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

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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. *(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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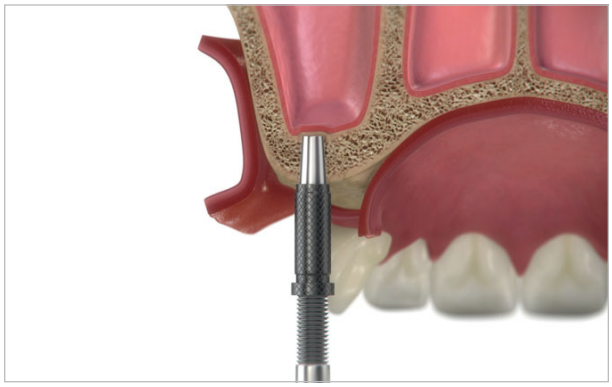

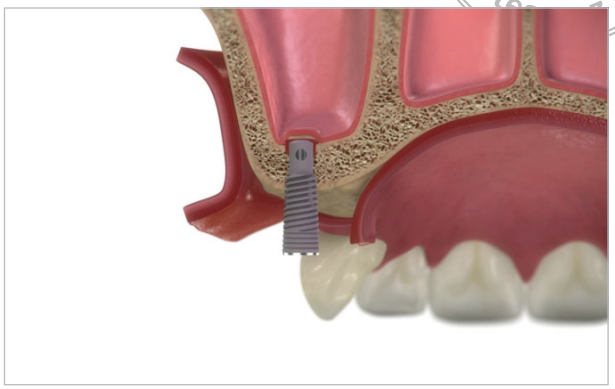

Figs 1a and 1b The DIVA implant is stabilized after the drilling and the osteotomy procedure. Note the separation of the sinus floor.

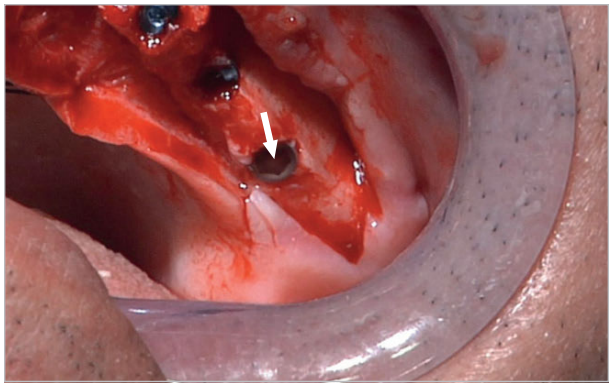

Fig 1c Bleeding from the internal port demonstrates the sinus floor fracture.

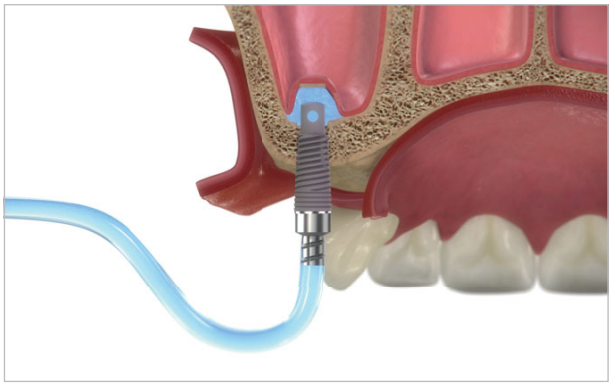

Fig 1d The irrigation via the internal port separates the sinus membrane from the sinus floor.

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

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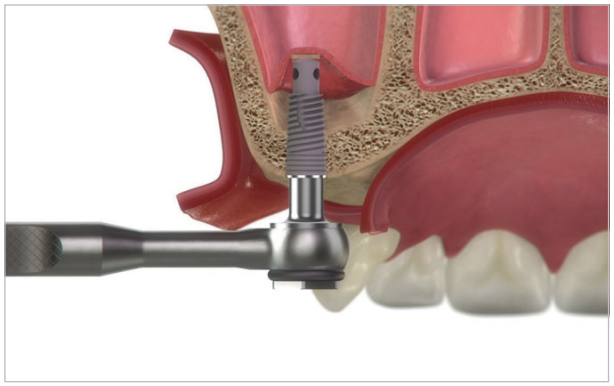


Fig 1e Slow ratcheting elevates the sinus membrane without perforation.

