successfully tested on the animal model. The additional fatigue test (EndoLab Mechanical Engineering) revealed that the run-out bending moment for the newly proposed implant was above the range reached by dental implants of the predicate devices (metal dental implants with a diameter of 3.75 mm were chosen for comparison). The implants were successfully tested for a possible inner screw leakage during screw-unscrew procedures (leakage sealing test, ISO 11737-2:2009; ISO 11737-1:2006; Milouda SOPs – 200.04.01[16]. In this test, no bacteria growth was detected and the test group and control group met the test's acceptance criteria.

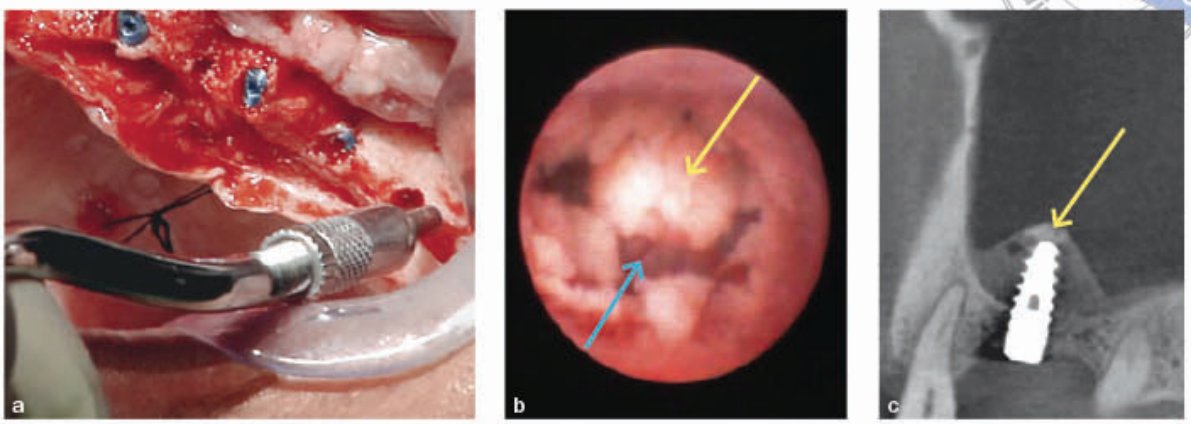

Fig 3 **a** The ostetome technique – preparation of the implant site with 2.7 mm curved osteotome. **b** Endoscopic view following the ostetome technique. The yellow arrow directed to the bony disk, the blue arrow directed to the Schneiderian membrane. **c** CBCT demonstrating the creation of the stable tent with the bony disk supported by the implant (the yellow arrow directed to the bony disk).

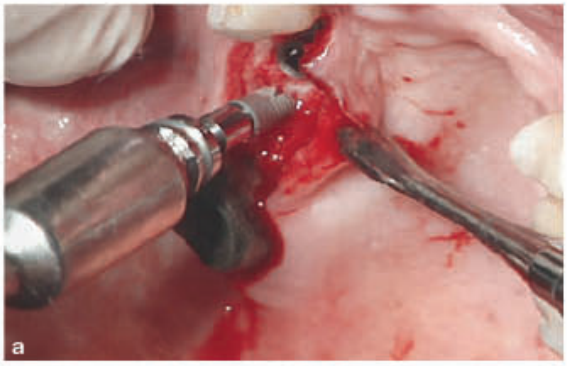

Fig 4a Insertion of the DIVA implant till the implant is stable.

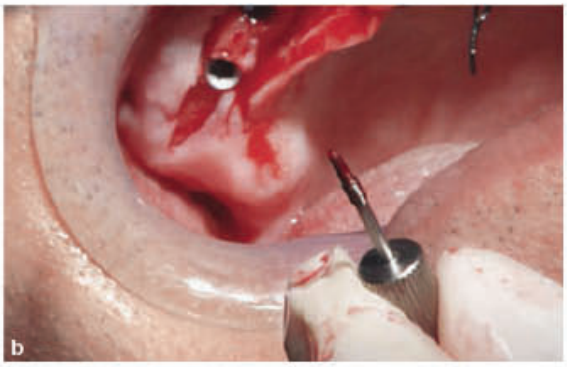

Fig 4b Removal of the sealing screw.

