ESTHETICS IN IMPLANTOLOGY

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MINIMALLY INVASIVE (FLAPLESS) SINUS FLOOR AUGMENTATION AND IMPLANTATION USING A NOVEL DRILL AND HIGH PRESSURE HYDRAULIC TECHNIQUE (JEDER-SYSTEM®). A TECHNICAL REPORT

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Abstract

Objective: To demonstrate the operational sequence and safe application of a novel technique (Jeder-System®) for minimally invasive sinus floor augmentation (MISFA) by means of a single case operation.

Materials and Methods: Initially, a soft tissue punch (ATP-Punch®) is used at the planned implantation site without mucoperiosteal flap retraction. A blind hole is drilled until approximately 2mm below the sinus floor and the Jeder-drill® is plugged into the bore hole (pressure-sealed). The Jeder-System® consists of the Jeder-drill®, the Jeder-pump®, and a connecting tube-set. The Jeder-pump® generates high hydraulic pressure (1.5 bar) in the pressure-sealed system, thus pushing back the sinus membrane from the drill at the first perforation of the remaining bone. The pump also generates hydraulic vibrations to further raise the membrane from the bone. Ostim® is used as bone grafting material and the implant is placed immediately. Additionally, the Jeder-pump® monitors the whole procedure by constantly measuring pressure and volume of the inserted fluid.

Results: The Jeder-System® enables the dentist to simultaneously perform the operation in a truly minimally invasive way (flapless), achieve a secure first entry into the maxillary sinus, separate the Schneiderian membrane from the sinus floor and safely elevate it in a controlled way. Furthermore, the system documents crucial parameters of the whole procedure in a quantitative way in order to make it reproducible.

Conclusion: Provided that possible contraindications are respected, the operation is linked with high success. The step-by-step procedure makes the minimally invasive procedure effortless while at the same time being safe and predictable. The benefits from a patient's perspective - compared to the classical lateral fenestration technique - are absence of or significantly reduced postoperative pain, hematoma, and swelling. The operating time is reduced, whilst at the same time reducing the risk of membrane rupture.

The lateral window technique using a modified Caldwell-Luc approach still represents the standard procedure for sinus floor augmentation in the posterior maxilla region. However, since considerable pain and swelling are frequently encountered postoperative complications, efforts have been made to develop less invasive techniques which aim at reducing patient discomfort.

In 1986, Tatum (Tatum 1986) suggested a transalveolar technique with subsequent placement of implants. In 1994, the procedure was further developed as an osteotome technique by Summers (Summers 1994). Various modifications of the Summers technique as well as new methods have been conceived and developed over the past 15 years. To safely elevate the sinus membrane, the use of balloons has been reported (Hu, et al. 2009, Kfir, et al. 2009, Rodrigues, et al. 2010). Alternatively, the application of hydraulic pressure (Sotirakis & Gonshor 2005) has been described, and a preliminary cadaveric study using a gel-pressure technique in human cadavers (Pommer & Watzek 2009) has been published recently. Although these techniques provide a safer elevation of the Schneiderian membrane, they do not resolve the problem of the uncontrolled primary entry of the osteotome into the maxillary sinus. This problem has been tackled by Kim et al (Kim 2008) using an "intelligent" drill ("hatch reamer"). However, this technique neither can provide a controlled elevation of the sinus membrane nor can it quantitatively document the procedure. Addressing these problems, Chen and Cha (Chen & Cha 2005) published an 8-year retrospective study evaluating a hydraulic sinus condensing technique. Although membrane perforation was reported in fewer than a half dozen out of 1,100 cases, this procedure is highly operator dependant and therefore does not seem to be suitable for routine use.

To achieve this suitability for routine use, Hochman (Hochman 2009) has suggested 4 criteria that have to be fulfilled simultaneously: (1) minimal invasiveness, (2) secure primary entry into the maxillary sinus, (3) controlled elevation of the Schneiderian membrane, and (4) quantitative documentation of the whole procedure to make it reproducible. The purpose of our technical report is to present a newly developed transalveolar sinus floor augmentation technique that fulfills Hochman's criteria.

Materials and methods / surgical technique

The treatment plan for a minimally invasive sinus floor augmentation (MISFA) using the Jeder-System® should be established based on clinical evaluation and radiographic information from a panoramic radiograph and a dental computed tomography. Exclusion criteria are: residual alveolar ridge height of less than 3mm impeding implantation directly after augmentation; poor bone quality corresponding to type 4 as described by Lekholm and Zarb (Lekholm, et al. 1985) which would result in insufficient primary implant stability; Underwood (Underwood 1910) septa localized in intended implant position; sinus membrane thickness greater than 5mm; maxillary sinusitis or polyposis; poor oral hygiene; hypercortisolism; corticoid treatment; osteoporosis with i.v. bisphosphonate therapy; subjects suffering from severe chronic diseases as well as immunosuppressed patients.

The entire procedure (MISFA and implantation) takes place under local anesthesia. The implants used are screw-type, Ankylos® (Dentsply-Friadent, Mannheim, Germany). These are placed simultaneously (single stage) immediately after MISFA (Karabuda, et al. 2006, Lindenmuller & Lambrecht 2006, Marchetti, et al. 2007, Peleg, et al. 2006). The entire procedure (ATP-Punch® and Jeder-System®) is described in the following 4 steps:

