

ORIGINAL RESEARCH—SINONASAL DISORDERS

Feasibility of balloon dilatation in endoscopic sinus surgery simulator

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OBJECTIVE: Assess the feasibility of the use of a life-size model for ESS to perform balloon catheter dilatation of the paranasal sinus ostia.

STUDY DESIGN AND SETTING: Four validated sinus models were enrolled in this study. One experienced endoscopic surgeon performed all the dilatations of the paranasal sinus ostia. We used the Relieva Sinus Balloon Catheter System (Acclarent, Inc, Menlo Park, CA), and its described technique for fluoroscopic guided sinuplasty.

RESULTS: Twenty-four ostia were available. All sinuses were successfully catheterized and dilated. The total fluoroscopic time was 18 minutes and 8 seconds (mean, 45.3 seconds per sinus) and the total procedure time was 50 minutes and 56 seconds (mean, 2 minutes and 7 seconds per sinus).

CONCLUSION: It was feasible to perform a successful dilatation of the 24 available sinus ostia of the models: 8 maxillary, frontal and sphenoid. No major technical difficulties were encountered.

SIGNIFICANCE: This model could help surgeons in the training of sinus ostia balloon dilatation.

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Technologies such as endoscopes, powered instrumentation, and image guidance have changed the endoscopic sinus surgery (ESS).¹ Balloon catheter dilatation is a recently introduced minimally invasive tool in rhinology that uses the concept of remodeling the anatomy of the paranasal sinus ostia without removing tissue or bone. Its use in patients is proven to be feasible, safe, and its applications include chronic rhinosinusitis, barotrauma, and trauma among others.²⁻⁵ The system uses principles commonly used in other medical disciplines such as vascular surgery, urology, cardiology, and gastroenterology. What this tool accomplishes is the dilatation of the sinus ostia by advancing balloon catheters under fluoroscopic guidance and inflating them with high pressures.¹ As currently practiced, however, the use of this technology introduces intraoperative radiation both to the surgeon and the patient. Because

ionizing radiation is known to have inherent risks to tissues such as the skin, thyroid, and lens of the eye, it is desirable to reduce as much as possible the radiation exposure during these procedures.^{1,2}

Although this technique uses principles of ESS, it requires a learning curve in order to perform safe and successful dilatation of the paranasal sinus ostia, which reduces the time of the procedure and radiation exposure.⁶ Surgeons should practice sinus balloon dilatation before they use this device. This surgical training could include video sessions, lectures, and dilatation of cadaver sinus ostia under fluoroscopy.⁶ Human cadavers closely approximate reality, but their accessibility and utility are affected by their cost, limited availability, and poor compliance of cadaveric tissue.⁷⁻¹⁰

The efficacy of transfer of skills from the simulator to the clinical setting has been demonstrated in several recent studies.⁷⁻⁹ Life-size models for endoscopic sinus surgery have been recently developed. The main objective of our study was to assess the feasibility of the use of a life-size model for ESS to perform balloon catheter dilatation of the paranasal sinus ostia.

MATERIALS AND METHODS

In conjunction with the company Pro Delphus (www.prodelphus.com.br), from Recife, Brazil, we developed and validated a life-size model, named S.I.M.O.N.T. (Sinus Model Otorhino-Neuro Trainer) (Fig 1). Due to the nature of this project, no Institutional Review Board approval was necessary.

For the validation, 10 otolaryngologists, divided into 3 groups according to levels of experience, performed a traditional endoscopic dissection of the models. Scores were requested for consistency, tissue color, and identification of anatomic structures. The results were compared and analyzed statistically, and 70 percent of participants reported improvement in anatomic knowledge after the use of S.I.M.O.N.T.

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Figure 1 Head of S.I.M.O.N.T. (Sinus Model Otorhino-Neuro Trainer), developed by Prodelphus, from Brazil.

We purchased and used the Relieva Sinus Balloon Catheter System (Acclarent, Inc, Menlo Park, CA) and its described technique for fluoroscopic guided balloon dilatation.

