



Patency of Maxillary Sinus Ostia Following Dilation with a Novel Osmotic Expansion Device

Twelve-Month Results from a Multi-Center Prospective Study

Jerome Hester, MD

California Sleep Institute, Palo Alto CA;
Chief Medical Officer, SinuSys Corp., Palo Alto, CA

Janie Mandrusov, Ph.D.

SinuSys Corp., Palo Alto, CA

INTRODUCTION

Chronic rhinosinusitis (CRS) is a significant health problem, affecting approximately 13% of the US adult population¹. It has major impact on quality of life, academic and vocational pursuits and leads to immense socioeconomic costs. Treatment of CRS involves medical treatment, surgical treatment or a combination of both. Since introduction of balloon catheter technology in 2005, numerous studies²⁻¹² demonstrated sinuplasty as a viable option to enable sinus drainage while preserving mucosa and minimizing trauma to adjacent intranasal structures. The majority of the initial balloon catheter procedures were completed using general anesthesia and frequently were performed as a hybrid procedure in conjunction with Functional Endoscopic Sinus Surgery (FESS). Advances in technology now allow for the use of balloon sinuplasty with endoscopic guidance under local anesthesia.¹⁰⁻¹¹ In particular, an in-office sinuplasty treatment for patients with maxillary and ethmoid disease has recently been shown¹² to be non-inferior to FESS in terms of SNOT-20 scores and resulted in significantly shorter recovery time for these patients, with decreased pain medication use.

SinuSys Corporation has developed a device that dilates the ostium of the sinus to treat CRS. The present study was designed to evaluate basic usability and confirm expected safety and effectiveness of the Vent-Os[®] Sinus Dilation System when used to dilate maxillary sinus ostia in patients with CRS.

MATERIALS AND METHODS

Study Design

The study was designed as a multi-center, prospective, single arm, non-randomized, clinical trial to evaluate basic usability and confirm safety and effectiveness of the Vent-Os Sinus Dilation System when used to dilate maxillary sinus ostia in patients with CRS. The sinus dilation procedure was completed either under local or general anesthesia, as a stand-alone procedure or in conjunction with FESS, based on physician preference and accepted clinical practice. All subjects received appropriate standard of care therapy for their chronic rhinosinusitis. Subjects were followed out to six months to evaluate patency of the ostia and any late device-related complications.

Inclusion and Exclusion Criteria

Subjects between 18 and 75 years who were diagnosed with CRS and were in need of maxillary sinus ostia (MSO) dilation were included in the study. Subjects were excluded if they were diagnosed with conditions of cystic fibrosis, aspirin sensitivity, steroid dependent asthma, sinonasal tumors, allergic fungal sinusitis, ciliary dysfunction, atrophic nasal mucosa, and/or excessive osteogenesis that might preclude dilation. Also, the study excluded patients that had any anatomic abnormality that precluded access to the maxillary sinus ostium or previous antrostomy.

Endpoints

Primary endpoints were:

- Safety as evidenced by an assessment of acute complications potentially associated with the device, the device placement and/or removal procedure, and the associated MSO dilation procedure.
- Effectiveness defined by patency of the MSO immediately after removal of the SinuSys device.

Secondary endpoints were:

- Device success defined as successful access, deployment, and retention of the device at the target site.
- Patency of the MSO 1, 3, 6 and 12 months after device removal.
- Reports of any sinus-related adverse events during the follow-up periods.

Device Description

The Vent-Os Sinus Dilation System is comprised of osmotic elements encapsulated in a semipermeable, elastic membrane and a placement instrument (Figure 1).

Figure 1: The SinuSys Vent-Os System delivers simple, atraumatic sinus dilation. Its unique osmotic self-expanding technology provides gradual, low-pressure dilation to 5 mm in about 60 minutes.



Device Description
(continued)

When the dilation device is placed into the target ostium, it starts to expand due to uptake of surrounding liquid (approximately 150 μ L). It expands gradually from an initial diameter of 3 mm to a final diameter of 5 mm in about 60 minutes, at a pressure of 2.9 atmospheres (42 psi), resulting in ostium enlargement. The placement instrument accesses the sinus ostium through the nasal passageway and delivers the dilation device into the ostium (Figure 2). The dilation device resides in the ostium for 60 minutes, after which the dilation device is removed (Figure 3).

