Feasibility of an osmotically driven, self-expanding device for sinus dilation to treat chronic sinusitis

CALIFORNIA SLEEP INSTITUTE
1900 University Ave, Suite 101
E. Palo Alto, California 94303

Jerome Hester, MD[1,2], Dave Edgren[2], Jason Fox[2], Janie Mandrusov, PhD[2], Andrea Koreck, MD, PhD[2]
[1]California Sleep Institute , [2]SinuSys Corporation

ABSTRACT

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. The purpose of this investigation was to explore the feasibility of an osmotically driven, self expanding devices to dilate the sinus ostia in an animal model.

Methods
The osmotic technology can be tailored to enable device expansion at different rates. This study evaluated two different expansion rate devices (1-hour and 4-hours) with respect to their ability to safely and effectively expand and dilate the target ostium.

The 1-hour and 4-hours dilation devices were placed under endoscopic visualization into the maxillary sinus ostia of adult sheep. The devices were removed at the pre-determined time points and the measurements were taken of the diameter of both the expanded device and the resulting ostia. In a subset of animals endoscopy was repeated at 13 and 27 days after 4-hours device placement.

Results
Initial examination revealed strong correlation between the size of the dilated device and the resultant ostia. A smooth bore opening resulted with no signs of mucosal injury. All ostia were found to maintain essentially this same dilated size at the 27 day follow up examination.

Conclusion
This initial study indicates that the osmotically driven self expanding devices can dilate in vivo and produce a patent ostia that is maintained for at least 27 days.

CONTACT

Dr. Jerome Hester
California Sleep Institute
Email: jhester@calsleep.com
Phone: 650-328-0511

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 with demonstrated clinical success. SinuSys Corporation (Palo Alto, Ca. USA) has developed an osmotically driven, self-expanding dilation device to expand the sinus ostia. The SinuSys AerOs™ Dilation System is an instrument that is comprised of a Dilation Device that is pre-loaded on a Placement Instrument (Figure 1).

Figure 1. SinuSys Dilation Systems

The SinuSys devices are CE marked and available for commercial distribution in selected EU locations. Regulatory approval in US is pending.

The purpose of this investigation was to explore the feasibility of an osmotically driven, self-expanding dilation devices to expand the maxillary sinus ostium (MSO) in the ovine model.

MATERIALS AND METHODS

Animal Model
The studies were conducted in the MSO of the adult Dorper sheep model. The ovine MSO model has been used previously in resident teaching and experimental studies (see references).

Dilation Devices
The devices contain osmotic elements encapsulated in a semi-permeable, expandable membrane. When the Dilation Device is placed into the target ostium, it starts to expand due to uptake of surrounding fluid. The expansion of the Device causes ostium dilation and remodeling.

Before expansion **After expansion**

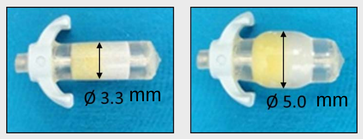

Figure 2. Dilation Device

4-hours devices procedure overview
Five 4-hours expansion rate devices were placed into 5 MSOs. The diameter of the devices, prior to expansion was 3.7 mm. Two devices were removed at 4 hours, one device at 6 hours, and two devices at 15 hours post placement. Diameter of the expanded device and the resulting ostia diameter were measured immediately post device removal. The ostium were evaluated for patency at day 13 and 27 post procedure.

1- hour devices procedure overview
Four 1-hour expansion rate devices were placed into 4 MSOs. The diameter of the devices, prior to expansion was 3.3 mm. The devices were then allowed to expand in-vivo and removed at 1 hour post placement. Both the diameters of the expanded device as well as resulting ostia diameters were measured immediately post device removal.

RESULTS

4-hours device

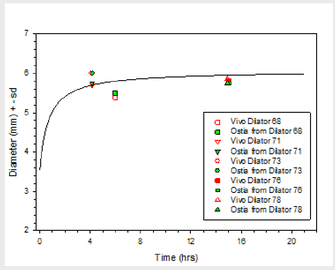

Figure 3 Diameter of the Dilation Device and diameter of the ostium measured immediately after treatment

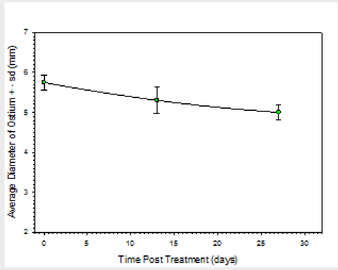

Figure 4 Patency of ostium immediately after treatment, 13 days, and 27 days after treatment

The ostia were also assessed for the amount of trauma and tearing post procedure as well as at 13 and 27 days. No tearing or mucosal injury was observed in any of the ostia evaluated. Representative image at 27 days is presented below.

