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RESEARCH ARTICLE

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Reduction in healthcare resource use through 24 months following sinus surgery with steroid-eluting implants in chronic rhinosinusitis patients with and without nasal polyps: a real-world study

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ABSTRACT

Objective: To investigate the impact of steroid-eluting implants after endoscopic sinus surgery (ESS) on health care resource use (HCRU) in chronic rhinosinusitis patients with (CRSwNP) and without (CRSsNP) nasal polyps.

Methods: This retrospective, observational cohort study using real-world evidence data included adult patients with CRS who underwent ESS in 2015–2019 with at least 24 months of data before and after ESS. Patients who received implants were matched to patients who did not based on a propensity score developed using baseline characteristics and NP status. HCRU was compared between cohorts within each CRSwNP and CRSsNP subgroup using chi-square tests (binary variables).

Results: The implant cohort in the CRSwNP subgroup had fewer all-cause outpatient (90.0% vs. 93.9%, $p < .001$) and all-cause otolaryngology (64.3% vs. 76.4%, $p < .001$) visits as well as fewer endoscopy (40.5% vs. 47.4%, $p = .005$) and debridement (48.8% vs. 55.6%, $p = .007$) procedures than the non-implant cohort. The implant cohort in the CRSsNP subgroup had fewer all-cause outpatient (88.9% vs. 94.2%, $p < .001$) and all-cause otolaryngology (53.5% vs. 74.4%, $p < .001$) visits as well as fewer endoscopy (31.8% vs. 41.7%, $p < .001$) and debridement (36.7% vs. 53.4%, $p < .001$) procedures than the non-implant cohort. Revision sinus surgery was reduced in the implant cohort in both subgroups, and reached statistical significance in the CRSwNP subgroup (3.8% vs. 6.0%, $p = .039$) but not in the CRSsNP subgroup (3.6% vs. 4.2%, $p = .539$).

Conclusions: Overall, patients receiving implants had lower HCRU for 24 months after sinus surgery independent of nasal polyp status, and revision surgery was reduced in CRSwNP patients. These findings provide additional evidence that long-term reductions in HCRU may be achieved with steroid-eluting implant use during sinus surgery.

WHAT IS KNOWN ON THIS TOPIC

- Patients with chronic rhinosinusitis with nasal polyps (CRSwNP) have a disproportionately higher burden of disease and consume greater healthcare resources than chronic rhinosinusitis patients without nasal polyps (CRSsNP).
- CRSwNP patients represent approximately 30% of CRS patients who undergo surgery, but their clinical course is disproportionally complicated by disease recurrence and revision surgery.
- Steroid-eluting sinus implants have been shown in clinical trials to improve short-term postoperative outcomes after endoscopic sinus surgery (ESS) in CRS patients in general.
- A recent real-world evidence study reported that steroid-eluting sinus implants following ESS were associated with a reduction in HCRU in CRS patients followed for 18 months, but the impact of implants on HCRU in CRSwNP and CRSsNP patients separately remains unknown.

WHAT THIS STUDY ADDS

- In this observational study, reduced HCRU was observed in CRSwNP and CRSsNP patients who receive steroid-eluting sinus implants.
- Use of implants in CRSwNP and CRSsNP patients was associated with a significant reduction in healthcare visits (all-cause outpatient, all-cause otolaryngology), and sinus procedures (endoscopy, debridement).
- Revision surgery was significantly reduced in the implant cohort of CRSwNP patients and trended lower in the implant cohort of CRSsNP patients.
- Use of implants had no significant impact on all-cause ER/urgent care visits or sinus-related imaging.

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Introduction

The overall prevalence of CRS in the United States is approximately 3–6%, while the direct costs to the US healthcare system are estimated to fall between $7 and $13 billion per year[1–3]. CRS presents in two broadly defined clinical phenotypes depending on the presence (CRSwNP) or absence (CRSsNP) of nasal polyps.

CRS patients who fail to respond to conservative medical therapy may be offered endoscopic sinus surgery (ESS)[4]. While estimates vary, CRSwNP patients represent nearly one-third of CRS patients who undergo ESS[5]. Patients with CRSwNP are widely recognized to have a greater burden of disease, to be more prone to disease recurrence, and to more frequently require revision surgery, resulting in greater overall healthcare resource utilization than CRS patients without nasal polyps[6]. While overall ESS success rates in CRS approach 76–98%[7], surgical success in CRSwNP patients is considerably lower and CRSwNP patients can expect to require more frequent revision surgeries[8].

