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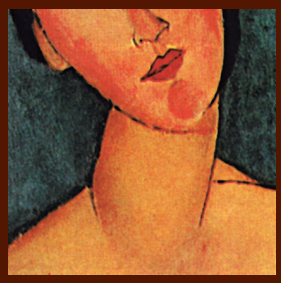

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REVIEW

Use of a novel osmotic self-expanding dilation device for the treatment of sinusitis

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ABSTRACT

Inflammation of the lining and outflow tracts of the paranasal sinuses can be due to many factors, including exposure to harmful viruses, bacteria, and fungi. When the inflammation is due to one or more of these pathogens, the condition is defined by the term sinusitis, which can be further refined by duration and associated features as either recurrent acute, chronic with or without polyps, fungal, or hyperplastic. The treatment of sinusitis is determined by its type, patient history, physical exam findings, imaging data, and patient wishes. In general, treatment can be described as holistic (to include saline nasal irrigations, herbal supplements, dietary measures, acupuncture, steam inhalation, watchful waiting, etc.), medicinal (to include over the counter and/or prescription medications with or without some holistic measures), and surgical. The latter has expanded in recent years to include conventional endoscopic sinus procedures (better known as functional endoscopic sinus surgery [FESS]), minimally invasive sinus procedures (better known as minimally invasive sinus techniques [MIST]), balloon dilation procedures (better known as balloon sinuplasty), or some combination of these procedures, better known as a hybrid technique.

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The evolution of sinus surgery has trended toward less invasive techniques that spare the natural nasal anatomy, while strategically enhancing the functional components of the nose and sinuses. Endoscopic sinus surgery was developed in Austria in the 1970's and eventually transported to the US by Kennedy in the mid-1980's. Use of the endoscope, or nasal telescope, greatly improved visualization of nasal and sinus anatomy, and helped foster the "functional concept", which revolutionized understanding of the physiology of the nose and sinuses. The functional concept stated that each sinus had mucociliary flow directed towards a predetermined sinus outflow tract which communicated the sinus to the nose. Thus, sinus contents would naturally drain through predetermined channels along a natural conveyor belt system from the sinuses into the nasal cavity, and then posteriorly towards the nasopharynx. FESS surgery targeted these outflow tracts, called transition spaces, to remove any blockage and restore natural sinus physiology. Reasons for transition space obstruction are many, including allergy, infection, polyps, anatomic abnormalities, trauma, and neoplasms. However, the FESS technique not only removed the blockage, but physically altered the sinus drain or ostia, thus grossly altering the physiology of the sinus. The impact of the latter was not fully appreciated at the time.

In the mid 1990's, the minimally invasive sinus technique, or MIST procedure was introduced by Reuben Setliff. MIST was an endoscopic surgical procedure that did not manipulate the natural sinus drain, or ostia, but

instead focused almost exclusively on eliminating the transition space. The latter is universally agreed to be the site of sinus obstruction in all patients, while the ostium itself is rarely problematic and its role in sinus obstruction remains unproven. The MIST technique was a highly targeted surgical procedure and introduced the concept of mucosal sparing surgery and the need to retain many of the natural nasal and sinus tissues. Thus, patients had a much quicker recovery after MIST, with much less pain, no need for nasal packing, and returned to work within 24 hours of surgery. MIST also introduced powered instrumentation in the form of a microdebrider — a rotating self-irrigating shaver blade with built-in real-time suction ability. Both MIST and powered instruments further revolutionized the surgical treatment of sinus disease. In 2003 the first outcome procedure comparing MIST to FESS was published and showed that the 2 year outcomes following MIST were at worst equal to, and in a majority of cases better then FESS.

Balloon sinuplasty

In 2005, Josh Makower, a physician-scientist, introduced the concept of balloon dilation technology, also known as balloon sinuplasty, through his company called Acclarent. Akin to angioplasty of the coronary arteries, balloon sinuplasty used a flexible wire introduced through the nostril via a tubular guide to access the sinus transition space and eventually the sinus itself. Once the wire was in the appropriate place, the balloon catheter was introduced or fed over the wire and placed across the sinus transition space, including the sinus ostia. The balloon was then inflated using a hand help pump to between and 8 and 12 atmospheres for approximately 1-2 seconds before deflation. The balloon catheter, guidewire and guide are all removed and the sinus outflow tract has now been opened without any tissue removal. This rapid expansion technique required a high pressure balloon dilation system (the pressure in a care tire averages 2 atmospheres) to expand the bone at the margins of the transition space, akin to a greenstick fracture of bone. Unlike the coronary artery, the newly dilated sinus transition space does not need an indwelling stent to maintain patency, however, it is known that use of the rapid dilation technique produces about 20% recoil of the maximum dilation diameter. Therefore, use of a 5mm balloon will result in a final opening measuring no more than 4mm in diameter. Current balloon sizes include 3.5, 5, 6, and 7 mm diameter balloons.

