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Case Report and Review of the Literature

Prolonged Implantation of Sinus Devices and Implications for Chronic Rhinosinusitis: A Case Report and Review of the Literature

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FESS: Functional Endoscopic Sinus Surgery
CT: Computed Tomography

ABSTRACT

Background: Implantation of sinus stents and spacers can be used as adjuvant management to maintain patency of sinuses after endoscopic sinus surgery for chronic rhinosinusitis. These implants are typically removed several weeks after surgery. We present two cases of different patients who were initially treated by different physicians and were found to have retained sinus spacers in their paranasal sinuses 6-10 years after implantation.

Case Presentation: Case 1: A 40-year-old male with chronic rhinosinusitis and history of balloon sinuplasty six years prior presented with worsening symptoms of chronic rhinosinusitis refractory to medical management. He underwent revision functional endoscopic sinus surgery and was found to have retained sinus implants in the left and right frontal sinus recesses. Case 2: A 48-year-old female with long-standing chronic rhinosinusitis refractory to medical management presented after two prior sinus surgeries most recently 10 years ago. She underwent revision functional endoscopic surgery and was found to have a retained sinus implant from prior surgery in the right frontal recess outflow tract embedded within scar tissue and reactive hyperostosis. Foreign bodies from both patients were removed without complication and patients were healing appropriately in the post-operative period.

Conclusions: While sinus stents and spacers can help with post-operative scarring, leaving then unmonitored and in place will eventually result in them becoming a nidus for scarring and infection. It is critical that patients are aware of any foreign bodies we place, if they need scheduled removal or routine observation, and what symptoms may indicate that they are causing a problem.

Background

Post-operative management of the frontal sinus after functional endoscopic sinus surgery (FESS) is difficult due to possibility of ostia stenosis and recurrent disease [1]. The implantation of corticosteroid-eluting implants in the frontal sinus outflow tract during functional endoscopic sinus surgery is believed to help maintain patency during post-operative healing and aid in mucosalization [2]. These are often temporarily implanted to provide steroid release into sinuses over a several week period [3]. Manufacturers typically recommend removal of these non-absorbable implants a few weeks after placement. Like other foreign bodies, prolonged presence of these non-absorbable spacers in the paranasal sinuses may lead to a variety of long-term complications by causing mechanical obstruction of sinuses or serving as a nidus for infection [4]. We present two cases of patients who were referred for recalcitrant sinusitis and were found to have retained sinus implants in the frontal sinuses following previous sinus surgery at outside hospitals.

Case Presentation

Case 1

A 40-year-old man presented with bilateral chronic rhinosinusitis symptoms of facial pain, facial pressure, nasal obstruction, post-nasal

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drip, decreased sense of smell, and purulent rhinorrhea. He developed several acute exacerbations of sinusitis every year. Previous treatment modalities included antibiotics, nasal and oral steroids, saline irrigation, and montelukast. He had undergone balloon sinuplasty six years prior after which he continued to endure severe bilateral frontal pain and pressure.

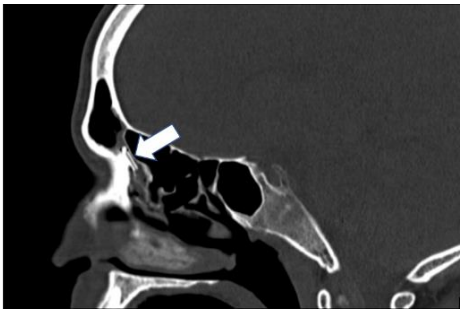

Figure 1: Pre-operative CT shows foreign body retained in left frontal sinus.

On sinonasal endoscopy the right side appeared healthy and normal, but the left side demonstrated purulence without polyps. There was evidence of a foreign body located lateral to the middle turbinate with fibrinous debris and surrounding inflammation. Pre-operative sinus Computed Tomography (CT) showed "mucosal thickening most predominantly involving bilateral anterior ethmoid air cells extending into bilateral frontal recesses with complete opacification bilaterally. Bilateral linear foreign bodies were noted in the frontal recess and on the right side the foreign body extended into the frontal sinus (Figures 1 & 2)."

