

Image Guidance Case Study

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Relieva Balloon Sinuplasty™ Devices Used:

Relieva Sinus Balloon Catheter (5x16mm)
Relieva Sinus Guide Catheters (F-70 & M-90)
ReliENT™ Navigation System
Standard *Relieva* Sinus Guidewire (0.035")
Relieva Sinus Lavage Catheter
Relieva Sinus Balloon Inflation Device

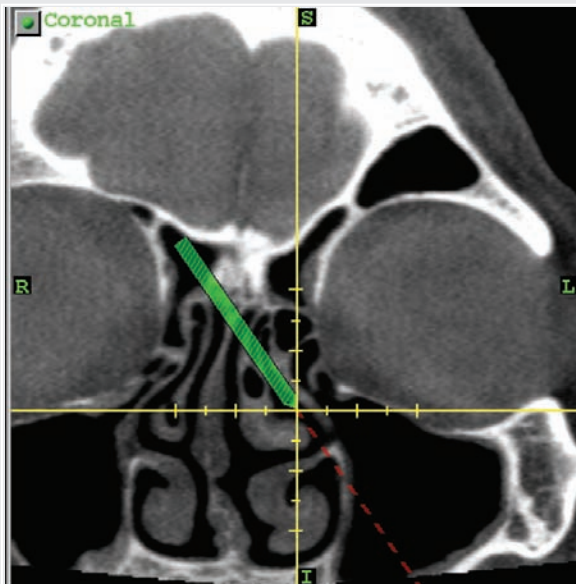


FIGURE 1

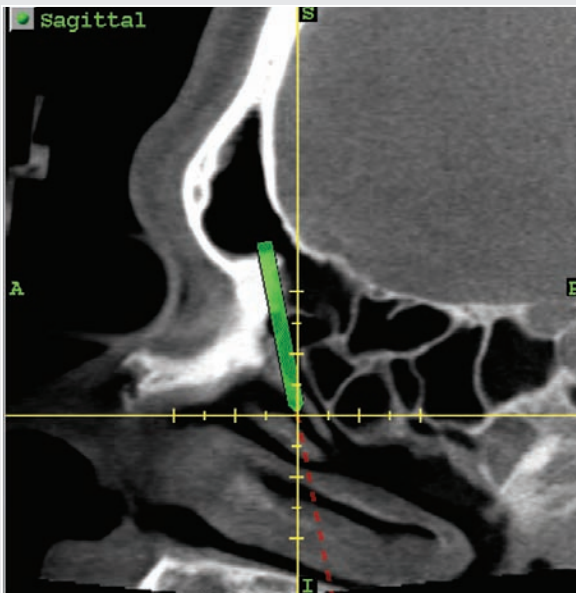


FIGURE 2

Background

This patient is a 55 year old male with more than a 1 year history of CRS symptoms including nasal congestion, frontal and occipital pressure-type headaches, PND, and decreased sense of smell. Despite previous treatment with three different antibiotics: Avelox®, Augmentin® x2, and Biaxin®, as well as systemic and inhaled steroids, he had remained refractory to medical treatment, and his symptoms had worsened. Three outside CTs showed extensive disease, with the most recent CT showing left maxillary, right ethmoid, and right frontal sinus mucosal thickening and severe nasal septal deformity. Diagnostic nasal endoscopy revealed a deviated nasal septum to the right preventing a view of the middle meatus. On the left, the middle turbinate was enlarged, possibly pneumatized, and the middle meatus showed edema and thick mucous, but no gross polyps.

Assessment included a deviated nasal septum, chronic maxillary sinusitis, and chronic ethmoidal sinusitis, refractory to medical therapy. The options of continued medical therapy versus surgical intervention were discussed. Surgical options included septoplasty and possible endoscopic sinus surgery on the maxillary and frontal sinuses using the *Relieva Balloon Sinuplasty™* devices in conjunction with ethmoidectomy. The patient opted to proceed with surgery.

Treatment

The patient was taken to the OR and placed under general anesthesia. The patient's preoperative CT data set was loaded on the GE Healthcare InstaTrak® 3500 Plus navigation system work station and reviewed. A straight aspirator as well as *Relieva* Sinus Guide Catheters (F-70 & M-110) attached to the *ReliENT* Navigation System were calibrated and verified. Target registration error was estimated at 1mm. After decongesting the nasal cavities, a standard septoplasty was performed. The left middle meatus was visualized with a 0 degree telescope and the lateral lamella of the left middle turbinate was resected. A small portion of the uncinata process was removed and an ethmoidectomy performed with cutting forceps and a microdebrider. A Sinus Guide Catheter (M-110) was used to locate the ostium of the maxillary sinus and once the appropriate trajectory was established (Figs. 1, 2, 3), a standard *Relieva* Sinus Guidewire (0.035") was placed into the maxillary sinus (Fig. 4) and verified with fluoroscopy. A *Relieva* Sinus Balloon Catheter (5x16mm) was passed over the Sinus Guidewire and inflated to 8 atm across the natural ostium of the maxillary sinus. After the Sinus Guide and Sinus Balloon Catheters were removed a 45 degree telescope was utilized and the dilated maxillary ostium was easily identified. On the patient's right side the middle turbinate was gently medialized. The medial extent of the uncinata process was resected as was the anterior superior wall of the ethmoid bulla.