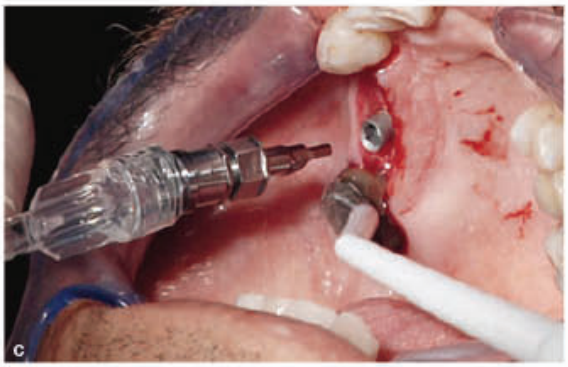

Fig 4c Connection of the DIVA implant to the saline irrigation device.

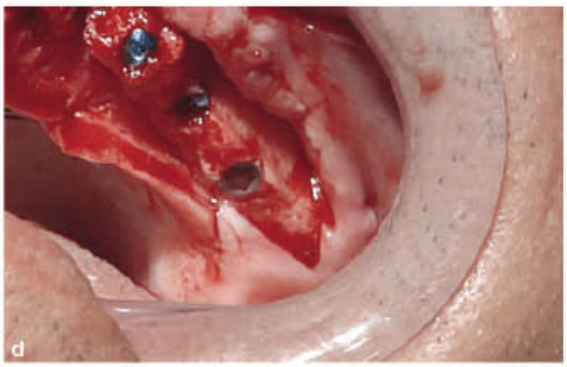

Fig 4d Bleeding sign from the implant coronal side – fracture of the sinus floor.

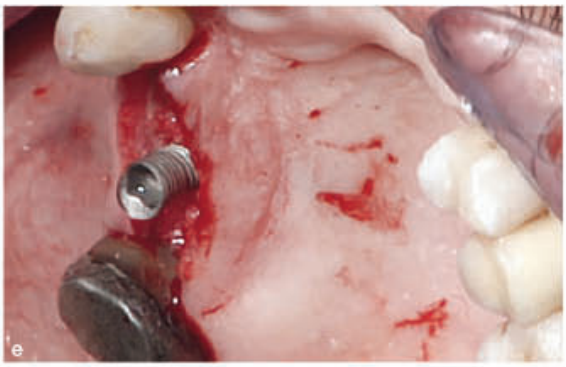

Fig 4e Saline movement according to the respiratory movement.

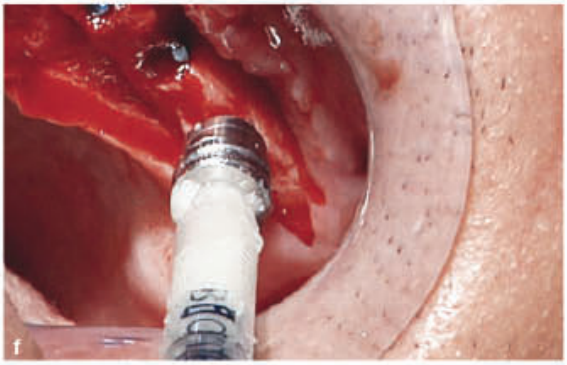

Fig 4f Injection of collagen gel via the implant port.

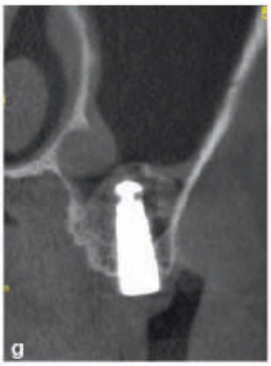

Fig 4g CBCT immediately following the insertion of the DIVA implant, demonstrating the creation of the selective sinus elevation.

The patients

During 2012 and 2013, 63 patients (31 women, 32 men, age range 33 to 67 years, mean age 49 years) were treated with DIVA and 218 new type implants were inserted. The main inclusion criterion was a need for maxillary sinus floor elevation/augmentation to be performed for successful implant insertion. The exclusion criteria were: unhealthy sinuses, thickness of the sinus walls less then 3 mm, and calculated suspicion that primary stability of the implant could not be achieved.

