



Treatment of Maxillary Sinusitis Using the SinuSys AerOs™ Sinus Dilation System

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INTRODUCTION

Establishment of patency of the sinus ostia is paramount to the treatment of chronic sinusitis. Endoscopic sinus surgery has been shown to be effective in accomplishing this. Recently, catheter based balloon dilation has been introduced as an alternative method to open the sinus ostia and have demonstrated clinical success. SinuSys Corporation (Palo Alto, California USA) have developed an osmotically driven, self-expanding dilation device to expand the sinus ostia.

SINUSYS OSMOTIC TECHNOLOGY THE AerOs SINUS DILATION SYSTEM

SinuSys' proprietary dilation is comprised of osmotic elements encapsulated in the semi-permeable, expandable membrane (*Figure 1*). When the dilation device is placed into the target ostium, it starts to expand due to uptake of surrounding fluid (approximately 150 μ L). It expands gradually from an initial diameter of 3mm to a final diameter of 5mm in 60 minutes at a pressure of 2.9 atmospheres (42 psi), resulting in ostium dilation and remodeling.

The SinuSys AerOs Sinus Dilation System is provided sterile with the dilation device preloaded in the placement instrument (*Figure 2*). The placement instrument accesses the sinus ostium of the sinus through the nasal passageway and delivers the dilation device into the ostium. The dilation device resides in the ostium for about 60 minutes, after which the dilation device is removed.

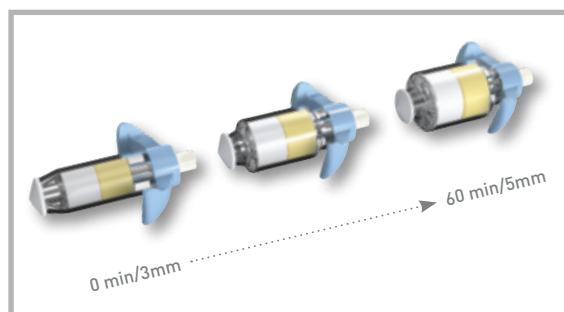


Figure 1: SinuSys' unique osmotic self-expanding technology provides gradual, low-pressure dilation to 5mm in about 60 minutes.



Figure 2: The simple design of the AerOs Sinus Dilation System makes the device compatible with office-based procedures performed under local anesthesia.

PRE-CLINICAL STUDY RESULTS

This study evaluated two different expansion rate devices (1-hour and 4-hours) with respect to their ability to safely and effectively dilate the ostium. The studies were conducted in the adult Dorper sheep model. The outcomes with 1-hour devices were evaluated 1 hour post-treatment and the outcomes for the 4-hour devices were evaluated 4, 6 and 15 hours post-placement as well as at 13 and 27 days post-treatment. Data provided demonstrates that both devices were able to dilate *in vivo* to produce a patent ostia. A strong correlation was established between post-expansion diameter of the dilation device and the final diameter of the ostium for both devices, suggesting that there is no acute recoil post-treatment (Figure 3).

Furthermore, endoscopic evaluation of the 4-hour devices revealed no sign of mucosal injury post-treatment and the openings remained patent for at least 27 days (Figure 4), providing encouraging results for long term efficacy¹.

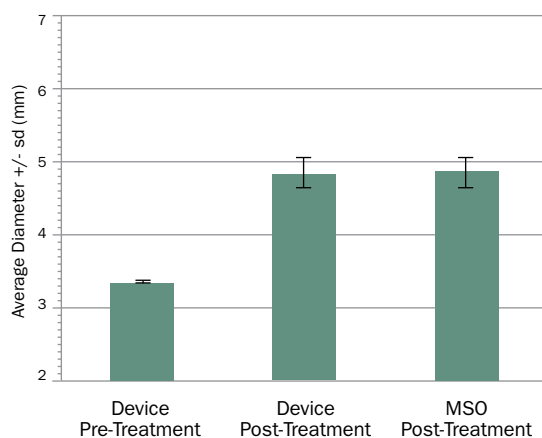


Figure 3: Changes in 1-hour dilation device diameter in relation to sinus diameter (ovine model).

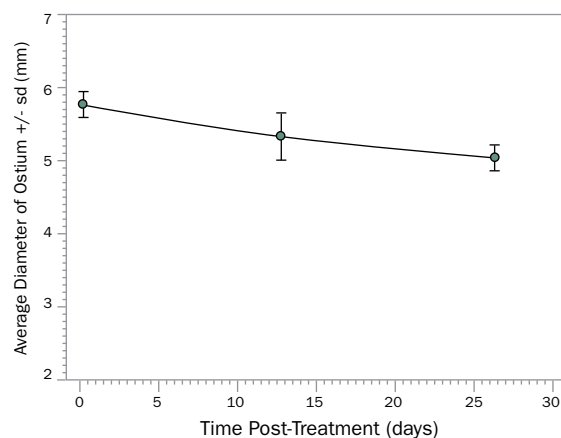


Figure 4: Patency of ovine model ostium immediately after treatment, 13 days, and 27 days after treatment (4-hour device.)