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Continued

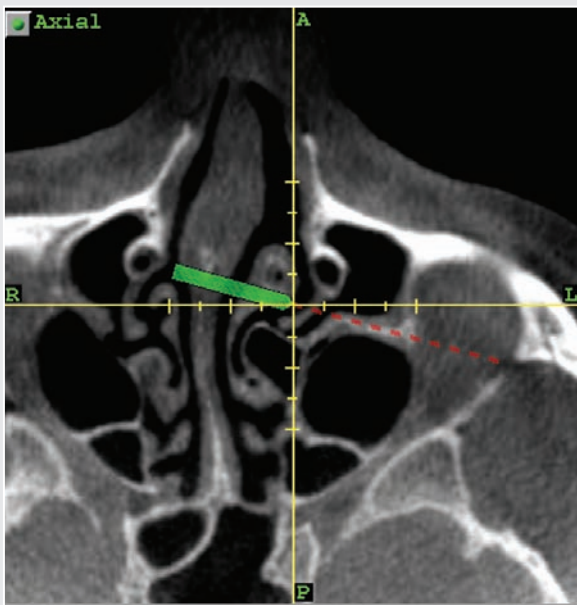


FIGURE 3

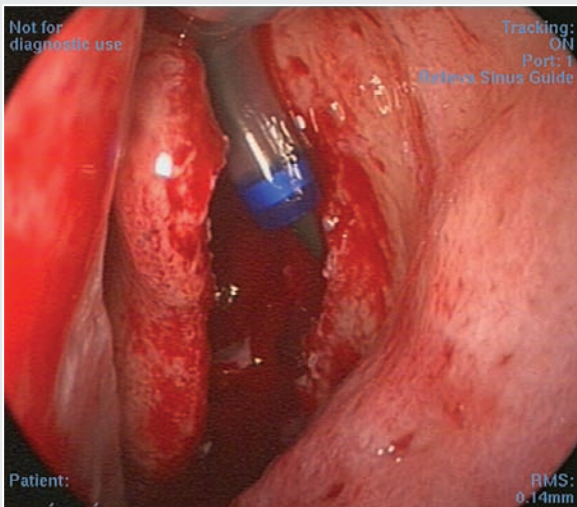


FIGURE 4

Using the *Relieva*[™] Sinus Guide Catheter (F-70) and the *ReliENT*[™] Navigation System adapter, the frontal recess was identified and a Sinus Guidewire was passed into the frontal sinus. Position was verified fluoroscopically. The Sinus Balloon Catheter was passed over the Sinus Guidewire, positioned, and inflated to 8 atm. Device positions were again verified fluoroscopically. The sinus balloon was moved approximately 1.5 mm inferiorly and dilated once again. New position was also verified fluoroscopically. Using the Sinus Guide Catheter (M-110), the maxillary sinus was cannulated and verified fluoroscopically. A guidewire was placed, over which the sinus balloon was tracked, positioned across the maxillary ostium, and dilated to 8 atm. The resulting dilated ostium was visually identified with a 45 degree telescope. The maxillary sinus was irrigated on each side, utilizing the *Relieva* Sinus Lavage Catheter. All blood, mucous and saline were aspirated from the middle meatus, nasal cavity, and nasopharynx. There was minimal bleeding. No packing was placed. The patient was extubated and taken to recovery in satisfactory condition.

Discussion

The GE navigation system proved to be helpful in this case, particularly in gaining access to the frontal sinus. The trajectory identified the direction, increased accuracy of device placement, and reduced fluoro time.

At the 6-day post-op visit, the patient complained of congestion and headaches. Diagnostic nasal endoscopy with debridement was performed with a rigid scope on the right and left side. Clot and crust from the ethmoidectomy were removed with forceps and suction. The ethmoid cavities were healing well and the middle turbinates were medialized nicely. The septum was intact, midline, and without perforation.

At the 20-day post-op, the patient had improved. He reported some continued congestion on the right, but his sense of smell was intact and he denied headaches. A diagnostic nasal endoscopy was performed, showing that the ethmoid cavities were patent and the frontal recess was without inflammatory changes. The left maxillary ostium was visualized and was patent. The right maxillary ostium could not be visualized because of patient discomfort with the examination. The nasal septum was midline without perforation. The patient is continuing a satisfactory post-op course and has resumed intranasal steroids with a planned follow-up in several weeks.

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