The bone quality of the patients was initially assessed by cone beam computed tomography (CBCT), and CT images were further evaluated by endoscopy during the surgery. The bone density was measured on the CT images by Hounsfield units (HU)[17].

The procedure

The DIVA approach is a minimally invasive approach procedure.

In cases of the bone level being smaller than 5 mm, the operative technique to gain primary stability and to achieve stable tent and bone connected to the sinus membrane was the osteotome technique, first described by Tatum and extensively used since[18-20]. As the first step, we used a 2 mm drill to move up to 1 mm from the sinus floor (according to the CT image). Following the drilling, we used a 2.7 mm curved osteotome to reach 1 mm level from the sinus floor (Figs 3a, 3b and 3c). This technique compressed the crestal bone and created a bone disk that was further transferred to the sinus by the implant slow ratcheting. The next step was to place a 5 mm collagen sponge in the drilling site to protect the membrane of the sinus. The implant (diameter: 3.75 mm; length: 13 mm) was inserted in the bone till the stability is reached (Fig 4a). After that, the internal screw was removed (Fig 4b). That followed by saline irrigation via the internal port; 1 cc of saline followed by 1 mm of slow ratcheting (Fig 4c). This procedure was performed until we reached the level needed for the length of the implant. The bleeding of the sinus floor at the site of a fracture could be seen by a naked eye or by the endoscope that was inserted into the implant (Fig 4d). The integrity of the membrane was evaluated by the respiratory movement of the saline level via the implant coronal space (Fig 4e).

Injection of jelly bony substitute via the inner channel space was an option (6 patients, 10%) after completion of the sinus elevation in flat sinus configuration in order to stabilise the tent formation (Fig 4d). We used 0.5 mL of either liquid Avitene Microfibilar Collagen (BARD Davol RI USA) or microporous biphasic calcium phosphate gel (MBCP, Biomatlantes) for optional augmentation purposes. These gels were delivered through the implant into the sinus (sub-antrally) via the DIVA injection adaptor. The screw was than inserted back and tightened. The procedure ended with ratcheting of the implant and primary closure of the flap (Fig 4f).

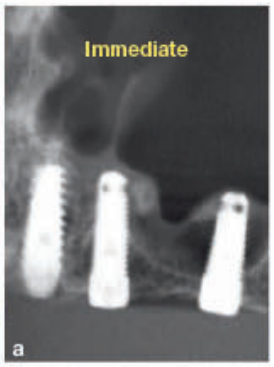

Fig 5a CBCT (sagittal view) of 56-year-old woman immediately after the selective sinus elevation of two DIVA implants and creation of the stable tent.

Fig 5b CBCT (sagittal view) 16 weeks after the procedure, demonstrating the formation of bone in the tent.

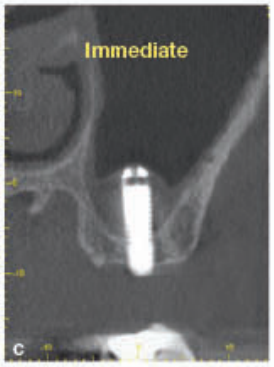

Fig 5c CBCT (coronal view) of the same patient immediately following the procedure.

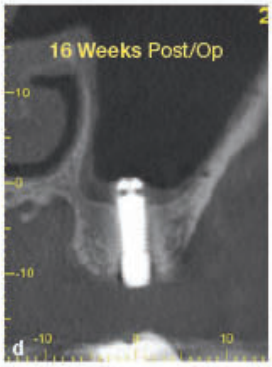

Fig 5d CBCT (coronal view) of the same patient 16 weeks following the procedure, demonstrating the formation of bone in the tent.

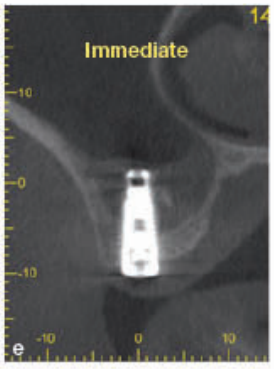

Fig 5e CBCT (coronal view) of 60-year-old man immediately following the procedure.