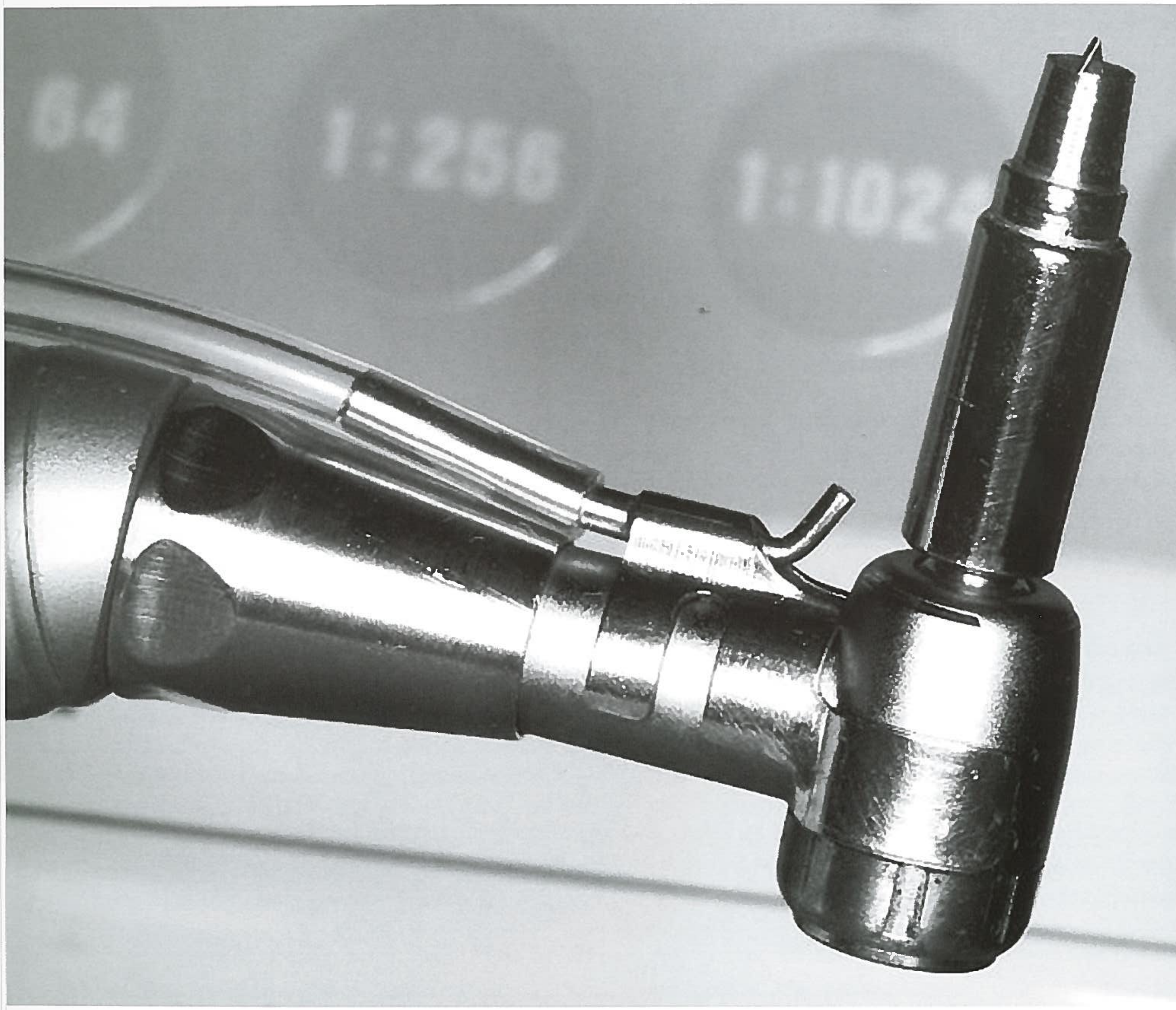

Figure 1. Soft tissue punch (ATP-Punch)

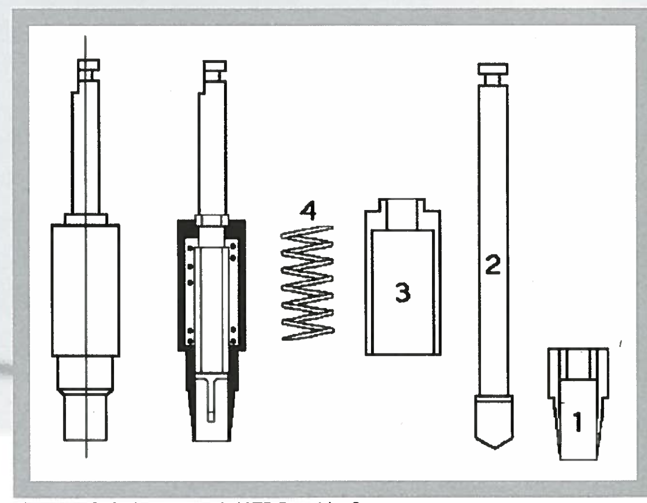

Figure 2. Soft tissue punch (ATP-Punch) - Components

1 Soft tissue punch (ATP-Punch®):

The primary minimally invasive approach to the alveolar crest through the mucoperiosteum is accomplished by using the Atraumatic Transgingival Perforation-Punch, short ATP-Punch® (Dentsply-Friadent, Mannheim; Germany) (Figure 1). The use of the ATP-Punch® ensures that the synthetic sealing element of the Jeder-drill® can be pressed against the mucosa in a pressure-sealed way.

The punch consists of four pieces (Figure 2): rotating blade (1), shredder (2), casing (3), and spring (4). When putting the instrument together, the shredder (2) is put on the rotating blade (1), then the spring (4) is placed on it and followed by the casing (3) that is held in place with a bayonet closure. The blade shreds the mucous membrane cylinder down to the periosteum creating a circular-shaped mucoperiosteal perforation at a diameter of 3.5mm. Arriving at the bone, further pressure is exerted onto the punch making the shredder protrude the rotating blade.