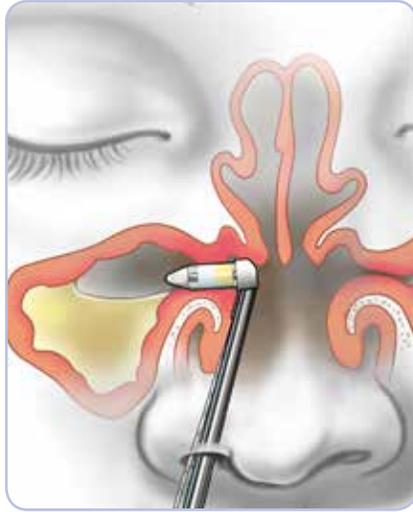


Figure 2: The Vent-Os placement cannula accesses the sinus ostium through the nasal passage, leaving the uncinate intact.

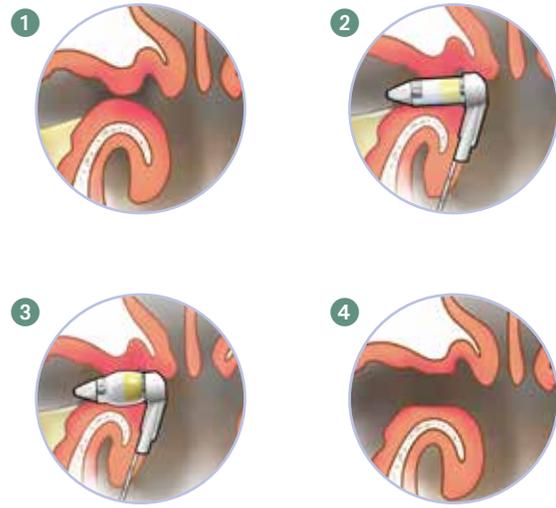


Figure 3: The osmotically-driven dilation device expands the ostium over 60 minutes, after which it is removed with forceps.

Study Procedures

The devices were placed under endoscopic guidance by the trained surgeons to the target maxillary sinuses. When the procedure was completed in conjunction with FESS, the devices were placed either prior to FESS procedure or immediately post FESS procedure in the operating room. In cases where devices were placed prior to FESS, the surgeon completed surgery with the device in place and removed it in the operating room. In cases where the device was placed post-FESS procedure, the device was removed in the recovery room, with the patient awake. The in-office procedures were completed with standard protocol, where aerosolized anesthetic was delivered, followed by a soaked pledget and then injection of anesthetic around the target treatment site. In cases where the device was used in-office or placed post-FESS, the device was tethered by tying a suture around one of its anchor petals.

The successful dilation was confirmed by endoscopic visualization of the space created by the device post device removal as well a confirmation of final device diameter. An “indeterminate” reading was assigned if the ostium could not be viewed and assessed for patency. Any device related adverse events were collected. Follow up visits at 1, 3, 6 and 12 months consisted of appropriate standard of care treatment and medical follow-up for subjects. At each follow-up visit a nasal endoscopy was performed to evaluate treated sinus patency as well as to record any late device procedure related adverse events.

RESULTS

A total of 36 patients were enrolled in the study. Two patients withdrew consent prior to treatment and 34 were patients treated. Twenty-two female (65%) and twelve male (35%) patients with a mean age of 45.1 years were studied. Twenty-nine (85%) patients had a dilation procedure that was conducted in conjunction with FESS and five patients (15%) had a dilation procedure carried out in an office setting under local anesthesia. The procedure was well tolerated in these 5 patients.

In the 34 patients treated, 57 ostia were accessed and dilated successfully. The average final device diameter was 5.0 +/-0.4 mm after the procedure. There were no device-related adverse events. Thirty-three (33) patients completed the three months follow up. One patient withdrew by the investigator prior to one month follow up. There were no late device procedure-related adverse events.

A total of 55 ostia were evaluated for patency at 1 and 3 months. There were no occluded ostia reported. If the investigator could not visualize the ostia, it was reported as “indeterminate”. At 1 month, 93% of the ostia were confirmed patent and 7% were reported as indeterminate. Similarly at 3 months, 93% of ostia were confirmed patent and 7% were reported as indeterminate. At 6 months, 30 patients were available for follow-up and 45/49 (92%) of treated ostia were visibly patent with 4/49 (8%) “indeterminate”; no maxillary ostia were clinically non-functional.

At 12 months, 27 patients with 45 treated ostia were available for evaluation, with 93 percent of ostia (42) visibly patent and seven percent (3) unable to be visualized. All ostia were clinically functional (Figure 4).