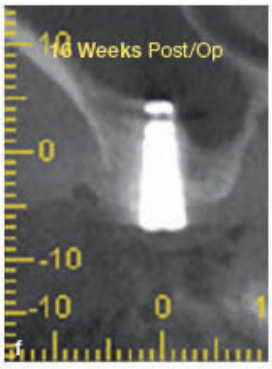

Fig 5f CBCT (coronal view) of the same patient 16 weeks following the procedure, demonstrating the formation of bone in the tent.

In cases of bone level exceeding 5 mm, we used regular drilling technique to reach 1 mm level from the sinus floor and then the same ratcheting and irrigating technique was implemented.

Perioperative antibiotics were administered. The follow-up period was from 1 to 18 months.

Statistics

The Chi-squared test was used to find a possible correlation between the results and the bone quality and density, and between the results and cases when a patient suffered from diabetes and osteoporosis.

Results

Out of 218 inserted implants, 146 implants were inserted in the maxilla with bone level < 5 mm, and 72 implants were inserted in the maxilla with bone level > 5 mm. The number of implants per patient varied from one to eight. The failure consisted of seven implants (3.2%) in five patients. Postoperative follow-up intervals of the patients were carried out after 1, 4, 6, 12 and 18 months. CBCT scans were taken immediately after the procedure and after 4 and 12 months.

Signs of local infection were the main cause of a failure (4 out of 5 patients) and the implants were removed two weeks after the insertion (average). The failure cases were tested for correlation with the bone quality and the bone density. The correlation was negative in both tests (failure vs D3 or D4 bone quality: $r = or < 0.21$, $P < 0.01$; failure vs density in HU: $r = or < 0.17$, $P < 0.01$). Three out of five patients with unsuccessful implantation suffered from diabetes but no statistically sound conclusions might be made because of the small numbers.

During the follow-up period, the assessment was made by taking subjective information from the patient, intraoral clinical observation, and by endoscopic control via the internal port (screw) of the implant. In 211 cases (96.8%), the implantation was totally successful both from objective CBCT clinical and subjective patients' viewpoints (Figs 5a to 5f).

Discussion

The aim of the present study was to report the first results of DIVA implant usage in adult humans after it was successfully tested on animals. While designing the type of the implant, we hypothesised that proper changes in the construction of the implant itself might solve several problems, i.e. 1) to reduce risk of complications; 2) to improve the maxillary sinus floor lifting/augmentation; and 3) to secure proper management of inflammatory diseases, bone loss, and low density bone. Having these three problems in mind, we developed the dynamic implant valve approach (DIVA) for the dental implant procedures that uses an implant with an inner sealing screw. This innovation was put to test successfully and the current article describes the results that we obtained in adult patients.

The current goal of the dental implantation development is to increase the longevity of oral implants by securing proper implant placement into bone of sufficient density. In the maxillary bone, this density varies significantly from 443 to 1,580 HU in various parts of the bone[17]. Hopefully the highest bone density is observed in the canine and premolar areas. It was shown that bone mineral density in the maxilla is significantly lower if compared with the mandible density[21]. Therefore, the bone augmentation is a frequent procedure for the maxilla. Another fundamental cause for differences in the survival of dental implants is that bone quality is also weaker in the maxilla (D3 or D4 types) than in the mandible (D1 and D2 types). Currently, the assessment of bone quality is based on radiographic evaluation, endoscopic observation, and on the subjective sensation of resistance experienced by the surgeon when preparing the implant site.

The first results from the DIVA implant use in cases when elevation of the sinus membrane and/or augmentation procedure of the maxilla were needed revealed that this minimally invasive procedure is simple, rarely requires the lateral open approach, and leads to immediate expansion of the sinus membrane. The procedure itself can be performed with or without endoscopic control, but the endoscopic observation is desirable for bone quality assessment and precise anatomical guidance.