Standard 0-degree and 45-degree, 4 mm endoscopes were used. Sinus guide catheters, flexible sinus guidewires, sinus balloons catheters, and a sinus balloon inflation device with a manometer were used (Fig 2). The sinus balloon inflation device and the sinus catheters were prepared following the manufacturer's instructions. A saline solution was used for injection into the balloon.

We used the standard sinus balloon with a size of 5 mm. The same sinus balloon was used to dilate multiple times. The manufacturer provided detailed explanation on how to re-prepare the sinus balloon for adequate functioning. We used C-arm fluoroscopy guidance just to confirm the successful positioning of the guidewire into the sinus, not the balloon.

Four life-size sinus models S.I.M.O.N.T. were enrolled in this study. For this study, because we wanted to determine the feasibility of balloon dilatation in this model, one experienced sinus surgeon performed all the dilatations of the paranasal sinus ostia.

RESULTS

Twenty-four ostia were available: eight maxillary, eight frontal, and eight sphenoid. All 24 sinuses were successfully catheterized and dilated. The balloon catheters were inflated to 10 atm. The inflation time was 10 seconds and the final pressure was maintained for 5 seconds. The total fluoroscopic time was 18 minutes and 8 seconds (mean, 45.3

seconds per sinus) and the total procedure time was 50 minutes and 56 seconds (mean, 2 minutes and 7 seconds per sinus).

DISCUSSION

Several important observations were made during the investigation. First, the easiest sinus to cannulate was the sphenoid sinus. These data are also present in studies of feasibility in cadavers and real patients.⁴⁻⁶

The sphenoid sinus was cannulated with the 0-degree 4 mm endoscope, by placing the 0-degree sphenoid guiding catheter, under endoscopy guidance, into the sphenoid recess (Fig 3). The balloon was inflated and deflated. Endoscopic examination after the procedure showed an ostium that resembled the shape of the balloon.

The next easiest sinus to cannulate was the frontal. For this sinus we used a 45-degree, 4 mm endoscope. After the positioning of the 70-degree frontal guiding catheter into the middle meatus, the guidewire was advanced in the direction of the frontal sinus outflow tract. Correct positioning of the guidewire under fluoroscopy (Fig 4) resulted in prompt positioning of the balloon into the frontal recess. Balloon dilatation was performed and endoscopic examination showed an enlarged ostium (Fig 5).

The trickiest sinus to cannulate was the maxillary, mostly because of its natural ostium position behind the uncinate process. The uncinate was softly displaced with the 90-degree maxillary guiding catheter (Fig 6). The natural os-

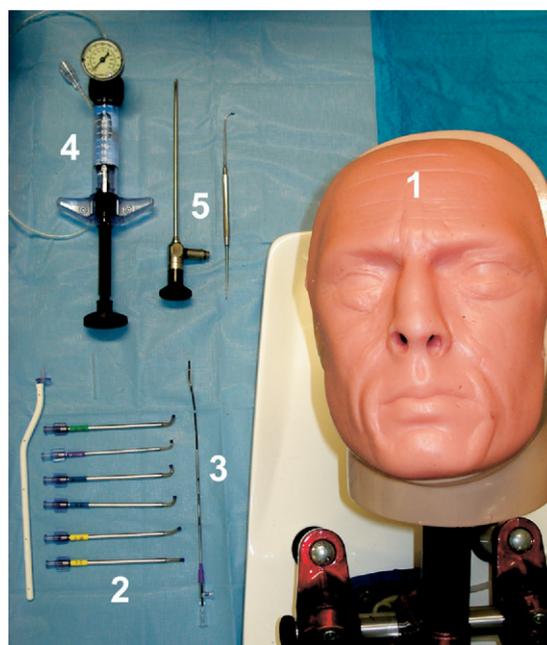


Figure 2 Equipment used: 1, life size sinus anatomy model (S.I.M.O.N.T.); 2, sinus guiding catheters; 3, balloon catheter; 4, balloon pump with manometer; 5, set of instruments and endoscope.