PATIENT SELECTION

The AerOs device is designed for the treatment of chronic sinusitis which has failed medical management. It can be used for patients in whom dilation of the ostium to provide ventilation and drainage is indicated.

Contraindications include any anatomic abnormality that precludes access to the maxillary sinus ostium (e.g. deviated septum); history of facial trauma that resulted in distortion of the nasal and/or sinus anatomy; or diagnosis of medical or hematologic diseases which could preclude even a minimally invasive procedure.

Through nasal endoscopy and imaging studies, the physician will assess the anatomy of the nasal septum, uncinate process, and ethmoid bulla to determine accessibility for the placement of the device. Prominence of any of these structures may preclude placement.

The low-pressure, gradual expansion and the simplicity of the device make it compatible with use in office-based procedures under local anesthesia. In-office placement of the AerOs device may be used for isolated chronic maxillary sinus disease. In addition, treatment of recurrent acute sinusitis can also be performed to reduce or eliminate the need for recurrent medical management. In the post-operative patient, the AerOs system can be used to dilate and manage sinus openings to prevent stenosis.

TECHNIQUE

The AerOs Dilation System should be presented and maintained sterile. Appropriate nasal endoscopy equipment should be present and in working order. Endoscopic sinus surgery instrumentation such as grasping forceps and suction should be available.

Setup and Patient Preparation

In the operating room, the use of general anesthesia or sedation will be determined by the surgeon and anesthesiologist. The application of topical and/or infiltrative anesthesia and vasoconstriction is per the surgeon's practice.

In the office setting, a stepwise approach to maximize patient comfort and acceptance of the procedure is desirable. It is important to educate patients on the steps involved in the in-office placement of the AerOs device. Concerns by the physician or patient regarding the procedure and the patient's ability to tolerate and complete the procedure should be evaluated before deciding to proceed. Although SinuSys does not recommend a specific protocol, the use of both topical and infiltrative anesthesia and vasoconstriction may be necessary as well as oral anxiolytics in specific patients. Device expansion will require 1 hour; in the office setting, the patient can be allowed to wait comfortably until the device is removed.

Device Insertion

- 1) Enter the nasal cavity with the device oriented vertically and the device tip superiorly.



- 2) Rotate the device just posterior to the uncinate, using the tip to gently lift up the uncinate.



- 3) Continue to rotate the device to angle the tip slightly inferiorly.



- 4) Exert gentle pressure to palpate the lateral wall and find the natural ostium.



- 5) Once found, engage the device completely with further gentle lateral pressure and release the device.



Device expansion requires 1 hour. In the operating room, the remainder of the operating procedure can be performed during this time. In the office setting, the patient can be allowed to wait comfortably until removal.

Device Removal

- 1) Under direct endoscopic vision, grasp the exposed proximal end of the dilation device using forceps.



- 2) Gently remove the dilation device. The procedural site may be examined at this time.



Follow-Up

Routine follow up should be performed by the surgeon to confirm healing and patency of the ostium.

CLINICAL STUDY AND FUTURE DIRECTIONS

SinuSys Corp. is currently sponsoring a clinical study at the University of British Columbia, Vancouver, Canada. The Company is designing frontal and sphenoid configurations of the AerOs Sinus Dilation System, and is pursuing plans to develop additional uses of its unique, osmotic self-expanding technology for other ENT applications.

ABOUT THE AUTHOR

Dr. Jerome Hester co-founded SinuSys in 2010 and serves as an attending surgeon at Stanford University Hospital and Clinics and at Lucile Packard Children's Hospital. After receiving his medical degree from The University of Texas at Houston, he completed his specialty training in Otolaryngology/Head and Neck Surgery at Stanford University. As a board certified otolaryngologist, Dr. Hester has remained active in the clinical practice of all aspects of the specialty and is an established author and lecturer on a national level.

SinuSys devices are CE marked and available for commercial distribution in selected EU locations. FDA 510(k) review is pending. AerOs and SinuSys are trademarks of SinuSys Corporation.

REFERENCE

¹Assessment of the short term patency of the maxillary sinus ostium following dilatation with an osmotic device in a sheep model. Jerome E. Hester, MD, David Edgren, BS, Janie Mandrusov, Ph.D., Andrea Koreck, MD, PhD, Jason Fox, BS, East Palo Alto, CA USA (Annual Meeting of American Rhinologic Society, September 2012, Poster# P-7)



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