There are several reports in the literature supporting the technique of sinus elevation using stable tent formation and creation of bone via the osteogenic potential of the Schneiderian membrane[18-20,22]. The use of the osteotome technique creates a vital bone disk, which is connected to the Schneiderian membrane and is supported by the DIVA implant. When dealing with narrow or curved sinus topography (the majority of cases) the elevation of the sinus floor with our DIVA implant system irrigation and slow ratcheting technique separates the membrane with the hydro dissection procedure and the ratcheting stretches the membrane without tearing it. Thus, building a tent includes a vascularised bone, the Schneiderian membrane and the blood around the implant that can stabilise the tent. In such a condition, the bone formation takes 4 to 6 months.

In cases of flat sinus configuration, in order to stabilise the tent, bone substitute gel might be injected through the screw channel before sealing the inner channel. This procedure is, however, optional as some studies show that this procedure might not be necessary[22]. The implant channel, however, can serve many purposes, such as delivering drugs inside the bone in cases of inflammatory diseases, further bone augmentation, delivering other agents when the bone quality is poor, and for endoscopic monitoring during and after the procedure. Our previous research using an animal model and the results of the current study led us to believe that the DIVA approach might successfully serve in all three scenarios of the implant insertion:

1) when a sinus floor lift is needed, 2) when bone augmentation is needed, and 3) when floor lifting and bone augmentation are needed for the same patient. The reliability and longevity of medical devices are very important issues. In the case of our new implant, the fatigue tests revealed that hollow structures like the new implant are more fatigue resistant than solid implants because of better force redistribution. The tests also revealed that bacteria cannot penetrate the bone via tight screw while infection, like in cases with any other type of an implant, finds its way in outside the implant. Fortunately, the literature indicates this complication to occur in less than 5% of all implantation cases.

The new approach permits a closed sinus lifting procedure via the implant itself, drug delivery via the implant port, intraosseous feedback via the same port, augmentation procedures via the implant, and endoscopic control over the implant and the surrounding bone during the entire period of the usage of the implant, which are all advantages of the DIVA implant system.

Conclusion

The new dynamic implant valve approach simplified dental implantation procedure and postoperative treatment. The implant with an inner sealing screw could be considered for use in cases when elevation of the maxillary sinus membrane is needed, as well as in cases when bone augmentation procedures or future treatment might be suspected.

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A Novel Dental Implant System with an Internal Port for Endoscopic Closed Sinus Augmentation: A Feasibility Study in Pigs

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Purpose: *This study describes the use of an innovative dynamic implant valve approach (DIVA) for dental implant placement and sinus augmentation procedures.* ***Materials and Methods:*** *The DIVA implant system was tested in vitro for leakage and mechanical fatigue. A closed sinus elevation procedure with a gel-type bone substitute was performed using the DIVA implant in a swine model (n = 6). Implants were placed and evaluated radiographically and histologically.* ***Results:*** *Elevation of the maxillary sinus membrane and augmentation were performed in a simple, minimally invasive fashion. Histologic analyses demonstrated complete sealing of the DIVA implant and excellent osseointegration.* ***Conclusion:*** *The DIVA can be used as a simplified viable option for dental implantation and augmentation procedures. Hermetic sealing of this implant system, which features an inner screw, renders it safe.* Int J Oral Maxillofac Implants 2013;28:e556–e561. doi: 10.11607/jomi.te36

Key words: dental endoscopy, implant dentistry, maxillary sinus elevation

The use of endoscopy in oral and maxillofacial surgery is now considered the state of the art, as it encompasses nearly the full scope of the discipline. Some applications have been in place for more than two decades, whereas more recent technologic advancements have helped to introduce the endoscope to new areas of practice. For example, white light endoscopy has been used routinely for many years for diagnosis of squamous cell carcinoma in the digestive tract/head and neck region. Similarly, in the field of temporomandibular joint diseases, arthroscopy and arthrocentesis have been employed since the 1990s. In contrast, endoscopic or endoscopic-assisted surgery for the treatment of trauma-induced and dentofacial deformities has been suggested only recently. Technologic advancements, which have scaled down the external diameter of the endoscope to less than 1 mm, improved the lens to a 120-degree field/10,000 pixels, and incorporated a flexible nickel-titanium coating, helped bring the dental endoscope to other disciplines in dentistry. For example, newer dental endoscopes, which combine magnification, light, irrigation/suction, and surgical microinstrumentation in one device, are now used in endodontics.[1,2] For the treatment of salivary gland disorders, minimally invasive procedures were first suggested in 1990. Several years later, a miniature, rigid endoscope was introduced for diagnosis and treatment of obstructive sialadenitis. The indications for sialendoscopy include diagnostic purposes, eg, recurrent swelling without an obvious cause, sialolithotomy, identification of strictures or kinks of the ductal system, management of submandibular and parotid sialadenitis by irrigation, and management of recurrent pathology in children

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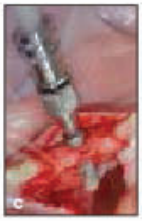

Fig 1a The outer view of the DIVA implant.

