Supplementary Online Content

Luong A, Ow RA, Singh A, et al. Safety and effectiveness of a bioabsorbable steroid-releasing implant for the paranasal sinus ostia: a randomized clinical trial. *JAMA Otolaryngol–Head Neck Surg*. doi: 10.1001/jamaoto.2017.1859

This supplementary material has been provided by the authors to give readers additional information about their work.

Supplemental eTable 1. Efficacy Results with Imputation in Patients who Received Oral Steroids Prior to Day 30

Endpoints	Treatment (N = 80)		Control (N = 80)		
	N[a]	**Value**	**N[a]**	**Value**	**Mean difference [95% CI]**
By Independent Reviewer at Day 30[b]					
Need for post-operative intervention, N (%)[c]	66[d]	17 (25.8)	66[d]	30 (45.5)	-19.7% [-33.3, -6.1]
Need for surgical intervention, N (%)	61[d]	6 (9.8)	61[d]	17 (27.9)	-18.0% [-32.1, -3.9]
Need for oral steroid intervention, N (%)	66[d]	14 (21.2)	66[d]	20 (30.3)	-9.1% [-19.7, 1.6]

a. Number of patients with evaluable sinuses.

b. Seven patients received oral steroids interventions: 3 prior to Day 21 and 4 prior to day 30. Based on when the patients received oral steroids or surgical interventions, the day 30 independent reviewer grades were replaced by the grades given by the clinical investigator at the visit preceding commencement of oral steroids or surgical interventions (either day 7 or day 21).

c. Post-operative intervention was a composite endpoint including surgical intervention required to debride obstructive adhesions/scarring formation in the FSO (defined as grade 2 or 3 on the adhesion/scarring scale), and/or oral steroid intervention warranted to resolve recurrent inflammation or polypoid edema in the frontal recess/FSO.

d. The number of sinuses evaluable based on grading of video endoscopies by independent reviewer varied by parameter. Data were considered missing if the independent reviewer could not grade a video due to sub-optimal video quality or inadequate imaging of the relevant anatomy. Inadequate imaging of the relevant anatomy can occur when polyps in ethmoid cavity or an adhesion of the middle turbinate prevents visualization of the FSO.

Supplemental eTable 2. Secondary Efficacy Endpoint Results at Day 30

Endpoints	Treatment (N = 80) N[a]	Treatment (N = 80) Value	Control (N = 80) N[a]	Control (N = 80) Value	Mean difference [95% CI][f]
By Independent Reviewer at Day 30					
Inflammation (100mm VAS), mean (SD)[b]	70	28.5 (18.2)	65	30.0 (19.0)	-2.9 [-7.3, 1.6]
Adhesion/Scarring – clinically significant amount (Grades 2, 3)[c], N (%)[d]	58	4 (6.9)	58	15 (25.9)	-19.0% [-32.8, -5.1]
Polypoid Edema – expanded amount (Grade 2)[e], N (%)[d]	61	6 (9.8)	61	10 (16.4)	-10.3% [-26.7, 6.2]
By Clinical Investigators at Day 30					
Adhesion/Scarring – clinically significant amount (Grades 2, 3)[c], N (%)[d]	75	3 (4.0)	75	11 (14.7)	-10.7% [-19.0, -2.3]
Polypoid Edema – expanded amount (Grade 2)[e], N (%)[d]	77	8 (10.4)	77	17 (22.1)	-7.6% [-16.5, 1.3]

a. Number of patients with evaluable sinuses.
b. 95% CI for mean values was obtained assuming a normal distribution.
c. Adhesion/scarring scale: 0=No visible granulation/scarring in the FSO, 1=Minimal amount of granulation, scarring or contraction observed but not obstructing the FSO (intervention not warranted), 2=Moderate amount of obstructive granulation, scarring or contraction present in the FSO (intervention is warranted), 3=Significant amount of scarring or contraction causing obstruction of the FSO requiring intervention (likely to compromise patency if not removed), Clinically significant amount was defined as grades 2 and 3.
d. 95% CI was computed using the method of Clopper and Pearson.
e. Polypoid edema in the frontal recess/FSO scale: 0=Normal mucosa, no visible polyps at the frontal recess or FSO, 1=Minimal amount of mucosal edema at the frontal recess or FSO, 2=Expanded amount of polypoid edema at the frontal recess or FSO.
f. Mean difference was computed using the difference in means in the treatment and control sides. 95% CI for the continuous variables was obtained assuming normal distribution.