Oral steroids remain integral to the management of nasal polyp recurrence in CRSwNP patients, but their use may be complicated by harmful systemic side effects[9]. The search for alternative, better-tolerated therapies has yielded the development of new treatments such as monoclonal antibody therapy, but these therapies are expensive and their cost-effectiveness has been called into question[10]. Conversely, economic analyses of steroid-eluting sinus implants have demonstrated that the upfront costs of implants are offset by ultimate downstream savings[2,11,12].

Placed at the completion of ESS, corticosteroid-eluting sinus implants (implants) each deliver localized, sustained release of 370 micrograms of mometasone furoate directly onto healing sinus tissue for up to 30 days after surgery. Implants have been shown in clinical trials to improve short-term surgical outcomes, reducing the need for post-operative interventions, oral steroid use, and rates of occlusion or restenosis through post-operative day 30[13]. Corticosteroid-eluting sinus implants[i] have been approved by the US Food and Drug Administration (FDA) for use in patients 18 years of age and older following ethmoid, frontal, or maxillary sinus surgery. Currently, none of the implants is approved for use in the sphenoid sinus.

A recent real-world evidence data study of CRS patients who received steroid-eluting sinus implants after ESS documented reductions in healthcare resource use for up to 18 months after surgery[14]. While the study included both CRSwNP and CRSsNP patients, separate data for each clinical phenotypes were not provided.

This study seeks to examine whether ESS performed with-sinus implants is associated with reductions in HCRU in CRSwNP patients, despite their greater disease severity, and in CRSsNP patients separately. The analysis incorporates data from the Reg-ENT^{SM} registry (an otolaryngology-based specialty-specific data source), refinements to inclusion and exclusion criteria used previously[14], and a 24-month post-operative study period.

Methods

Study design

This retrospective observational cohort study included adult patients with CRS who underwent ESS between 1 January 2015 and 31 December 2019. The study population was derived from multisource databases containing healthcare claims and electronic medical record (EMR) data in the US. The datasets are de-identified and compliant with the Health Insurance Portability and Accountability Act. Descriptions of the datasets were submitted to an Institutional Review Board for approval, and the datasets were determined to be exempt.

This study included comparisons between patients who received a corticosteroid-eluting sinus implant ("implant cohort") and those who did not ("non-implant cohort"), and between the implant and non-implant cohorts within subgroups based on the presence (CRSwNP) or absence (CRSsNP) of nasal polyps. The frequency of select HCRU measures was summarized and compared between cohorts and within subgroups.

Data sources

This study was conducted using data from the OM1 Real-World Data Cloud (OM1, Inc, Boston, MA) and the Reg-ENT^{SM} registry (American Academy of Otolaryngology-Head and Neck Surgery/Foundation [AAO-HNS/F], Alexandria, VA). The Reg-ENT registry is connected to OM1's real-world data and evidence platforms through a data partnership between OM1, Inc and AAO-HNS/F[15,16]. This data linkage enables a more rapid and complete assessment of otolaryngology-specific data for real-world evidence research.

The OM1 dataset is derived from deterministically linked, de-identified, individual-level healthcare claims, EMR records, and other data sources covering over 300 million patients in the US since 2013. The EMR data are from sources geographically representative of the US population and include medication history, prescription information, laboratory results, and diagnoses documented by a health care provider. Medical and pharmacy claims data are linked to the clinical data to fill gaps in patients' clinical care. The medical and pharmacy claims contain billing and coding history on inpatient and outpatient encounters from acute care facilities, ambulatory surgery centers, and clinics.

AAO-HNS/F's Reg-ENT registry is the first and largest national-level repository of otolaryngology-specific data. The registry collects complete EMR and billing data from a large, representative network of clinical otolaryngology practices in the US, as well as from ancillary services such as audiometry. The data are derived directly from EMRs on a regular basis and stored in a central repository covering the full range of ear, nose, and throat (ENT) conditions seen in clinical practice, their treatments, and outcomes. All data are de-identified. The registry includes data from approximately 3000 clinicians, 500 practices, and 25 million ENT patient visits since 2015.

Table 1. Diagnosis and procedure codes for identification of CRS, NP, Sinus Implants, ESS, and Sinus-related Procedures.