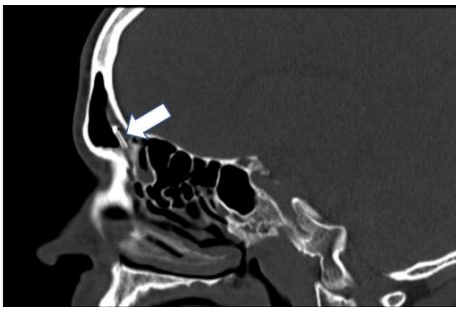

Figure 2: Pre-operative CT shows foreign body retained in right frontal recess.

The patient underwent FESS with removal of the foreign bodies in the frontal sinuses. Upon removal they were found to be retained sinus spacers from prior sinus surgery (Figure 3E). In post-operative follow-up, the patient was healing appropriately with all sinuses remaining widely patent.

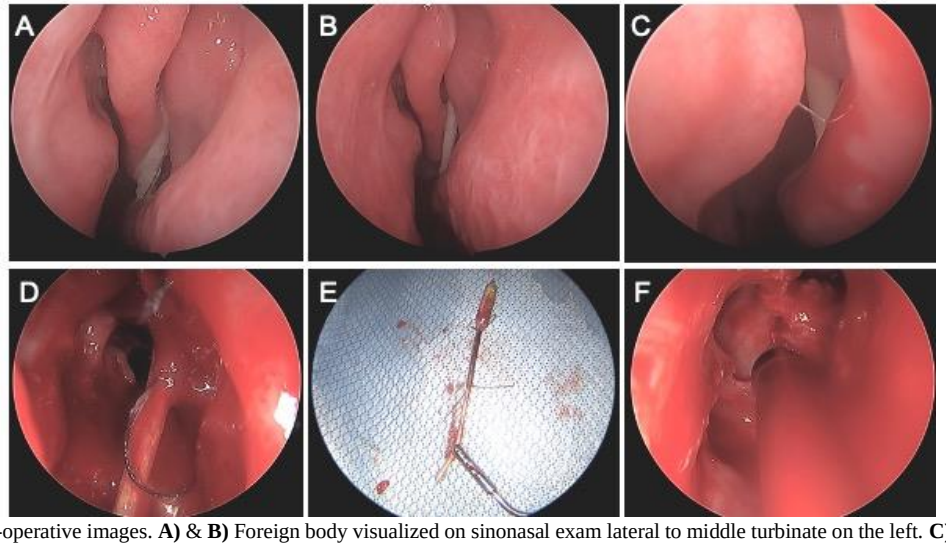

Figure 3: Case 1 intra-operative images. **A)** & **B)** Foreign body visualized on sinonasal exam lateral to middle turbinate on the left. **C)** Foreign body lateral to middle turbinate on the right. **D)** Left-sided intraoperative view with foreign bod/ stent in the frontal sinus. **E)** Stent removed from the left frontal sinus. **F)** Right frontal sinus opening after removal of stent.

Case 2

A 48-year-old female with a history of allergic rhinitis presented for the evaluation of long-standing sinonasal symptoms. She had experienced refractory right greater than left sinus symptoms including nasal congestion, facial pressure, and drainage. Previous treatment modalities included antibiotics, intranasal steroids, and saline irrigation. Previously, she had undergone septoplasty and two previous FESS. Her most recent surgery was 10 years prior. Sinonasal endoscopy of the left showed a normal sinonasal cavity. The right middle meatus and sphenoethmoidal recess revealed edema with clear, thick drainage that was suctioned without difficulty. A sinus CT showed mucosal thickening involving the right ethmoid and frontal sinus with a frontal recess linear foreign body. Regions of hyperostosis versus calcification were also noted in the right ethmoid cavity (Figure 4).

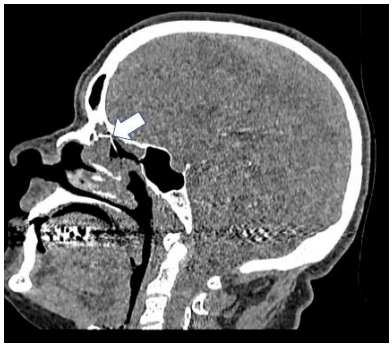

Figure 4: Pre-operative CT shows hyperostosis in the right ethmoid cavity, which was found to be a retained sinus implant.