Fig 1b The inner sealing screw.

Fig 1c Injection of gel bone substitute through the DIVA implant.

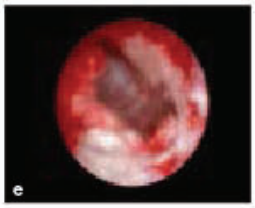

Fig 1d Endoscopic view from the coronal side of the sealing screw.

Fig 1e Endoscopic view of the sinus membrane following drilling.

Fig 1f Periapical view demonstrating the DIVA implant in the canine area of the animal.

(ie, juvenile recurrent parotitis).[3,4] More recently and not unexpectedly, the use of a dental endoscope was also reported in the field of implant dentistry. Endoscopy was suggested as a tool for assessing bone quality and the dimensions of extraction sockets being prepared for implant placement. Additionally, it was reported that a dental endoscope could assist in augmentation of the maxillary sinus.[5]

Augmentation of the maxillary sinus (sinus elevation) is considered an attractive and predictable solution for vertical deficiencies of the posterior maxilla. Nevertheless, some clinicians refrain from using the lateral open technique because of patient discomfort and concern regarding possible infection. Although maxillary sinusitis following implant placement is relatively rare,[6,7] the search for better—and preferably minimally invasive—techniques for sinus elevation continues. Sinus augmentation is performed either in an open lateral technique, under direct visualization, or in a closed transcrestal indirect fashion. Originally described in the 1970s by Tatum,[8] sinus augmentation was later modified to include implant placement in the same procedure.[9,10] Other modifications include osteotome sinus floor elevation[11] and the use of balloon expanders for elevation of the sinus membrane.[12] Previously, the transcrestal approach was recommended only when the residual bone height was greater than 5 mm.[13] This was based on the presumed increased risk of membrane perforation with this technique. A study in cadavers demonstrated that 25% of sinus membrane elevations of 4 to 8 mm resulted in perforations.[14] Although the rate of failed sinus grafts is low,[15] nearly 25% of these failures occur in patients with perforated sinus membranes.[16] Currently, subantral bone height is not the sole determinant for whether implants can be placed simultaneously with sinus floor elevation or whether a staged approach should be preferred.[17] Rather, the possibility of achieving primary stability of the implant determines the sequence of events.

In accord with recent trends in maxillofacial surgery and the high demand for minimally invasive procedures, the present report describes the use of an innovative endoscopic technique—the dynamic implant valve approach (DIVA)—for single-stage transcrestal augmentation of the sinus and implant placement. Furthermore, by means of the endoscope, the procedure is done under direct visualization, which further reduces the risk of inadvertently tearing the sinus membrane. The features of this system were characterized in vitro and its feasibility was tested in a large animal model.

Fig 2a Endoscopic view through the DIVA implant following elevation of the sinus membrane.

Fig 2b View of the injection procedure. The syringe with the DIVA injection adaptor is connected to the implant.

Fig 2c Endoscopic view via the DIVA implant after elevation with collagen gel.

Fig 2d Sagittal view through the animal's maxillary sinus following sinus elevation.

Fig 2e Micro-CT view of the maxillary sinus in the same animal, demonstrating the elevation procedure.

MATERIALS AND METHODS

The implant (titanium-aluminum-vanadium alloy, ELI), designed with an internal sealing screw, serves as a drug delivery system (Fig 1). Temporary removal of its internal screw creates a channel for endoscopic direct vision and for the passage of solutions or gels. Implants with external diameters of 3.25 and 3.75 mm (standard platform) were subjected to dynamic fatigue testing in the ISRAC (Israel Laboratory Accreditation Authority), as required for endosseous dental implants (ISO 14801:2007). Implants were also tested for microbiologic leakage prior to removal of the inner screw and following its replacement (ISO 11737-2, 2009; ISO 11737-1, 2006; Milouda SOPs, 200.04.01).