Variable	Code Type	Codes
CRS	ICD-9 diagnosis	473.0, 473.1, 473.2, 473.3, 473.8, 473.9
	ICD-10 diagnosis	J32.0, J32.1, J32.2, J32.3, J32.4, J32.8, J32.9
NP	ICD-9 diagnosis	471, 471.8, 471.9
	ICD-10 diagnosis	J33.0, J33.8, J33.9
Steroid-eluting sinus implants	HCPCS	S1090
	HCPCS + NDC	HCPCS J3490 plus NDC 10599-0000-01, 10599-0001-01, or 10599-0002-01
ESS (ethmoid)[a,b]	CPT	31254, 31255, 31257, 31259
ESS (maxillary)[a]	CPT	31256, 31267
ESS (frontal)[a]	CPT	31276
ESS (sphenoid)[a,b]	CPT	31287, 31288, 31257, 31259
ESS (concha bullosa resection)	CPT	31240
Sinus endoscopy	CPT	31231
Sinus debridement	CPT	31237
	HCPCS	S2342
Polypectomy	CPT	30110, 30115

Abbreviations. CPT, Current Procedural Terminology; CRS, chronic rhinosinusitis; ESS, endoscopic sinus surgery; HCPCS, Healthcare Common Procedure Coding System; ICD-9, International Classification of Diseases, 9th Revision; ICD-10, International Classification of Diseases, 10th Revision; NP, nasal polyps.
[a]CPT codes were used to identify both index and repeat sinus surgeries.
[b]CPT 31257 and 31259 involve surgery of both the ethmoid and sphenoid sinuses and are counted as such in analyses of surgery by sinus type.

Patient selection and cohort assignment

Patients were required to have a diagnosis of CRS on the date of their ESS or within 24 months prior. All patients were required to have at least 24 months of claims data before and after their ESS. Patients with a prior history of ESS and patients who underwent balloon sinus dilation only were excluded. Use of sinus implants was identified on the day of the surgery. For subgroup analyses, patients were further classified as CRSwNP or CRSsNP. CRS and NP were identified based on relevant International Classification of Diseases (ICD-9th or 10th Revision) diagnosis codes, and ESS and sinus implants were identified based on the presence of relevant procedure codes (Table 1).

Healthcare resource use

The following HCRU measures were ascertained over a 24-month period after the index surgery: revision sinus surgery (excluding balloon sinus dilation), all-cause outpatient visits, all-cause otolaryngology visits, all-cause emergency room (ER)/urgent care visits, sinus-related procedures (endoscopy, debridement, polypectomy), and sinus-related imaging (CT, MRI). Revision sinus surgery, endoscopy, debridement, and polypectomy were identified based on relevant procedure codes listed in Table 1.

Statistical methods

To account for differences in CRS severity and other pre-surgery characteristics, patients in the non-implant cohort were matched to patients in the implant cohort based on a propensity score (PS) that predicted implant use versus no implant use. The PS was calculated using logistic regression modeling for the probability of receiving an implant. The logistic regression model included the following baseline variables: demographics (age, sex, race), presence of allergic rhinitis and/or asthma, the overall comorbidity burden as measured by the Deyo-Charlson comorbidity index (an overall measure of health based on ICD 9th and 10th Revision diagnosis codes for a range of comorbidities), sinus type treated at index surgery, year of surgery, and duration of the baseline period. Baseline variables were assessed during the 24 months prior to and including the index surgery. To reduce the potential for residual confounding in subgroup analyses, re-matching was performed within each subgroup (i.e., CRSwNP, with and without implants; CRSsNP, with and without implants) using PS generated for the overall cohort[17,18].

Descriptive statistics were used to summarize baseline demographics, surgery history and clinical characteristics, and HCRU during follow-up. Chi-square tests were used to compare outcomes between patients who received implants and those who did not, in the overall cohort and within subgroups stratified by the absence or presence of nasal polyps. All tests were two-sided with alpha = 0.05. Statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

Results

The overall study population comprised 3418 patients (1709 in the implant and non-implant cohort, respectively). There were 1638 patients with CRSwNP (819 in each cohort) and 1780 patients with CRSsNP (890 in each cohort).