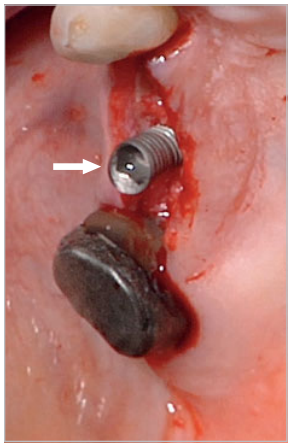
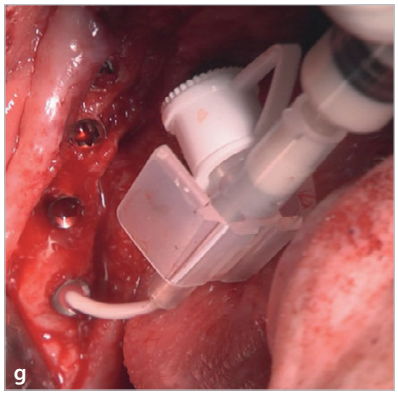
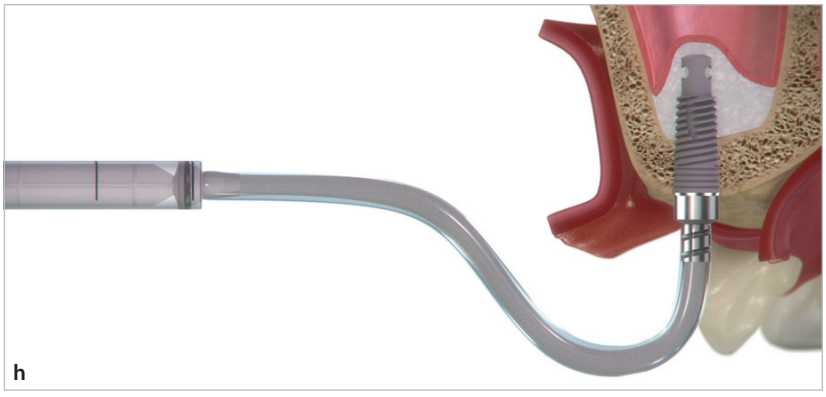


Fig 1f Saline movements in the implant coronal space during respiratory movements show the integrity of the sinus membrane.





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.

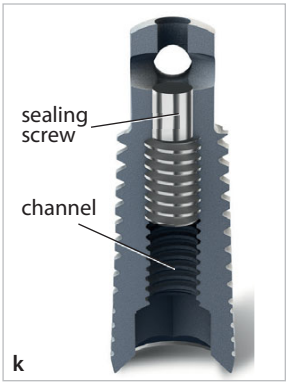


Fig 1j and 1k The sealing screw totally obstructs the channel due to friction and titanium features.

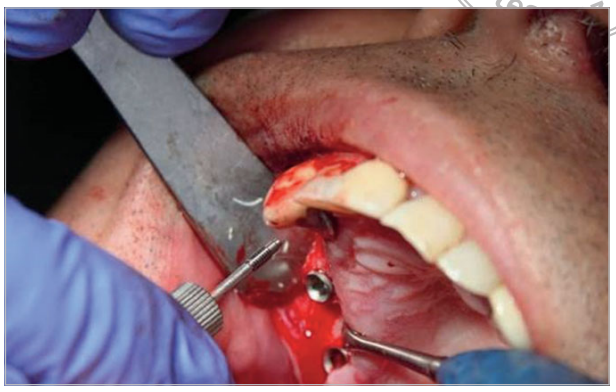


Fig 1l The sealing screw is inserted into the implant channel after completion of the bony substitute gel injection.

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.

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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/cm^2. 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

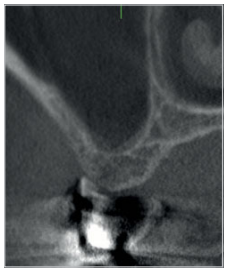

Fig 2a CBCT scan before implantation and the implant installation. Note the bone level of 4 mm.

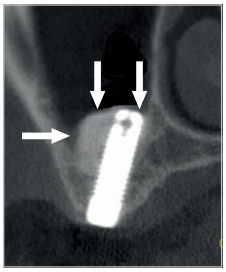

Fig 2b CBCT scan taken immediately after the DIVA implant procedure with sinus elevation and the injection of beta-tricalcium phosphate with hyaluronic acid. Note the perfect elevation of the membrane (arrows).

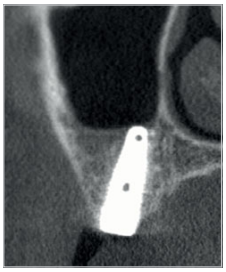

Fig 2c CBCT scan 4 months postoperatively. Note the good bony restoration around the implant.

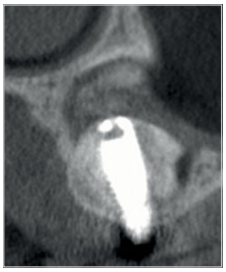

Fig 3a CBCT scan obtained immediately after DIVA implantation and the sinus elevation with the Cerasorb gel.

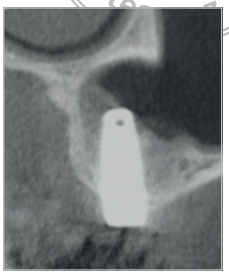

Fig 3b CBCT scan 6 months after the surgery. Note the bony regeneration around the implant.

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-

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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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