Balloon sinuplasty both revolutionized and polarized the medical community due to its truly disruptive technology. Otolaryngologists had never been taught catheter-based surgery, and therefore had to be trained in order to perform the procedure, and while MIST had shown us that less invasive sinus procedures can yield excellent outcomes, never before had a sinus procedure been introduced wherein NO tissue was removed! Many physicians viewed sinuplasty as a “fly by night” technology that would never stand the test of time, nor the hype that surrounded its introduction to market. Further angst was generated when the procedure was marketed directly to consumers at a time when many believed the technology was yet unproven. However, numerous studies have since been published on the short and long-term efficacy, safety, economic benefit, and patient experience after balloon sinuplasty. In fact, no other technology in otolaryngology has been vetted, examined, tested, criticized, hailed, compared, cross-examined, and villainized more than sinuplasty. Over the past ten years, there is now consensus that sinuplasty is an effective and viable alternative to treat many, but not all types of sinusitis, and that hybrid procedures which combine FESS or MIST with sinuplasty are commonly performed world-wide.

Since the introduction of sinuplasty, there has been significant evolution in the field. The first procedures were performed using a stiffer guidewire that would kink after use in 1 or 2 sinuses, fluoroscopy was required to visualize the location and track the wires position during surgery, contrast material was used to dilate the balloons for easy visibility on fluoroscopy, only 2 balloon sizes were available (5 and 6 mm), and balloons did not recoil or fold up easily after their initial dilation. Use of fluoroscopy introduced radiation exposure to both the patient and surgeon, adding more concern to an already controversial procedure. Over the past several years fluoroscopy has been replaced by transillumination whereby a tiny (<1mm) light is imbedded into the tip of the guidewire and will brightly shine through the sinus walls when it is in correct position within the target sinus. The new guidewires are very durable and kink-resistant, and the saline or water can now be used to dilate the balloon since flouroscopy is no longer used.

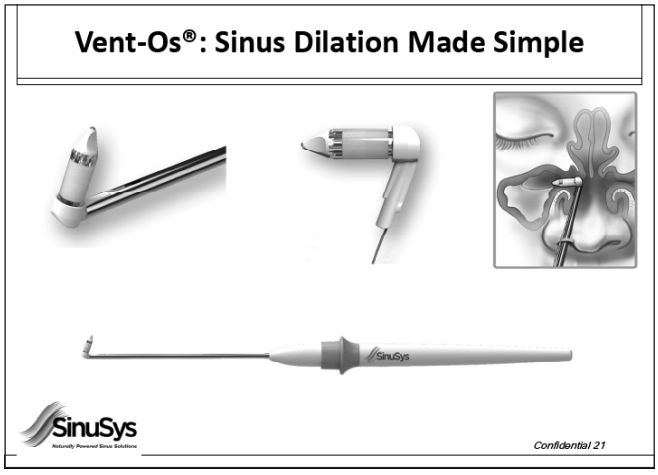

Figure 1.—Vent-Os™ system for the maxillary and sphenoid sinuses. The same handle can be used for both targets.

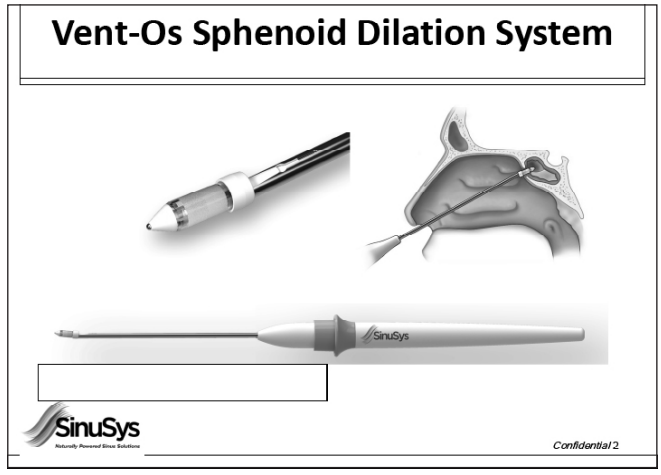

Figure 2.—Vent-Os™ system for the frontal sinus. Handle is curved, and includes a lighted guidewire for sinus transillumination.