Figure 4. Preoperative dental CT scan

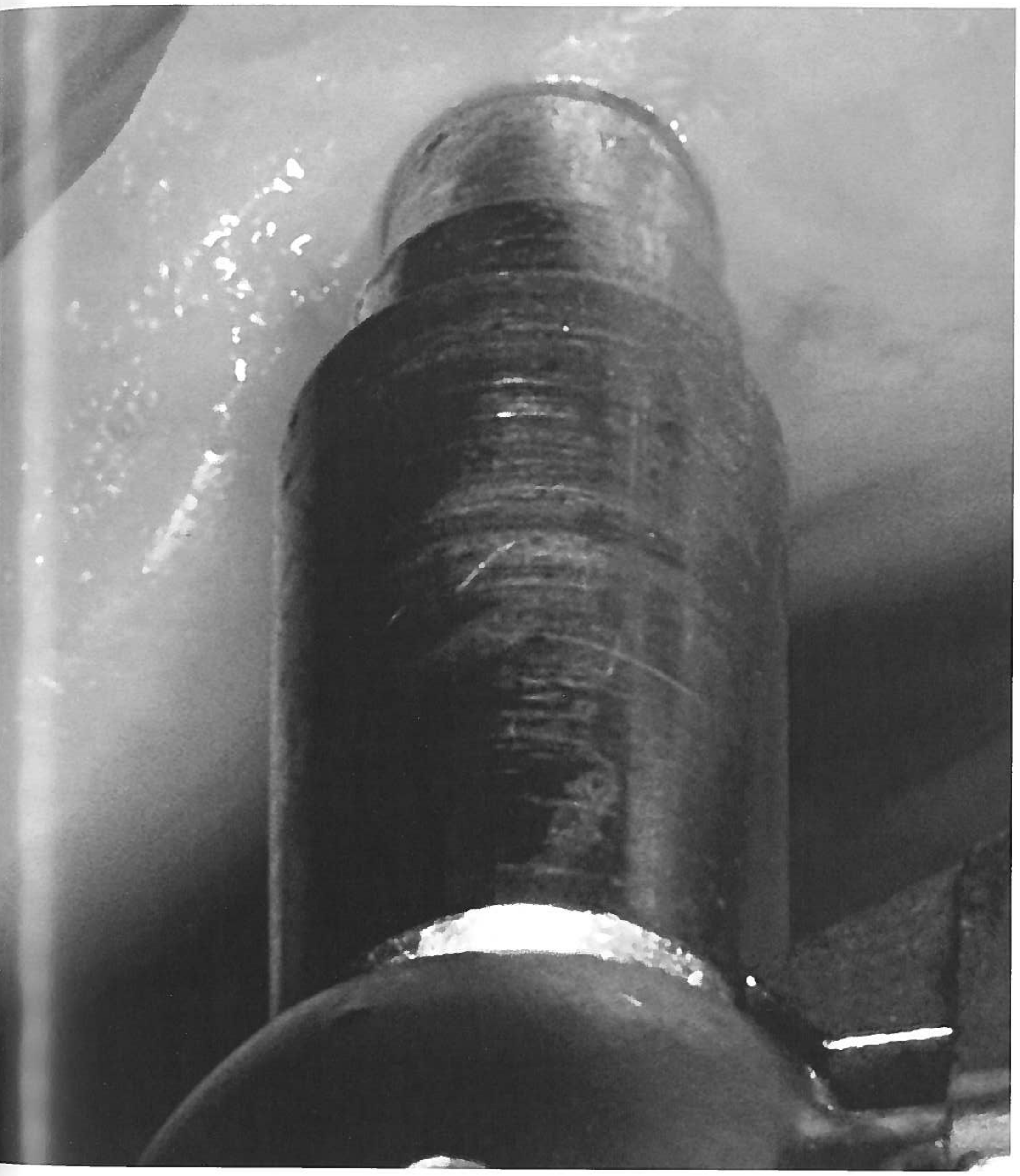

Figure 3. Soft tissue punch (ATP-Punch) - Intraoral

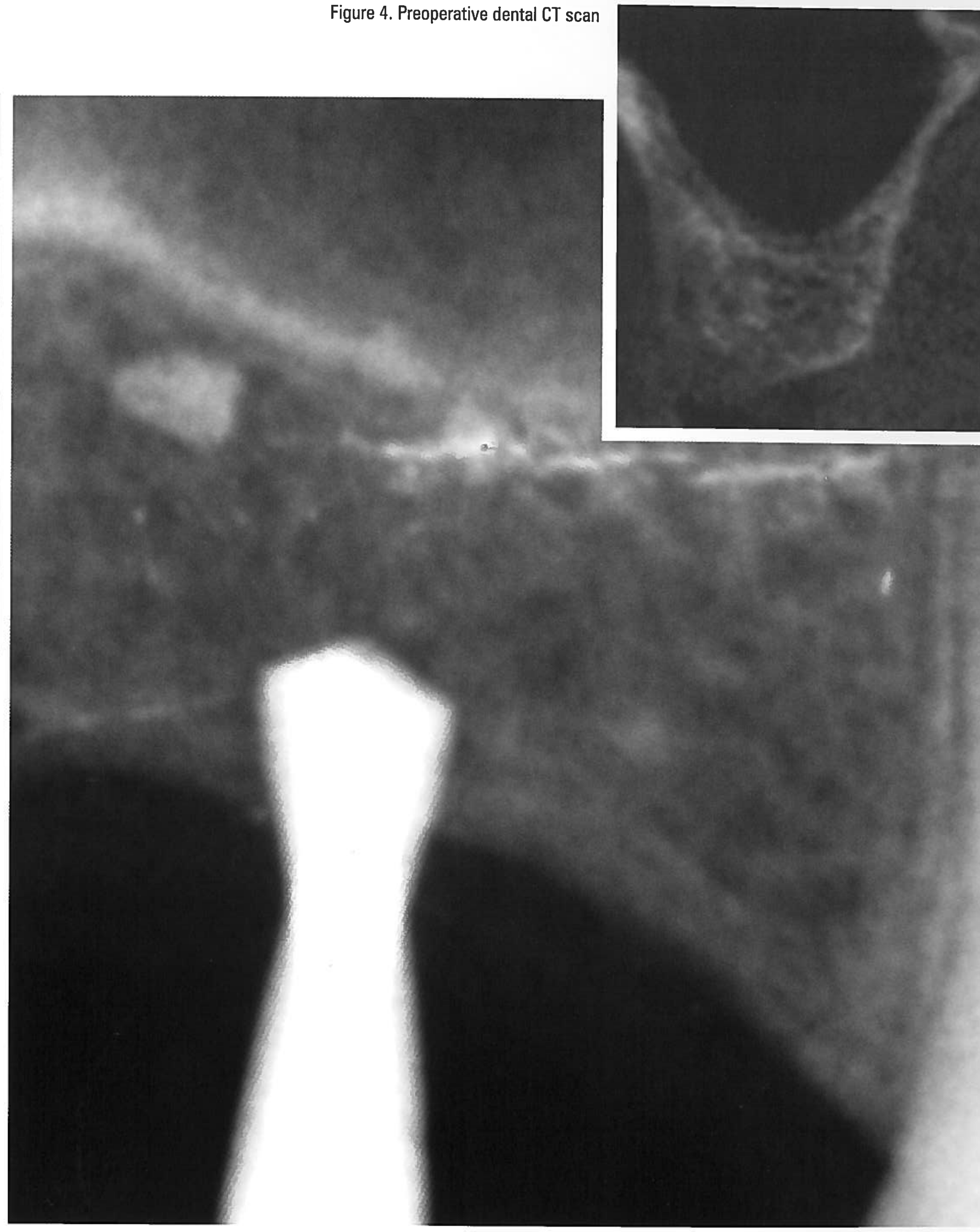

Figure 5. Intraoperative radiograph / Depth verification

This results in shredding the mucoperiosteum whilst at the same time creating a small, circular plateau with a central notch in the cortical bone for easy resting of the primary drill. This process takes place under continuous physiological saline solution cooling. Mucoperiosteal remnants and bone splinters are collected in the upper area of the punch between the rotating blade and the shredder and can be removed after detachment of the punch. Similar approaches to minimal invasive implantation have been described in the past (Hahn 2000, Halpern, et al. 2006, Tee 2011).