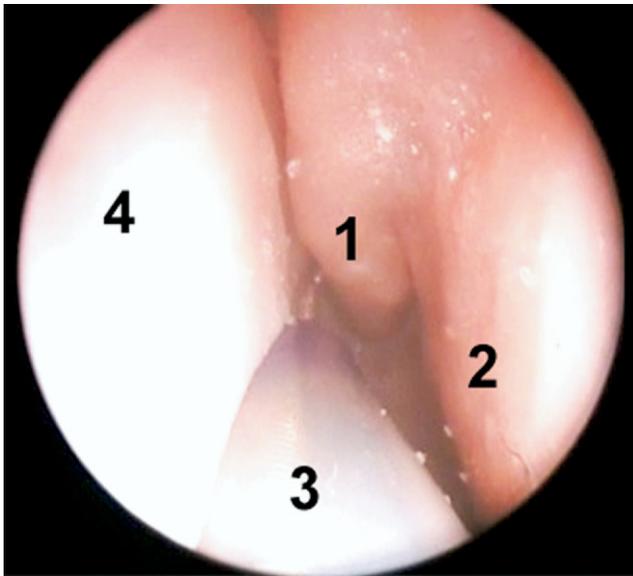


Figure 3 Endoscopic placement of the 0-degree sphenoid guiding catheter guidance into the left sphenoid recess: 1, superior turbinate; 2, middle turbinate; 3, 0-degree sphenoid guiding catheter; 4, nasal septum.

tium was catheterized using the 45-degree, 4 mm endoscope. Fluoroscopy was performed to confirm the correct positioning of the wire catheter. Balloon dilatation was performed and endoscopic examination showed an enlarged ostium.

The technical difficulties were the limited space, similar to the life size anatomy, and the sticky mucosa present on the model. However, these problems did not jeopardize the successful dilatation of the sinus ostia.

The models were built based on a normal paranasal sinus computer tomography and validated for endoscopic nasal

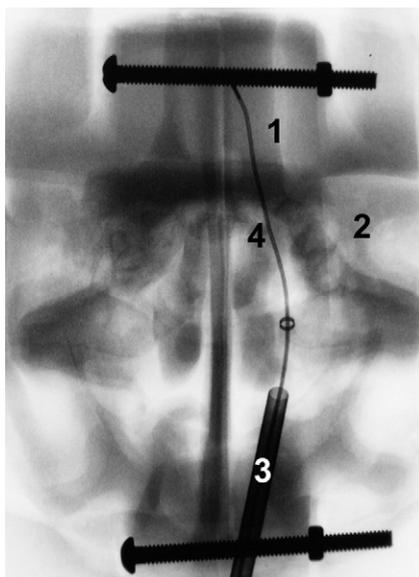


Figure 4 Fluoroscopic view of the placement of guidewire into the left frontal sinus: 1, left frontal sinus; 2, left orbit; 3, 70-degree frontal guiding catheter; 4, guidewire.

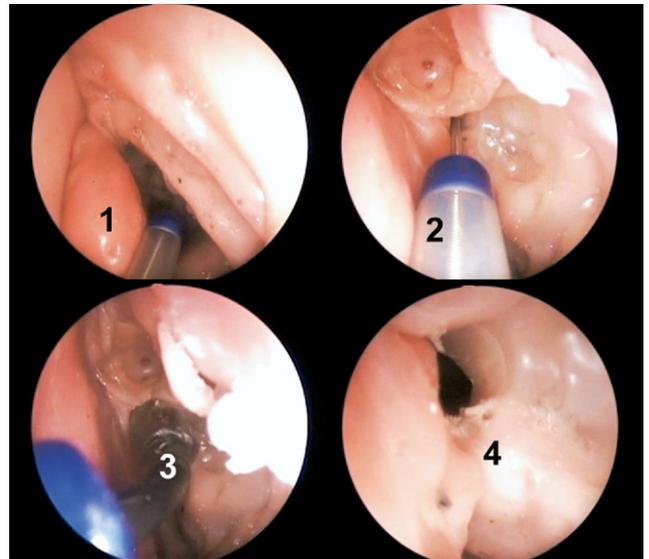


Figure 5 Endoscopic view with a 45-degree endoscope of the steps of a balloon dilatation performed at the left frontal sinus ostia: 1, left middle turbinate; 2, 70-degree frontal guiding catheter; 3, balloon dilated; 4, endoscopic examination shows an enlarged left frontal sinus ostium.

dissection. They were made with special bone-like resin and Neoderma, a special material that simulates the consistency of the mucosa and soft tissues. The S.I.M.O.N.T. had all paranasal sinuses with ostia and other structures, such as nasal septum, inferior, middle, and superior turbinates, unciniate process, ethmoid bulla, sphenopalatine artery, and its branches, orbital content, and lamina papyracea.