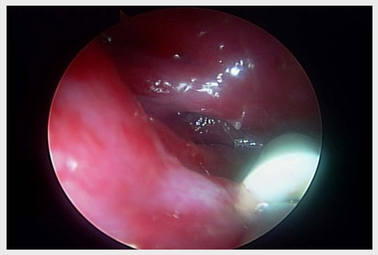

Figure 5 Endoscopic image of the ovine maxillary ostium at day 27

1-hour device

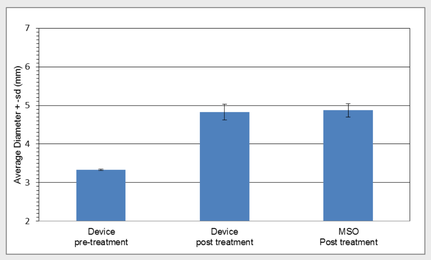

Figure 6 Changes in Dilation Device Diameter in Relation to the Sinus Diameter

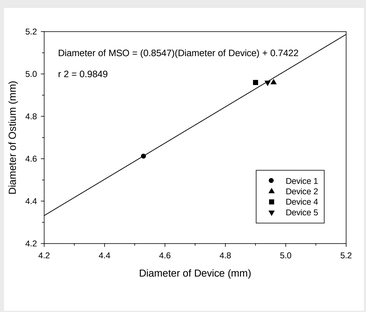

Figure 7 Relationship between post-treatment Dilation Device diameter and ostium diameter

DISCUSSION AND CONCLUSIONS

The osmotic technology has a potential to be tailored to different expansion rates to dilate the constricted ostia. Data provided demonstrates that both 1 hour and 4 hour Dilation Devices were able to dilate in vivo to produce a patent ostia. Strong correlation was established between post expansion diameter of the Dilation Device and the final diameter of the ostium for both devices, suggestive that there is no acute recoil post treatment. Furthermore, endoscopic evaluation revealed no sign of mucosal injury post treatment and the created openings remained patent for at least 27 days, providing an encouraging result for long term efficacy.

Promising pre-clinical data has led to the initiation of a "first-in-man" study at the University of British Columbia, Vancouver, Canada. Images of a typically-treated maxillary ostium are shown in figure 8.

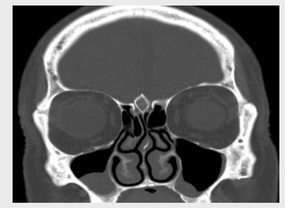

Figure 8-a. CT scan prior to treatment.

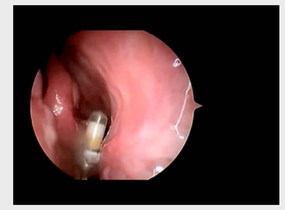

Figure 8-b Delivery of Dilation Device to MSO.

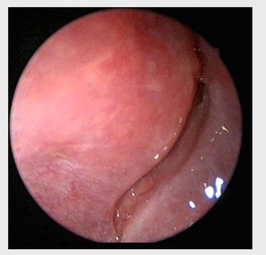

Figure 8-c Endoscopic follow up at 1 month.

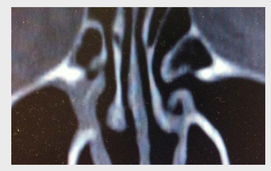

Figure 8-d. CT scan follow up at 1 month

REFERENCES

Acar B, Gunbey E, Bababemez MA, Karabulut H, Gunbey HP, Karasen RM. Utilization and dissection for endoscopic sinus surgery training in the residency program. J Craniofac Surg. 2010 Nov;21(6):1715-8.
Gardiner Q, Oluwole M, Tan L, White PS. An animal model for training in endoscopic nasal and sinus surgery. J Laryngol Otol 1996; 110(5):425-428.
Shaw, C.-K.L., Dymock, R.B., Cowin, A., Wormald, P.-J. Effect of packing on nasal mucosa of sheep. Journal of Laryngology and Otology, 114 (7), pp. 506-509.
McIntosh, D., Cowin, A., Adams, D., Rayner, T.,Ormald, P.-J. The effect of a dissolvable hyaluronic acid-based pack on the healing of the nasal mucosa of sheep. American Journal of Rhinology, 16 (2), pp. 85-90.
Rajapaksa, SP,; Cowin, A., Adams, D., Wormald, PJ. The Effect of a Hyaluronic Acid–Based Nasal Pack on Mucosal Healing in a Sheep Model of Sinusitis.
Brumund KT, Graham SM, Beck KC, Hoffman EA, McLennan G. The effect of maxillary sinus antrostomy size on xenon ventilation in the sheep model. Otolaryngol Head Neck Surg. 2004 Oct;131(4):528-33.