The patient was taken to the operating room for a right-sided FESS with ethmoidectomy, sphenoidotomy, frontal sinusotomy, and debridement of inflammatory mucosa. Intra-operatively a foreign body was encountered in the right frontal recess outflow tract embedded within scar tissue and reactive hyperostosis. The imbedded foreign body (Figure 5) was removed and was found to be a sinus implant from prior FESS. In post-operative follow-up, the patient was healing well with all operated sinuses remaining widely patent and mucosal appearance as expected after FESS.

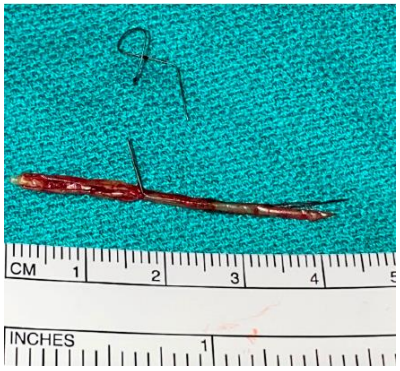

Figure 5: Removed foreign body, which was found to be retained sinus implant from prior FESS, from right frontal recess.

Discussion

Placement of implants in the paranasal sinuses has become a widespread treatment option for patients with recurrent chronic rhinosinusitis with the incidence of implantation of corticosteroid-eluting stents increasing 12.3-fold between 2012 and 2016 [5]. Prolonged stenting of the frontal sinus has been extensively discussed in the literature, although the optimal length of stenting of the frontal sinus remains a topic of debate [6, 7]. The reported duration of stent placement ranges in time from five days to seventeen years and is frequently dependent on the composition material of the stent [8]. Multiple different types of stents have been investigated with particular focus on the role of steroid eluting stents [9]. While typically uncomplicated, long-term stenting of the frontal sinus can lead to complications that range from chronic sinusitis to posterior table and skull base erosion [10]. In particular, frontal recess stents have been demonstrated to serve as a nidus for bacterial biofilm formation [11, 12]. If not clinically monitored, the potential clinical consequences of adverse effects due to long term retention of spacers in the frontal sinus is not insignificant.

After these cases, we queried the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database for reports regarding Relieva Stratus™ MicroFlow Frontal Sinus Spacers, the brand of sinus implant removed from both patients. The MAUDE database was developed by the FDA to compile all adverse events reported for a particular product, and both manufactures, and providers are required to submit reports whenever an adverse event occurs [13]. We identified eight adverse events attributed to the Relieva Stratus™ MicroFlow Frontal Sinus Spacers, two of which were cases of a retained spacer in the frontal sinus [14]. The first incident reported a retained spacer of unknown duration identified during subsequent balloon sinuplasty and the second incident reported a retained spacer of unknown duration that was identified in the frontal recess on CT imaging. In both instances, the retained Stratus™ spacers were surgically removed without further complications.

One additional case report was identified detailing a patient with a retained Stratus™ Sinus Spacer in the left sphenoethmoid recess for 7 months, which resulted in recurrent chronic rhinosinusitits [15]. In this patient, the spacer was surgically removed and treated with postoperative antibiotics, resulting in resolution of his symptoms. The Relieva Stratus™ MicroFlow Frontal Sinus Spacer was FDA approved to remain in place for 14-28 days and was discontinued in May 2013 due to limited clinical efficacy [16, 17].

Our cases demonstrate the potential for inadvertent retention of sinus implants following endoscopic sinus surgery and highlight that prolonged retention of sinus implants may serve as a nidus for scarring and infection. These cases also highlight the critical importance of having an informed discussion with patients prior to placement of foreign bodies in the post-surgical cavity to discuss expectations for follow-up and removal as well as what symptoms may signify a complication. Both of the cases we have recently treated were unaware that these devices were placed and required removal. While the onus is not completely on the physician nor the patient, careful patient selection as well as good preoperative counseling is essential.

Declaration

The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Ethics Approval and Consent to Participate

Not applicable.

Consent for Publication

Written informed consent was obtained from the patients for publication of the case report.

Availability of Data and Materials

Data are not available for public access due to patient privacy concerns.

Competing Interests

None.

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Author Contributions

All authors contributed to the interpretation of data and writing of this manuscript. AJK, MWG, WCB, BDT, AMZ, CSE were engaged in patient's care in his hospital course. All authors have read and approved the final manuscript for publication.

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