2 Primary drill:

After using the ATP-Punch® for the mucoperiosteal transsection (Figure 3), the standard drill procedure for implantation begins. A minimum of 3mm crestal bone at the implantation site is recommended and can be determined with a preoperative dental CT scan (Figure 4). The primary drill is taken to a depth of 1 to 2mm from the sinus floor as measured from the preoperative CT scan. The width of the crestal bone drill hole should remain at about 3 to 3.5mm. To verify depth, an intraoperative radiograph can be done (Figure 5).

Figure 7. The Jeder-drill

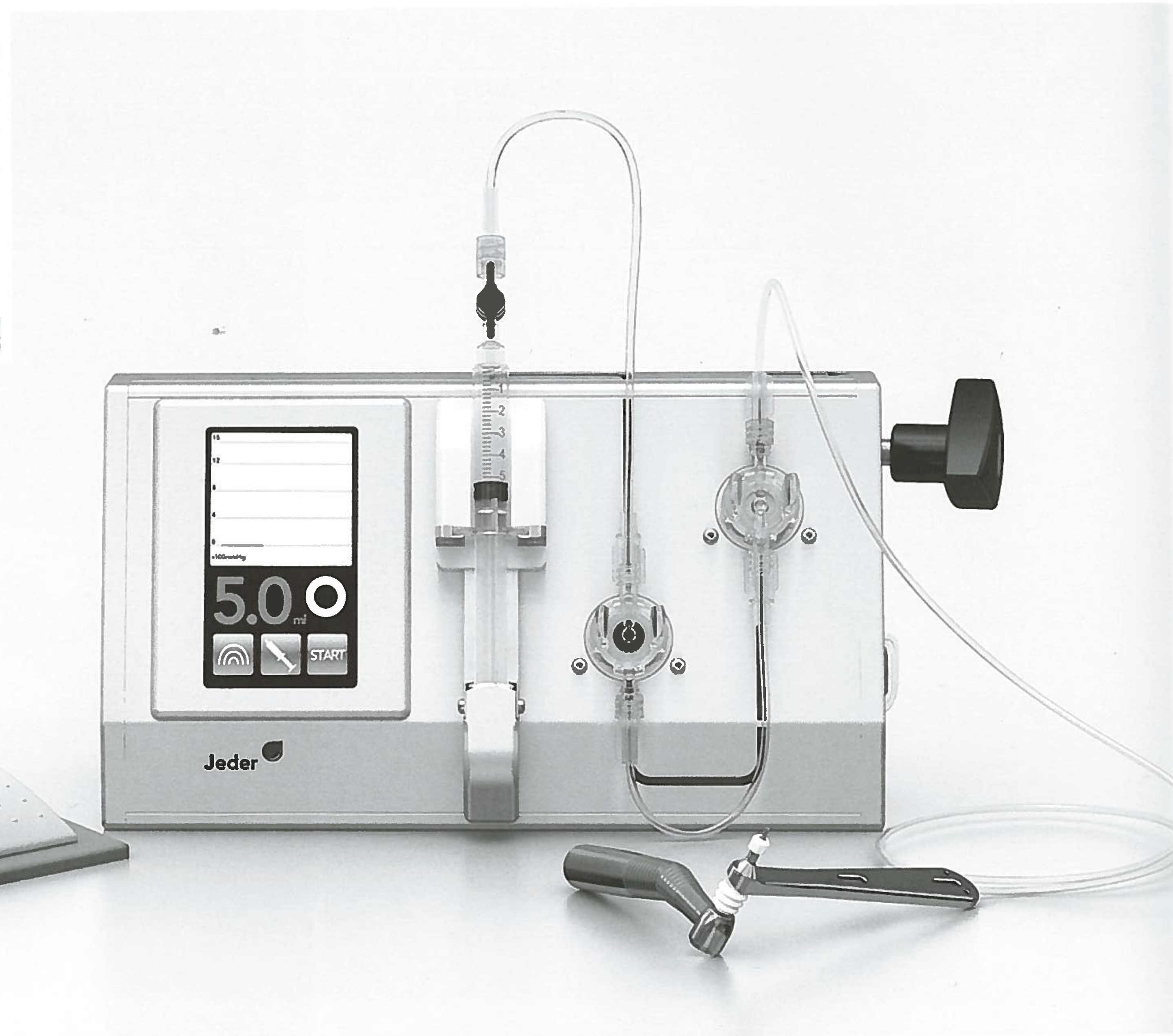

Figure 6. The Jeder-System

3 Jeder-System®:

After this drill procedure is completed, the Jeder-System® (Jeder GmbH, Dental Technology, Vienna, Austria) (Figure 6), is applied. The system consists of the Jeder-drill® (Figure 7), the Jeder-pump® (Figure 8) and a connecting hydraulic tube-set. The Jeder-drill® is the actual surgical tool. The Jeder-pump® generates hydraulic pressure and vibrations while constantly measuring the pressure and volume of the inserted fluid.

