

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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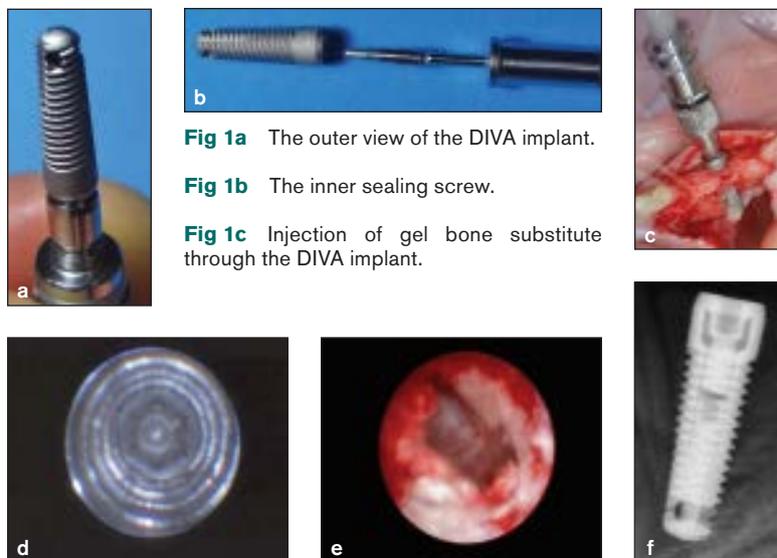


Fig 1a The outer view of the DIVA implant.

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 elevation¹¹ and the use of balloon expanders for elevation of the sinus membrane.¹² Previously, the transcrestal approach was recom-

mended 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.

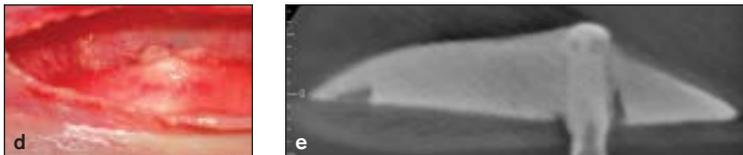


Fig 2d Sagittal view through the animal's maxillary sinus following sinus elevation.

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 (sub-antrally) 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.

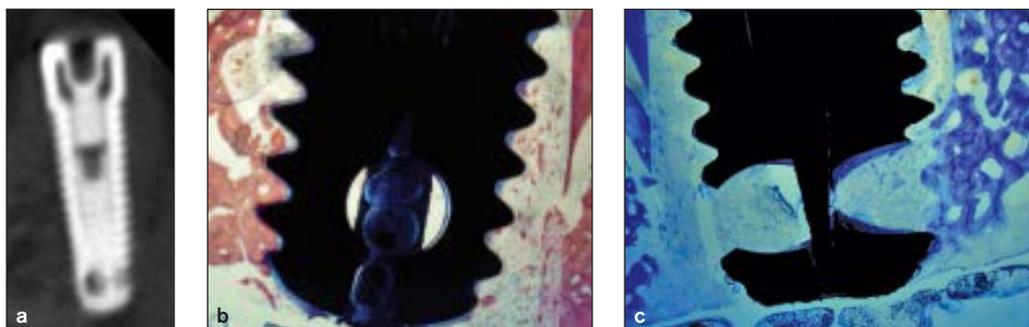


Fig 3a Micro-CT view of the DIVA implant 2 weeks after placement following the augmentation procedure.

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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