The matched cohorts in the subgroups and in the overall population were similar with respect to age, sex, and race. Within the subgroups, a male predominance was observed for CRSwNP (54.3% vs. 45.7%), while a female predominance was observed for CRSsNP (57.5% vs. 42.3%). A higher proportion of the implant cohort than non-implant cohort had commercial insurance (87.2% vs. 81.8%), while a lower proportion had Medicaid or Medicare insurance (3.1% vs. 8.3%) (Table 2). Comorbid conditions in the CRSwNP and CRSsNP subgroups were well-balanced, with prevalence differences of $\leq$5% between the implant and non-implant cohorts (Table 3).

Independent of implant status, CRSwNP patients underwent more extensive index sinus surgery than CRSsNP patients for all sinus types. All surgeries were primary per

Table 2. Demographic characteristics by subgroup and cohort.

	CRSwNP[a]		CRSsNP[a]		Overall	
	Implant $N = 819$	Non-implant $N = 819$	Implant $N = 890$	Non-implant $N = 890$	Implant $N = 1709$	Non-implant $N = 1709$
Age (Mean, SD)	48.4 (14.3)	48.8 (15.0)	46.7 (14.2)	46.8 (15.1)	47.5 (14.2)	47.9 (15.2)
Sex (*N*, %)						
Female	379 (46.3%)	370 (45.2%)	511 (57.4%)	513 (57.6%)	890 (52.1%)	878 (51.4%)
Male	440 (53.7%)	449 (54.8%)	379 (42.6%)	377 (42.4%)	819 (47.9%)	831 (48.6%)
Race (*N*, %)[b]						
N reported patients	306	310	328	334	634	643
Caucasian	253 (82.7%)	254 (81.9%)	279 (85.1%)	290 (86.8%)	532 (83.9%)	543 (84.4%)
African American	43 (14.1%)	40 (12.9%)	31 (9.5%)	32 (9.6%)	74 (11.7%)	73 (11.4%)
Asian	2 (0.7%)	12 (3.9%)	13 (4.0%)	6 (1.8%)	15 (2.4%)	18 (2.8%)
Other	8 (2.6%)	4 (1.3%)	5 (1.5%)	6 (1.8%)	13 (2.1%)	9 (1.4%)
Insurance type (*N*, %)[b]						
N reported patients	643	667	667	695	1310	1362
Commercial	550 (85.5%)	546 (81.9%)	592 (88.8%)	566 (81.4%)	1142 (87.2%)	1114 (81.8%)
Medicaid or Medicare	18 (2.8%)	56 (8.4%)	22 (3.3%)	53 (7.6%)	40 (3.1%)	113 (8.3%)
Other	75 (11.7%)	65 (9.7%)	53 (7.9%)	76 (10.9%)	128 (9.8%)	135 (9.9%)

Abbreviations. CRSsNP, chronic rhinosinusitis without nasal polyps; CRSwNP, chronic rhinosinusitis with nasal polyps; SD, standard deviation.
[a]Due to the propensity score re-matching done within the CRSsNP and CRSwNP subgroups, numbers in the implant and non-implant cohorts across subgroups may not sum to the implant and non-implant cohorts in the overall study population.
[b]Percentages were calculated using the N reported patients as the denominator.

Table 3. Baseline characteristics by subgroup and cohort.

	CRSwNP[a]		CRSsNP[a]		Overall	
	Implant $N = 819$	Non-implant $N = 819$	Implant $N = 890$	Non-implant $N = 890$	Implant $N = 1709$	Non-implant $N = 1709$
Deyo-Charlson comorbidity index (Mean, SD)	1.0 (1.2)	0.9 (1.2)	0.7 (1.2)	0.8 (1.3)	0.9 (1.2)	0.9 (1.3)
Co-morbid condition of interest (*N*, %)						
Allergic rhinitis	443 (54.1%)	440 (53.7%)	480 (53.9%)	503 (56.5%)	923 (54.0%)	936 (54.8%)
Asthma	299 (36.5%)	298 (36.4%)	152 (17.1%)	160 (18.0%)	451 (26.4%)	457 (26.7%)
Sleep disorders[b]	147 (17.9%)	178 (21.7%)	195 (21.9%)	211 (23.7%)	342 (20.0%)	395 (23.1%)
COPD	107 (13.1%)	116 (14.2%)	96 (10.8%)	97 (10.9%)	203 (11.9%)	205 (12.0%)
Eustachian tube dysfunction	66 (8.1%)	55 (6.7%)	110 (12.4%)	112 (12.6%)	176 (10.3%)	165 (9.7%)
Immunodeficiency disorders	14 (1.7%)	19 (2.3%)	20 (2.2%)	28 (3.1%)	34 (2.0%)	44 (2.6%)
Sensitivity/allergy to aspirin or NSAIDs	17 (2.1%)	18 (2.2%)	9 (1.0%)	8 (0.9%)	26 (1.5%)	25 (1.5%)
Allergic fungal rhinosinusitis	0 (0.0%)	0 (0.0%)	1 (0.1%)	1 (0.1%)	1 (0.1%)	1 (0.1%)