Animal Experiments

The animal study was approved by the institutional Animal Care and Use Committee. In brief, six adult male domestic pigs (*Sus scrofa*) were placed under general anesthesia via endotracheal intubation and were placed in a supine position for better surgical access. A small full mucoperiosteal flap was elevated at the surgical site, where the bone height was approximately 3 mm, and the sinus floor was reached with standard drills. The sinus membrane was observed with a dental endoscope (Sialotechnology) and elevated from the sinus floor using irrigation with saline. A small 5-mm collagen sponge was placed in the drilling site to protect the sinus membrane. A DIVA implant with a diameter of 3.25 mm and length of 13 mm was screwed with slow ratcheting (5 minutes per implant) up to 1 mm from the final depth of osteotomy. At this stage, the inner sealing screw was removed and the injection system was attached. Then, 0.5 mL of either liquid Avitene microfibrillar collagen (BARD Davol) or microporous biphasic calcium phosphate gel (Biomatlantes) was delivered through the implant into the sinus (subantrally) with the injection adaptor. The sealing screw was then reinserted and tightened. Final ratcheting of the implant and primary closure of the flap followed (Fig 2).

The animal was then placed prone and a mandibular mucoperiosteal flap was elevated in the canine area. Intentional angulated drilling was performed to perforate the lateral aspect of the mandible, and the periosteum was observed with the endoscope. A 3.25- × 13-mm DIVA implant was inserted slowly (5 minutes per implant) to its final depth and the inner sealing screw was removed to allow endoscopic observation of the intact periosteum. Then, 0.5 mL of either Avitene liquid microfibrillar collagen or microporous biphasic calcium phosphate gel was delivered through the implant into the subperiosteal space, and the sealing screw was reinserted and tightened. Primary closure of the flap was performed. Perioperative antibiotics were administered to the animals. Two weeks (one animal) and 2 (one animal), 3 (two animals), and 6 (two animals) months after surgery, the animals were euthanized and their jaws were harvested for micro-cone beam computed tomography (CT) (Acuitomo Morita) and histologic evaluation.

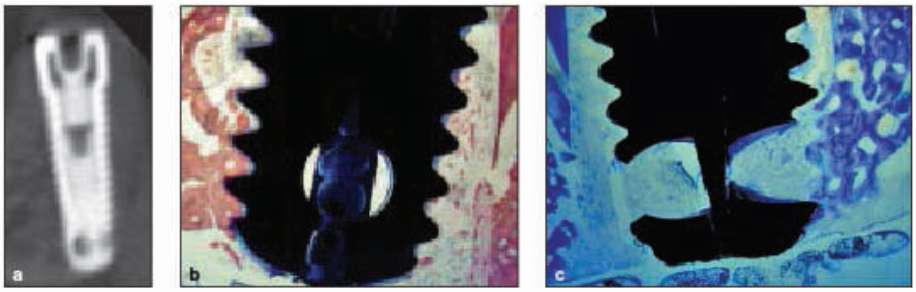

Fig 3a Micro-CT view of the DIVA implant 2 weeks after placement following the augmentation procedure.

Fig 3b and 3c Histologic specimens from the mandibular region *(b)* Hematoxylin-eosin; *(c)* toluidine blue. At 2 weeks, complete sealing of the inner screw and initial osseointegration of the DIVA implant can be observed.

Histologic Analysis

Bone specimens containing the implants were fixed for 7 days in 10% buffered paraformaldehyde, dehydrated in a series of alcohols (24 hours each in 50%, 75%, 95%, and 100%), and embedded in methyl methacrylate. Blocks were then sectioned along a longitudinal plane using a Leica 1600 diamond saw microtome (Ernst Leitz), yielding undecalcified sections of 0.2 mm in thickness. The sections were ground and polished (Struers Dap-7, Struers Tech A/S), stained with hematoxylin-eosin and toluidine blue, and observed under a light microscope.

