Safety and Effectiveness of a Bioabsorbable Steroid-Releasing Implant for the Paranasal Sinus Ostia
A Randomized Clinical Trial

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IMPORTANCE Suboptimal outcomes of endoscopic sinus surgery (ESS) are often associated with restenosis and inflammation of frontal sinus ostia. Steroid-releasing sinus implants have been shown to maintain sinus patency by minimizing inflammation and scar tissue formation. An hourglass-shaped, bioabsorbable, steroid-releasing implant was developed to provide mechanical support and optimize drug delivery to paranasal sinus ostia.

OBJECTIVE To assess the safety and efficacy of the hourglass-shaped, bioabsorbable, steroid-releasing sinus implant in improving postoperative outcomes when placed in the frontal sinus ostia (FSO) following ESS in patients with chronic rhinosinusitis (CRS).

DESIGN, SETTING, AND PARTICIPANTS In a prospective, multicenter, randomized clinical trial using an intrapatient control design (ESS followed by implant placement within 1 FSO vs ESS alone on the contralateral side) 80 adult patients, with a mean (SD) age of 49.5 (13.4) years and consisting of 53 (66%) men and 27 (34%) women, were enrolled and underwent bilateral frontal sinusotomies with 1 frontal sinus randomized to receive a steroid-releasing implant. The study was carried out in 12 US centers between July 2015 and March 2016.

INTERVENTIONS A bioabsorbable steroid-releasing implant with hourglass shape containing 370 µg of mometasone furoate. All patients received standardized postoperative care.

MAIN OUTCOMES AND MEASURES The need for postoperative interventions, medical and surgical, in the FSO at day 30, as determined based on review of video endoscopic findings by an independent blinded surgeon. Also, endoscopic grading by the independent reviewer and clinical investigators at day 30 and day 90 and computed tomographic scan at day 90.

RESULTS The mean (SD) age of patients was 49.5 (13.4) years, 53 (66%) were men. Implants were successfully placed in all 80 randomized treatment sinuses. At day 30, steroid-releasing implants significantly reduced the need for postoperative interventions to 11.5% compared with 32.8% by surgery alone (mean difference, −21.3%; 95% CI, −35.1% to −7.6%), as assessed by the independent reviewer. Real-time endoscopic assessment by clinical investigators at day 30 demonstrated significant reduction in need for postoperative intervention (mean difference, −17.3%; 95% CI, −27.9% to −6.7%), significant reduction in inflammation score (mean difference, −12.3 mm; 95% CI, −18.3 to −6.4 mm), and significant reduction in rate of frontal restenosis or occlusion (mean difference, −22.7%; 95% CI, −33.5% to −11.9%) on treated compared with control sides. The results favoring the treatment sides were sustained through day 90: reduced need for postoperative interventions (mean difference, −11.7%; 95% CI, −21.0% to −2.4%) and reduction in restenosis and/or occlusion of the frontal ostium (mean difference, −17.4%; 95% CI, −28.6% to −6.1%). No implant-related adverse events were observed.

CONCLUSIONS AND RELEVANCE The hourglass-shaped steroid-releasing sinus implant was safe and more effective in maintaining FSO patency and improving surgical outcomes compared with surgery alone in the setting where no other immediate postoperative corticosteroids were administered.

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