	Total Number of Ostia Evaluated	Confirmed Patency	Could Not Visualize	Non-Patent
Post Procedure (34 patients)	57	95%	5%	-
One Month (33 patients)	55	93%	7%	-
Three Months (33 patients)	55	93%	7%	-
Six Months (29 Patients)	47	91%	9%	-
12 months (27 patients)	45	93%	7%	-

Figure 4: Maxillary Ostia patency over time

Results Continued on next page.

**RESULTS
(CONTINUED)**

Selected images of the ostia treated with the Vent-Os Sinus Dilation System are presented below to provide illustration of the appearance of the ostia before placement of the dilation device and at one-month and three-month examinations (Figure 5). As can be seen in these representative photographs, the mucosal surface is intact with no apparent adhesions or crusting.



Figure 5: Maxillary ostia of a typical study subject before dilation with the Vent-Os device, and one and three months following dilation.

Data obtained in this study compares favorably to that obtained by Bolger³ that reported on 12 weeks (three months) and 24 weeks (six months) and Kuhn⁴ that reported on 12 months maxillary ostia patency outcomes as part of a prospective evaluation of sinusotomy using balloon catheter devices in patients with sinusitis for whom endoscopic sinus surgery was recommended. These studies reported the status of each balloon-treated sinus ostium as either patent, not patent, or indeterminate on endoscopic examination. An “indeterminate” rating was used if the ostium could not be viewed with endoscopy or if the patient did not tolerate a complete endoscopic examination. Figure below compares patency outcomes using the Vent-Os dilator to that of sinuplasty balloon (Figure 6).

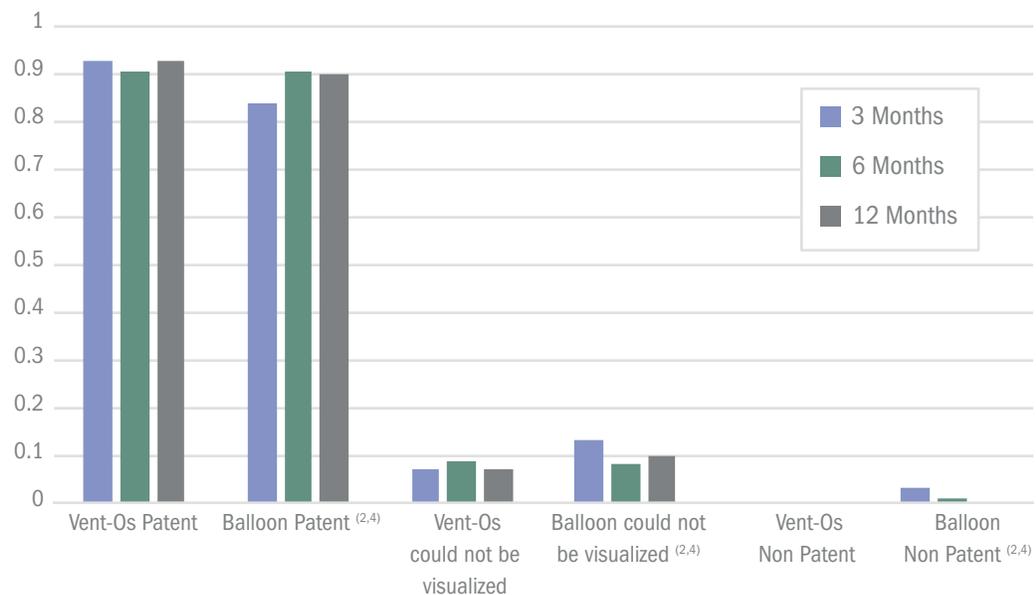


Figure 6: Patency outcomes for osmotic dilator vs balloon

CONCLUSIONS

In 34 patients that have undergone dilation, no device related adverse events were reported. Sustained ostium patency was exhibited up to 12 months post procedure. The patency outcomes are comparable to that published by Bolger et al.⁴, where procedures were conducted using a standard balloon sinuplasty. This data demonstrated basic usability and confirmed safety and effectiveness of Vent-Os Sinus Dilation System when used to dilate maxillary sinus ostia in patients with chronic rhinosinusitis.

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The Vent-Os® Sinus Dilation System is an instrument intended to provide a means to access the sinus space and to dilate the maxillary sinus ostia and associated spaces in adults for diagnostic and therapeutic procedures.



SinuSys Corp. | 2468 Embarcadero Way | Palo Alto CA USA 94303
Tel: +1-650-213-9988 | Fax: +1-650-213-9688 | www.sinusys.com

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