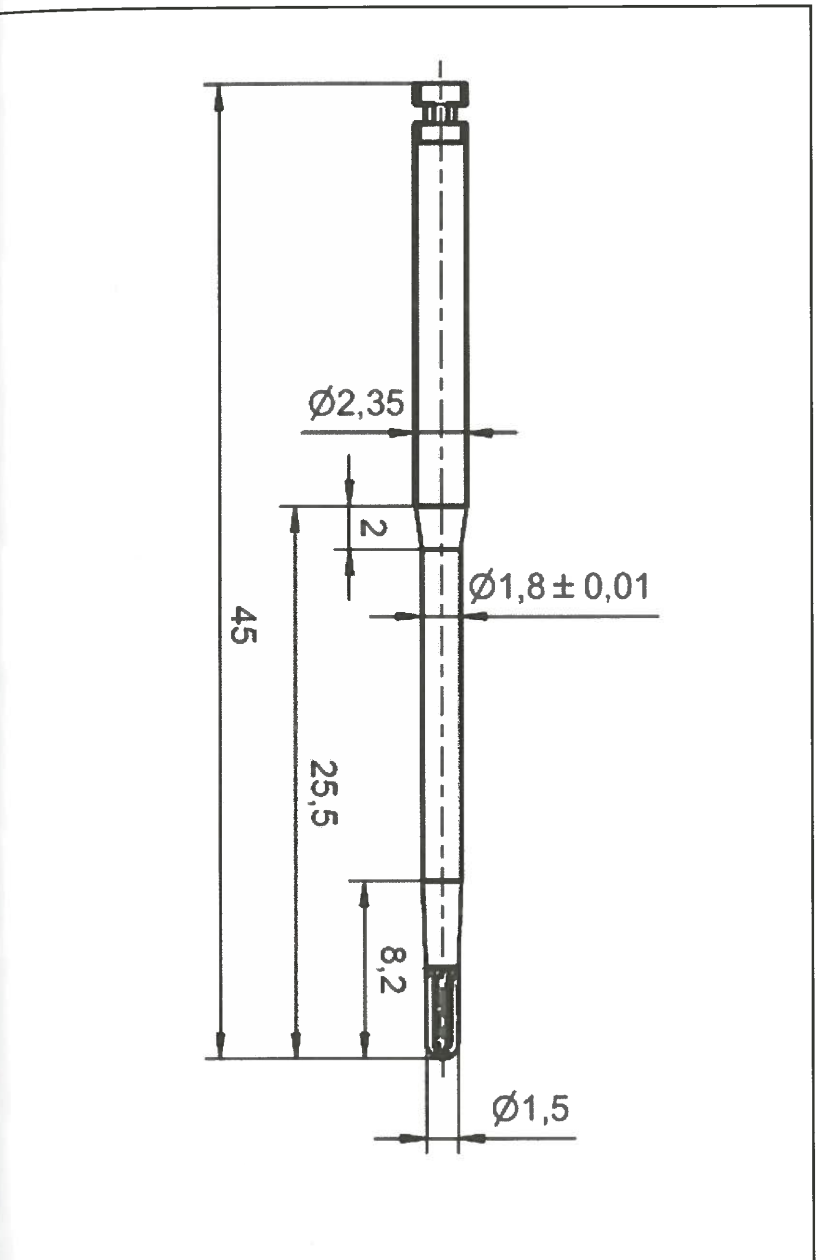

Figure 9. Customized Drill

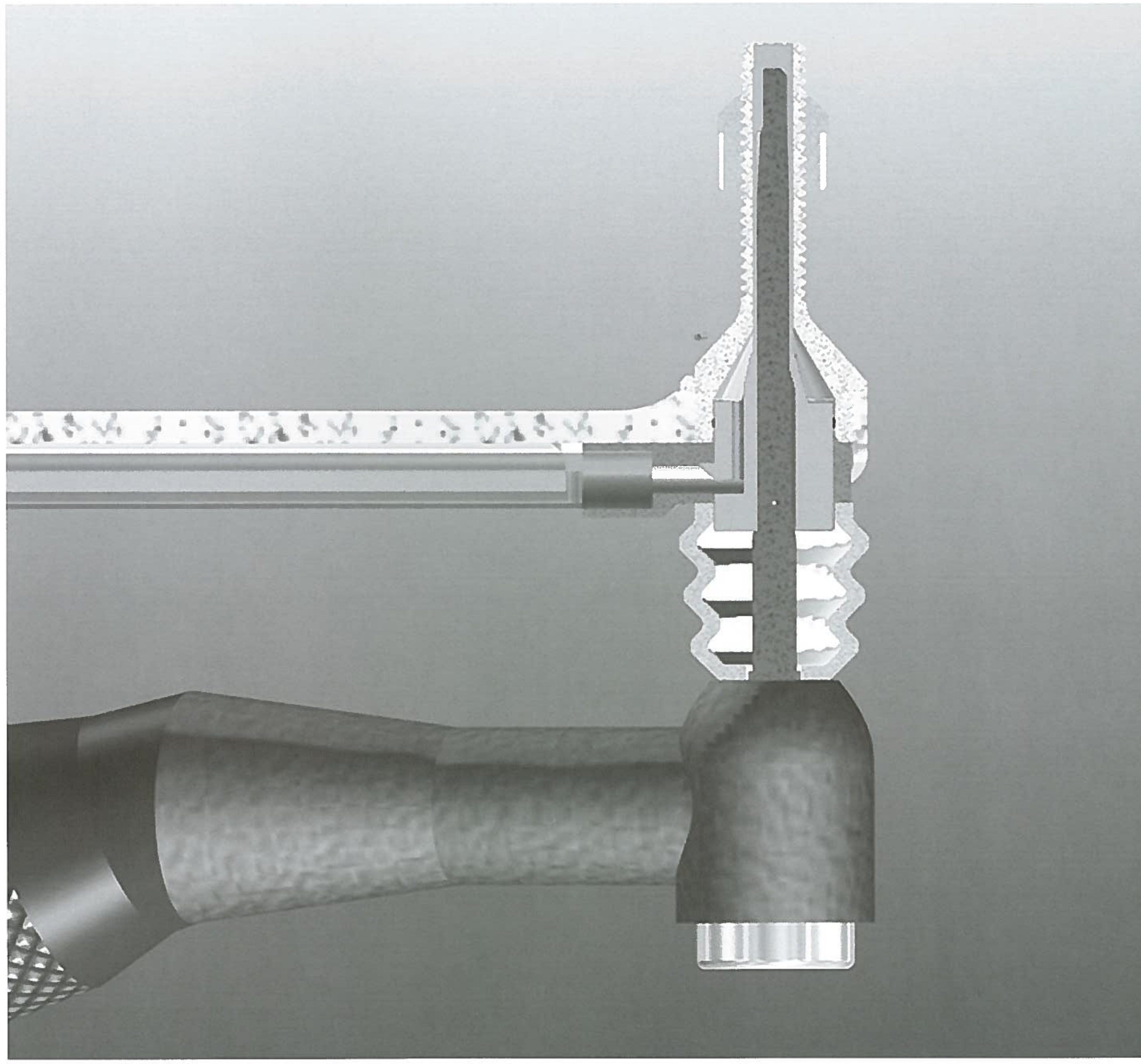

Figure 10. Jeder-drill® hydraulic pressure chamber – Graphic Representation

The Jeder-drill®

After fitting the customized drill (Figure 9) to a standard angle piece, the drill is placed through the Jeder-drill®. At the end of the Jeder-drill's® tubular body is an adjustable synthetic sealing element. This sealing element ensures a pressure-sealed fit between the apparatus and the mucosa. The head of the Jeder-drill® (through which the customized drill is fitted) allows the progression of the drill without causing any loss in pressure and is connected to the tube-set, therefore enabling the saline solution to be pumped into the pressure chamber of the Jeder-drill® (Figure 10).

