ABSTRACT

Establishment of patency of the sinus ostia is paramount to the treatment of chronic sinusitis. Endoscopic sinus surgery has been shown to be effective in accomplishing this. Recently, catheter based balloon dilation has been introduced as an alternative method to open the sinus ostia. The purpose of this investigation was to explore the feasibility of an osmotically driven, self-expanding device to dilate the sinus ostia in an animal model.

RESULTS

Four 1-hour devices were placed into 4 MSOs. The diameter of the devices, prior to expansion was 3.7 mm. Two devices were removed at 4 hours, one device at 6 hours, and one device at 13 hours post placement. The ostium was evaluated for patency at day 13 and 27 post procedure.

1-hour devices procedure overview

Four 1-hour expansion rate devices were placed into 4 MSOs. The diameter of the devices, prior to expansion was 3.7 mm. The devices were then allowed to expand in vivo and removed at 1 hour post placement. Both the diameters of the expanded device as well as resulting ostia diameters were measured immediately post device removal.

DISCUSSION AND CONCLUSIONS

The osmotic technology has a potential to be tailored to different expansion rates to dilate the constricted ostia. Data provided demonstrates that both 1-hour and 4-hour Dilation Devices were able to dilate in vivo to produce a patent ostia. Strong correlation was established between post expansion diameter of the Dilation Device and the final diameter of the ostium for both devices, suggestive that there is no acute recoil post treatment. Furthermore, endoscopic evaluation revealed no sign of mucosal injury post treatment and the created openings remained patent for at least 27 days, providing an encouraging result for long term efficacy.

REFERENCES