RESULTS

The implants were tested for mechanical fatigue and leakage. Both the 3.25- and 3.75-mm implants complied with industry standards and were mechanically comparable to other commercially available implant systems, demonstrating that the internal sealing screw does not affect the structural integrity of the implant. Microbiologic leakage tests showed that the sealing screw was tight and provided hermetic closure of the implant, a basic and crucial requirement.

With regard to the bilateral closed sinus elevation and unilateral lateral augmentation of the mandible using the DIVA implant in pigs, the average duration of surgery in the maxilla and mandible was 12 and 15 minutes, respectively. Minimal tears of the sinus membrane were observed endoscopically in 2 of the 12 sites. A typical view from within the implant, during elevation of the sinus membrane, is shown in Fig 2e. CT scans of the jaws containing the implants are presented in Fig 3a. The implants were seen to be intimately connected to the surrounding bone, suggesting adequate osseointegration. The histologic views also demonstrate that the internal screw sealed the implant, in accordance with the in vitro results (Figs 3b and 3c).

DISCUSSION

The aim of the present study was to determine the feasibility of using an endoscopic implant for closed sinus elevation and augmentation. The system's main advantages include: *(1)* direct visualization of the implantation/augmentation site, via an endoscope, during and after the procedure; *(2)* easy delivery of solution or gel through the implant; and *(3)* the ability to use the implant in a standard fashion following reinsertion and tightening of the sealing screw. The DIVA has been shown to be a simple, minimally invasive and relatively expedited method for closed sinus augmentation. The implant is constructed with lateral openings, which can be used not only for augmentation procedures, but also as a drug delivery system, eg, local administration of recombinant human bone morphogenetic protein. Specifically, this design allows for the administration of very high local concentrations of therapeutic agents that could not be achieved otherwise. This feature can be used both intraoperatively and postoperatively.

The DIVA should be further investigated as a possible treatment option for the difficult problem of ailing and failing implants.[18,19]

The system has additional advantages versus the traditional osteotome sinus elevation technique. The endoscopic implant is constructed with a blunt, atraumatic apical end that is designed to minimize membrane tears. As the implant is slowly inserted into its site, concomitant elevation of the sinus membrane will occur. Thus, primary stability is achieved simultaneous to the sinus elevation procedure. In contrast, in the osteotome technique, implant placement is sequential to the sinus elevation, which could compromise implant stability. The 0.9-mm-diameter dental endoscope has an external 2-mm sleeve, which allows its use in a site prepared with a 2-mm pilot drill. This also assists in the preservation of bone, as cortical integrity is maintained. The 20× magnification of the dental endoscope allows for intraoperative visualization of the drill site and the sinus membrane. This assists in the identification of membrane microstructures (eg, vasculature and thickness), ease of detachment and elevation of the membrane from bone, and membrane tears. For example, difficulties in membrane elevation or direct visualization of excessive membrane tears would indicate that an open lateral approach is needed. On the other hand, membrane mobility as seen via the eyepiece of the endoscope is a sign of its health and can serve as an indicator of the probable difficulty (or ease) of a closed endoscopic procedure. Furthermore, the endoscopic view can help clinicians to locate and remove microscopic foreign bodies such as gutta-percha, amalgam, and root remnants that may go undetected with cone beam CT. In contrast to conventional CT, cone beam CT does not allow for the measurement of bone density with Hounsfield units. In the authors' experience, there is occasionally poor correlation between the bone quality as imaged on cone beam CT and the actual endoscopic appearance (data not shown). Thus, intraoperative visualization with an endoscope should assist in clinical decision making.

Traditionally, in vivo studies involving dental implantation in large animals have been carried out in canine and swine models. Although human bone density and fracture stress values are lower than those of canine and swine, these models are well established and widely used. Recently, canines were used in a similar study.[20] The present authors selected swine, although their bone density does not resemble that of humans as closely as canine bone.[21] Nevertheless, since the swine's maxillary sinus resembles the human sinus more closely than the canine sinus, the former was selected.[22]

CONCLUSION

The new dynamic implant valve approach can be used for augmentation procedures, especially of the maxillary sinus. The implant can be used in a standard fashion and also for intraoperative or postoperative delivery of therapeutic agents.

DISCLOSURE

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