Figure 12. Jeder-drill® - Intraoral

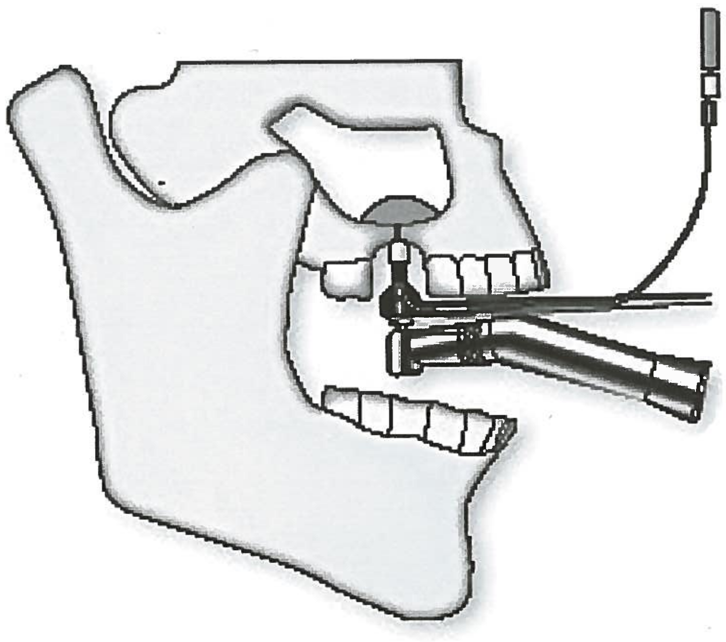

Figure 13. Jeder-pump® visual feed-back control – Pressure Drop

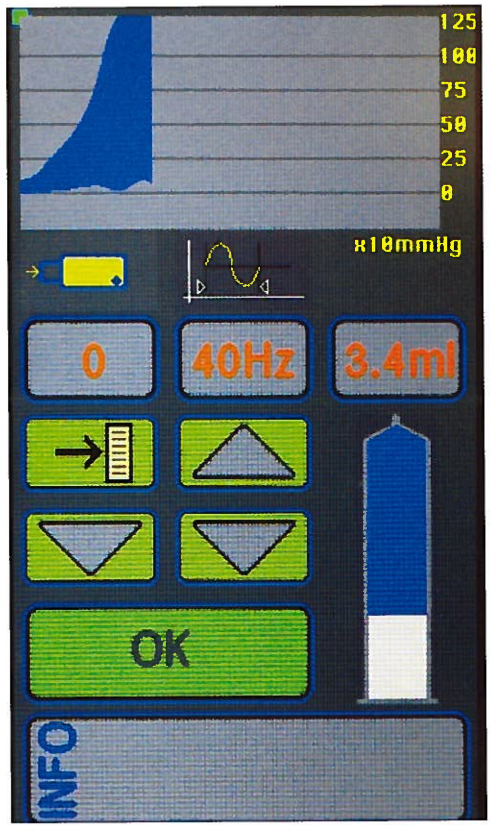

Figure 11. Jeder-pump® visual feed-back control – Pressure Increase

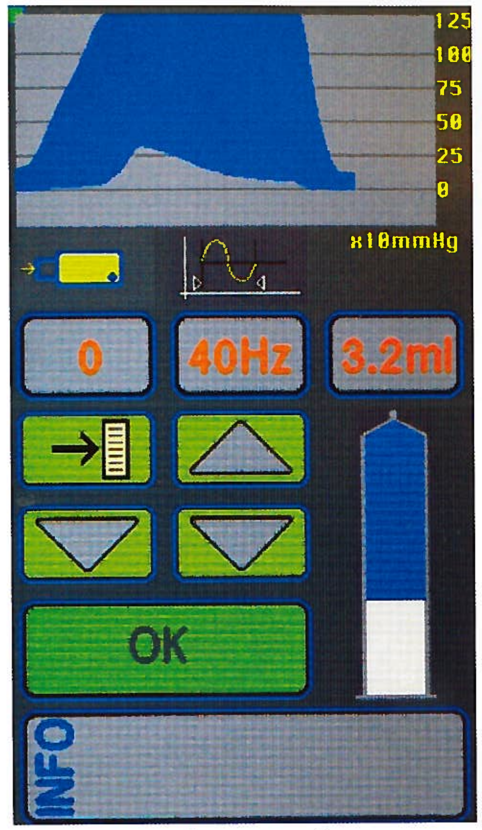

Figure 14. Jeder-drill® + Jeder-pump® creating a cavity filled with saline solution

The Jeder-pump® (Figure 8):

The other end of the hydraulic tube-set is connected to a 5ml syringe via a Luer-lock. The syringe is fitted into the syringe-pump, and the domes for pressure measurement and hydraulic vibration generation are connected. The system is filled with physiological saline solution (Fresenius Kabi Austria GmbH, Graz, Austria). The Jeder-pump® has the following functions:

- pressure generation (~1.5 bar) within the closed hydraulic system by means of volume displacement in increments of 0.2ml er step on the foot pedal (Figure 9).
- real-time monitoring of the pressure increase/decrease on the digital display (Figure11). This is an essential visual aid that helps indicating a successful primary perforation of the sinus floor bone.
- generating hydraulic vibrations in the saline solution (freqency ~5,000 cycles/minute) supporting the detachment of the Schneiderian membrane from the sinus floor.
- electronic data recording for documentation purposes and ex-post analysis.

Once the primary drilling has reached a sufficient depth shortly below the sinus floor, the Jeder-drill® is plugged into the bore (pressure-sealed) (Figure 12). Hydraulic pressure (1.5 bar) and vibrations are generated by the Jeder-pump®. The centrally placed drill within the Jeder-drill® slowly moves through the remaining crestal bone towards the sinus floor. A sudden drop in pressure, indicated on the display, corresponds to a miniscule primary perforation of the sinus floor bone (Figure 13). Due to the high pressure within the hydraulic system, the saline solution rapidly escapes into the area of low pressure through the miniscule primary bone perforation in the sinus floor. The Schneiderian membrane is pushed away, creating a cavity filled with saline solution (Figure14). The pursuing drill does not damage the membrane since the saline solution pushes the membrane away from harm. Since this drop in pressure is indicated on the display, the surgeon can abruptly stop the drill procedure. Once the primary entry into the maxillary sinus has been achieved, pumping additional saline solution into the cavity will not result in a significant pressure increase on the display, as the membrane is flexible in contrast to the sinus floor bone.