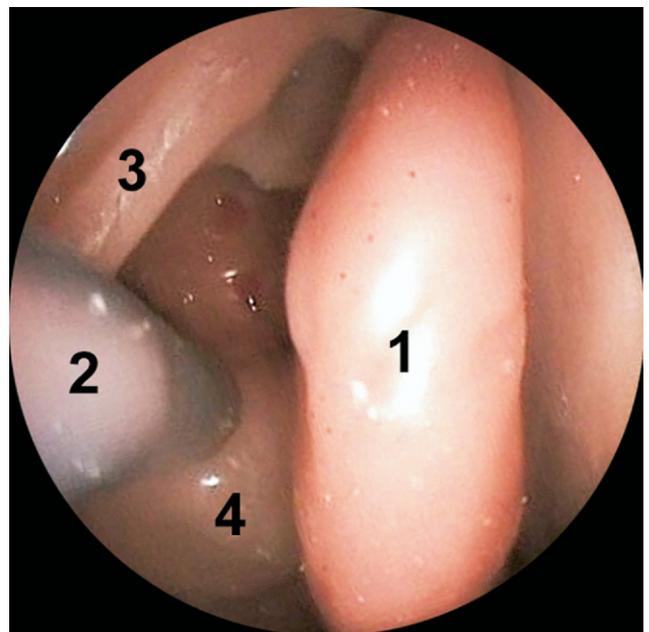


Figure 6 Endoscopic view with a 45-degree endoscope of the positioning of the 90-degree maxillary guiding catheter: 1, right middle turbinate; 2, maxillary guiding catheter; 3, unciniate process; 4, ethmoid bulla.

The region of the ostia was made with soft breakable adjacencies. This facilitated the dilatation and enlargement of the ostia. The model did not have any maxillary accessory ostia, but it is also important to state that different anatomic models can be made, putting diseases into the sinus, and creating environments in accord with the surgeon's training necessity.

The surgical materials, such as endoscopes, instruments, and tools for balloon dilatation were the same used in real procedures so the skills used were similar to the ones used in real procedures.

With new techniques and technologies, there is always a learning curve and training is an important consideration. Several studies showed that just like in ESS, cadaver training helped prepare the surgeon to handle the new balloon catheter devices in surgery.⁶

Most of the otolaryngologists are very experienced with endoscopes, microscopes, and an array of rigid instruments such as forceps, knives, and scissors. However, manipulating catheters and working from a fluoroscopy monitor is a different matter for most otolaryngologists, and cadaver training is very helpful in preparing one for actual patient care with the new devices.⁶

We also agree with the training experience, but, in the mean time, we are concerned with the crescent difficulties to get dissection specimens. This problem can be solved with the use of real model simulators, which bring similar life size anatomy, color, and consistency of tissues, not having inherent biohazard risks, as well as conservations issues.^{7,9,10}

In the future, we intend to perform more studies of simulation importance and its effect on education of otolaryngologists in balloon catheterization, outcomes, and safety of procedures.

CONCLUSION

The role of the balloon catheter devices in otolaryngology is promising and training will be paramount for the safety and feasibility of this new technology. Human dissectible cadavers are hard to get and have potential risks of dealing with biological material. It was feasible to perform a successful dilatation of the 24 available sinus ostia in the S.I.M.O.N.T.: 8 maxillary, frontal and sphenoid. No major technical difficulties were encountered.

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AUTHOR CONTRIBUTIONS

Aldo Stamm, writer, study design; **Joao Flavio Nogueira**, writer, study design; **Macos Lyra**, study design.

FINANCIAL DISCLOSURE

None.

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