The balloons are now designed to easily fold up tightly along the catheter shaft for re-use in multiple sinuses within a given patient, and balloons now come in 3.5 and 7 mm diameter sizes. The original sinuplasty systems required a minimum of 2, if not 3 people to effectively place the guide, guidewire, balloon catheter, and then inflate/deflate the balloon. Newer systems can now be solely operated by the surgeon, with the assistant needed simply to inflate and deflate the balloon. As I mentioned earlier, the first company to manufacture sinuplasty tools was Acclarent, however, there are now five other manufacturers of sinus balloon technology: Entellus, Medtronic, Fentex, Arthrocare, and SinuSys. Other than SinuSys, all other manufacturers use a similar high pressure balloon system with rapid inflation/deflation. Each has its own nuances that make it somewhat unique from the competition, but the "nuts and bolts" and operating principles are essentially the same.

The Vent-Os System

In 2012, SinuSys Corp introduced Vent-Os™, the first ever osmotic balloon system that self-dilates once placed within the target. This system was developed with several issues in mind, namely ease of operator use, patient comfort and tolerance, operator independence (no assistant required), patient safety, equivalent if not better efficacy compared to existing technologies, and a reduced cost of goods. These features make the Vent-Os™ system very attractive to both patients and surgeons. The Vent-Os™ system consists of 1 handle that connects to both the maxillary and sphenoid dilators (Figure 1), and a second handle designed specifically for the frontal sinus (Figure 2). The Vent-Os™ system also functions at a much lower pressure than any other system, exerting only 2.9 atm after 1 hour on the mucosa of the sinus transition space versus 10-12 atm typically used by all other sinus balloon systems. Thus, Vent-Os™ has proven that low pressure over a longer time period can effectively remodel and widen the sinus outflow tract. The major and clinically significant benefit of this feature is the marked reduction in postdilation recoil that occurs. With standard rapid balloon dilation systems, there is an approximately 20-25% recoil of the final targeted internal diameter of the outflow tract. Therefore, when using a 5 mm diameter balloon with a cross-sectional area of 25mm^2 to dilate the ethmoidal infundibulum and maxillary outflow tract, the final actual diameter of the maxillary outflow tract will be approximately 20mm^2, a reduction of 20%. If that same outflow tract was treated with the Vent-Os™ system, only a 5% recoil would occur, thus maintaining the final diameter of the outflow closer to the target dimensions.

In fact, while using conventional BSP technologies, experienced balloon sinuplasty surgeons choose balloon sizes larger than actually necessary to compensate for the recoil phenomenon. This proves problematic on 2 fronts: larger balloons cost more than smaller balloons,

and larger balloons cause more damage in the way of longitudinal mucosal tears which can lead to further reduction of the final internal diameter of the targeted outflow tract. It is also extremely unlikely for the low pressure Vent-Os™ system to cause any collateral damage to adjacent sino-nasal structures, such as the orbit and skull base. To date, the clinical trial and post-market data for Vent-Os™ have shown a perfect safety record, and while conventional BSP technologies also have a very safe clinical profile, there have been reported cases of cerebrospinal fluid leak and orbital penetration.

Because Vent-Os™ is a low pressure dilating system, it takes more time for the balloon to reach maximum dilation. Conventional dilating systems take approximately 10 seconds to reach 10-12 atm of pressure and maximum balloon diameter (5, 6, or 7mm). Whereas Vent-Os™ dilators reach maximum expansion after 60 minutes, requiring the patient to remain in the hospital or physician office for device removal after the 60 minutes have passed. Because Vent-Os™ is a self-dilating system, there is essentially no pain during the procedure or the 60-minute dilating period. While pain scores from conventional BSP procedures are generally favorable, especially when compared to more traditional FESS, they are not as predictably low as those seen with Ven-Os™. Some physicians and patients may prefer the conventional rapid dilation system because the overall procedure time may be 30 minutes less than that required when using Vent-Os™. However, the simplicity, ease of use, safety, and patient comfort afforded by Vent-Os is worth the extra 30 minutes that is required.

The Vent-Os™ system does not require any wire or guide when treating the maxillary or sphenoid sinuses (Figures 1, 2). The device is ergonomically designed for ease of use in order to maximize patient comfort and reduce procedure time. The distal end of each of these devices is tapered like a cone to accurately access the ethmoidal infundibulum or sphenoid sinus ostium. The maxillary device is held by the insertion tool at a 60 degree angle to afford easy access to the hiatus semilunaris. The sphenoid device is designed with a 10 degree angle from the main axis of the insertion tool. Once the dilator is positioned, there is a circular lever on the insertion tool that will separate the dilator and inserter allowing the latter to be removed from the nose. This one inserter can be used for both of the maxillary and sphenoid sinuses. Because of the complexity of the frontal sinus anatomy, the frontal system uses a 0.9mm flexible light-wire on a specially designed guide to safely and accurately identify the frontal sinus outflow tract and frontal sinus lumen. Illumination of the light-wire is achieved by a portable light source (Figure 3), or by connecting the distal end of the handle to a fiberoptic cable from a traditional Xenon light source. The guide is simply positioned in the frontal sinus recess under endoscopic control. The surgeon then uses his/her index finger to move a lever along the shaft of the guide which will then move the light-wire forward toward its anatomic target. Once the light-wire is confirmed in position via frontal sinus transillumination, the surgeon then uses the same index finger to push a second parallel lever (Figure 4) forward to introduce the frontal dilator into the target site under endoscopic visualization. Once the frontal device is in position and fully deployed it will separate from the guide and the light-wire can be retracted by moving the first lever backwards (in reverse). The guide can then be safely removed.