Figure 15. Application of bone grafting material

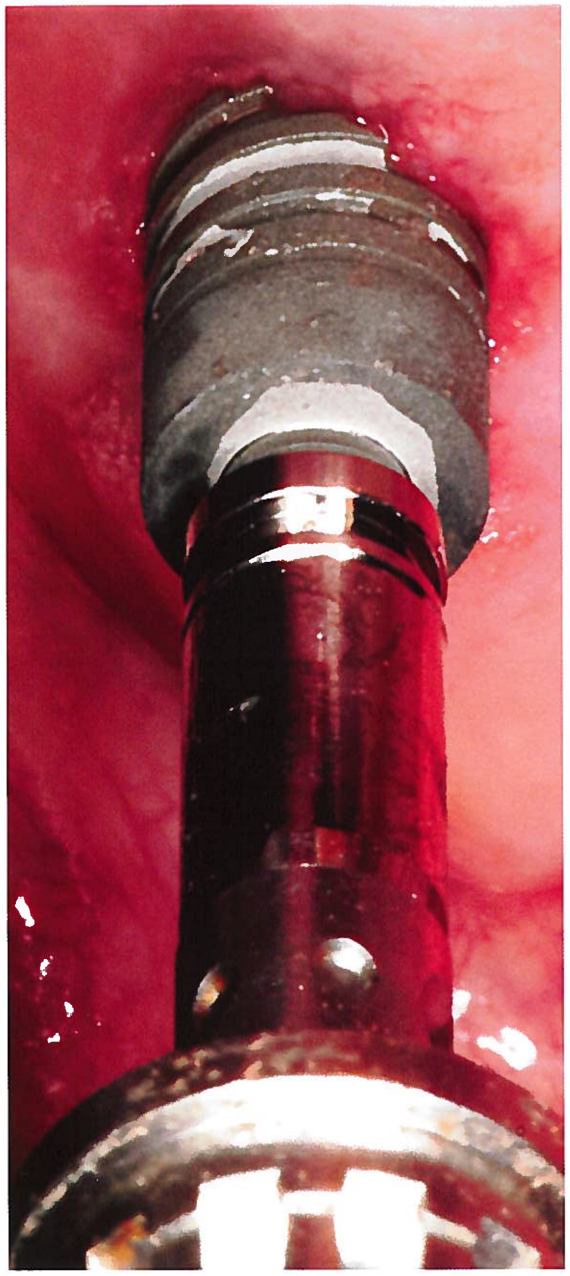
Figure 16. Immediate implant placement

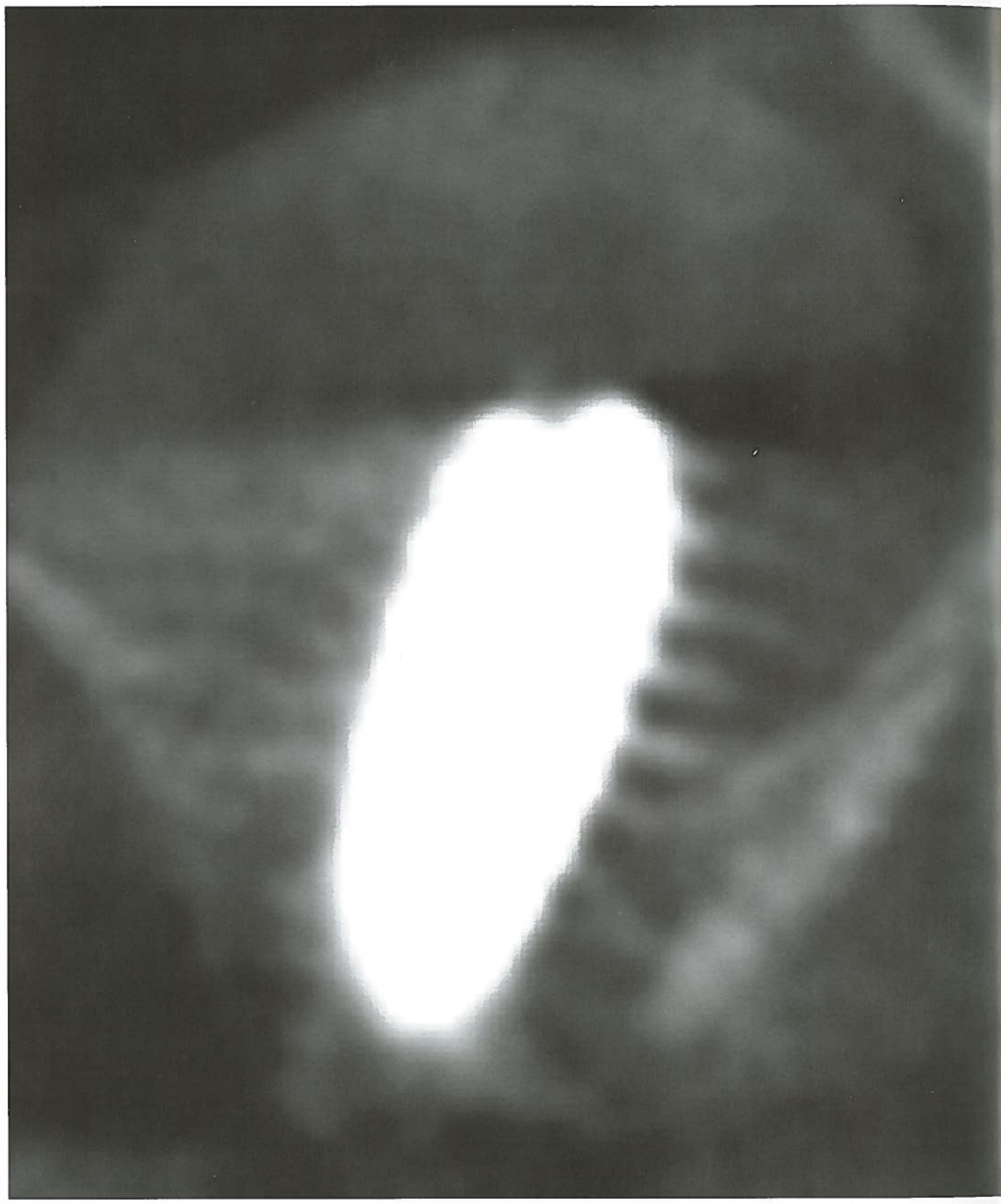
Figure 17. Postoperative dental CT scan

4 Augmentation and Implantation:

A sub-membrane cavity volume of 0.5mm3 to 1.5mm3 between membrane and sinus floor is created by adding saline solution in increments of 0.2 ml per step on the foot pedal. The surgeon can see the exact volume of inserted fluid on the display of the Jeder-pump®. This allows a prediction as to how much bone grafting material can be safely applied. To support the gentle lifting of the membrane, the Jeder-pump® also generates hydraulic vibrations to further separate the membrane from the bone. Once the desired volume of fluid is reached (usually not more than 1.5ml), the saline solution is extracted using the second pedal of the Jeder-pump® (0.2ml per step).

The crestal drill hole is now enlarged to accommodate the appropriate implant diameter. Once this has been done, the bone grafting material Ostim® (Heraeus Kulzer, Hanau, Germany) is applied (Figure 15). Although any bone grafting material can be applied, the paste-like property of Ostim® allows a simple application through the small crestal opening. Immediately after MISFA, an implant with appropriate diameter is placed (Figure 16). A postoperative dental CT scan documents a successful augmentation and immediate implant placement (Figure 17).

Discussion

The main finding of this technical report is that transalveolar sinus floor augmentation using the Jeder-System® is a safe and effective method and has several advantages in comparison to other approaches. As Hochman (Hochman 2009) has pointed out, current techniques for sinus elevation show deficiencies and limitations relating primarily to the ability of the dentist to simultaneously:

1. perform the surgical procedure in a minimally invasive way,
2. achieve a secure first entry into the maxillary sinus,
3. separate and elevate the Schneiderian membrane in a controlled and safe way, and
4. document the procedure in a quantitative way in order to make it reproducible and significantly shorten the learning curve.

Figure 18 compares current techniques for sinus elevation to the new technique on those 4 dimensions: the lateral window technique is clearly not minimally invasive and therefore cannot fulfill all 4 criteria simultaneously. All crestal procedures are considered minimally invasive, although many of those techniques are not flapless and therefore significantly more invasive (incisions, sutures) than a flapless approach. All procedures using an osteotome for first entry into the maxillary sinus (Hu, Lin, Metzmacher & Zhang 2009, Kfir, Goldstein, Yerushalmi, Rafaelov, Mazor, Kfir & Kaluski 2009, Rodrigues, Katayama & Cardoso 2010) are considered to not fulfill the second criterion ("secure first entry"), as they use a non-controllable fracture of the maxillary bone. "Intelligent" drills (Kim, et al. 2010, Kim 2008) are considered to fulfill the second criterion, but the drills cannot further lift the Schneiderian membrane and the results of those approaches are not quantifiable and therefore hard to reproduce (i.e., operator dependant). The Hydraulic Sinus Condensing Technique (Chen & Cha 2005) has multiple deficiencies owing primarily to the inability to control the pressure and forces applied as a result of the lack of precision of this technique (Hochman 2009).

	Criteria / Technology/product	Minimally invasive	Secure first entry	Gentle membrane lifting	Quantifiable results
	Classic sinus lift (Caldwell-Luc)	✗	✗ up to 60% perforation rate	✗ up to 60% perforation rate	✗ result not quantifiable
Crestale procedures	Osteotom & Ballor Sinus Lift Ba Icon* BallconLift Control**	✓	✗ non-conrtollable fracture	✓ direct contact	✗ result not quantifiable
Crestale procedures	„Intelligent" drills: Hatch Reamer MISE Set*	✓	✓	✗ Drill cannot lift membrane	✗ result not quantifiable
Crestale procedures	Drill & hydraulic Pressure: Hydraulic Sinus Condesing technique	✓	✓ Depending on skills of dentist, no reasurement	✗ Depending on skills of dentist, no reasurement	✗ result not quantifiable
Crestale procedures	Jader System	✓	✓ High pressure makes membrane „flee" from drill	✓ Aven pressure distribution (Achimed.), „percussion drill"	✓ Constant monitoring of pressure & volume during procedure

Figure 18. Comparison to other minimally invasive sinus lift systems

* Osseous Technologies of America USA ** Hager & Meisinger, Germany ***Dental Implant Institute of Las Vegas Source: Company webpages/flyers, Jader Gmbh analysis

The Jeder-System®, however, can fulfill all 4 criteria simultaneously. The approach is flapless and therefore truly minimally invasive. The secure first entry into the sinus is assured by high hydraulic pressure making the membrane "flee" from the drill. The third criterion, gentle membrane lifting, is also met: due to the optimized force transmission of the saline solution according to Pascal's principle, point forces that might exceed the elastic properties of the sinus membrane are avoided. Finally, by constantly measuring pressure and volume during the procedure and recording these data for ex-post analysis, the technique is reproducible to a high extent.

Compared to the conventional lateral fenestration, the main advantages of the new method are:

- significant reduction of risk of membrane rupture
- less/no swelling
- less/no discoloration (hematoma)
- less/no risk of wound dehiscence
- shorter/simplified surgical procedure
- less pain or discomfort after operation
- no suture

A limitation with the system is the lack of direct visual control. Yet, as with any minimally invasive procedure, an arthroscopic camera can be used adjacently, if required. Another possible limitation is that no long term results are available yet due to the novelty of the Jeder-System®. Furthermore, as with many other indications involving dental implants, the anatomy is crucial and exclusion criteria (see above) have to be observed.

Conclusions

The main aim to decrease postoperative pain for patients can only be achieved by decreasing operative trauma. This in turn can only be achieved by a minimally invasive approach during both augmentation and implantation. This novel surgical technique to a large extent avoids intraoperative trauma, and also significantly decreases the risk of Schneiderian membrane rupture – a key factor for success. Compared to other approaches, the Jeder-System® is truly minimally invasive. Yet, most importantly, it also provides visual feed-back (display) on the status of the procedure. This visual feed-back is probably the most essential information for the surgeon and often lacking in other minimally invasive approaches. If the exclusion criteria are respected, this novel technique can be applied safely and successfully.

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