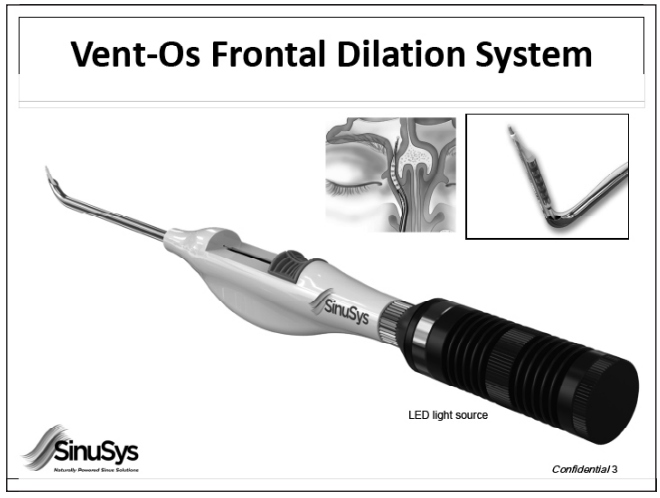

Figure 3.—Portable detachable light source for the frontal hand-piece. The hand-piece can also attach to a standard, larger light source.

Each Vent-Os™ dilator is attached to a single nylon string at its distal end to both aid in their retrieval as well as to prevent accidental loss of the device into the nose or upper airway. This string is typically fastened to the ipsilateral cheek with a small piece of tape until the dilators are removed after 60 minutes. Clinical trials have shown the ease with which the Vent-Os™ dilators are removed from each of the sinuses using an endoscope and small Blakesley forceps or the equivalent.

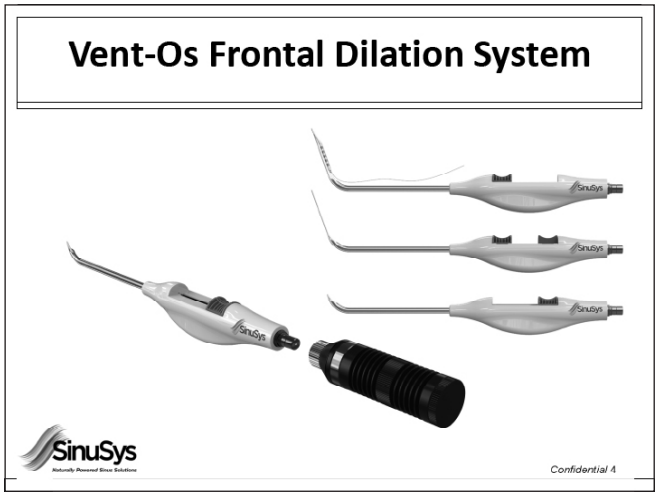

Figure 4.—Finger control levers on the frontal hand-piece for moving the lighted guidewire into the frontal sinus, followed by the frontal dilation device which will follow the guidewire.

Clinical outcomes data thus far for patients between 18 and 75 years of age have shown an excellent safety and efficacy profile for the Vent-Os™ system. The complete Vent-Os portfolio has already received CE Mark approval, and the maxillary device has received FDA approval. At the time of this manuscript, FDA approval is pending for the frontal and sphenoid devices. The Vent-Os™ system has shown 6 month visible patency rates of 93% for each sinus (maxillary, frontal, and sphenoid) with no patients requiring revision surgery up to 6 months. In the remaining 7% of patients, the ostia could not be visualized in the office setting, however, the patients were clinically asymptomatic.

Conclusions

In summary, the Vent-Os™ self-dilating system for the treatment of chronic or recurrent acute sinusitis is safe, effective, easy to use, comfortable for patients, affordable, and offers durable results. It can be performed in the office setting or operating room either as a standalone procedure or as a hybrid with other procedures such as septoplasty, turbinate reduction, swell body ablation, ethmoidectomy, or nasal valve repair. The self-dilating device exerts low pressure on the sinus mucosa, thus minimizing the risk of mucosal injury or ciliary dysfunction. The system also has a less than 5% recoil effect after dilation which translates to predictable and durable outcomes. The frontal and sphenoid devices are not yet approved for use in the USA.

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Conflicts of interest.—Peter J. Catalano was a consultant for SinuSys Corp.