Abbreviations. COPD, chronic obstructive pulmonary disease; CRSsNP, chronic rhinosinusitis without nasal polyps; CRSwNP, chronic rhinosinusitis with nasal polyps; NSAIDs, nonsteroidal anti-inflammatory drugs; SD, standard deviation.
[a]Due to the propensity score re-matching done within the CRSsNP and CRSwNP subgroups, numbers in the implant and non-implant cohorts across subgroups may not sum to the implant and non-implant cohorts in the overall study population.
[b]Includes sleep apnea, nighttime awakening due to congestion, and snoring.

study design and nearly all index surgeries were performed in outpatient facilities (Table 4).

During 24 months after the index surgery, revision surgery was significantly lower in the implant cohort than in the non-implant cohort within the CRSwNP subgroup (3.8% vs. 6.0%, $p = .039$) and trended in the same direction within the CRSsNP subgroup but did not reach statistical significance (3.6 vs. 4.2%, $p = .539$) (Table 5).

For the CRSwNP subgroup, all-cause outpatient visits (90.0% vs. 93.9%, $p = .004$) and all-cause ENT visits (64.3% vs. 76.4%, $p < .001$) were significantly lower in the implant cohort. In the CRSsNP subgroup, all-cause outpatient visits (88.9% vs. 94.2%, $p < .001$) and all-cause ENT visits (53.5% vs. 74.4%, $p < .001$) were likewise significantly reduced in the implant cohort. The percentage of patients with all-cause ER/urgent care visits was similar within the CRSwNP and CRSsNP subgroups, as well as within the overall study population (Table 6).

Patients in the implant cohort were significantly less likely to undergo endoscopy (36.0% vs. 44.6%, $p < .001$) and debridement (42.5% vs. 54.5%, $p < .001$) compared to those in the non-implant cohort. Subgroup analyses showed similar reductions in sinus procedures in both CRSwNP patients (endoscopy 40.5% vs. 47.4%, $p = .005$; debridement 48.8% vs. 55.6%, $p = .007$) and CRSsNP patients (endoscopy 31.8% vs. 41.7%, $p < .001$; debridement 36.7% vs. 53.4%, $p < .001$) (Table 6).

Sinus-related imagings were broadly similar in CRSwNP and CRSsNP subgroups regardless of whether patients received implants (Table 6). A significantly higher percentage of CRSsNP patients who received implants underwent a sinus-related MRI than patients who did not receive an implant. (2.0% vs. 0.8%, $p = .027$). The proportion of patients in the overall study population who underwent sinus-related imaging during the 24 months following surgery was nearly identical between the implant and non-implant cohorts (CT: 9.2% vs. 9.1%, $p = .906$; MRI: 1.8% vs. 1.4%; $p = .410$).

Discussion

This observational RWE study found reductions in HCRU for 24 months postoperatively in both CRSwNP and CRSsNP

Table 4. Characterization of index sinus surgery by subgroup and cohort.

	CRSwNP[a]		CRSsNP[a]		Overall	
	Implant $N = 819$	Non-implant $N = 819$	Implant $N = 890$	Non-implant $N = 890$	Implant $N = 1709$	Non-implant $N = 1709$
Index surgery by sinus type[b]						
Maxillary	715 (87.3%)	715 (87.3%)	599 (67.3%)	599 (67.3%)	1314 (76.9%)	1314 (76.9%)
Ethmoid	753 (91.9%)	753 (91.9%)	777 (87.3%)	777 (87.3%)	1530 (89.5%)	1530 (89.5%)
Frontal	508 (62.0%)	508 (62.0%)	350 (39.3%)	350 (39.3%)	858 (50.2%)	858 (50.2%)
Sphenoid	517 (63.1%)	517 (63.1%)	298 (33.5%)	298 (33.5%)	815 (47.7%)	815 (47.7%)
Year of index surgery						
2015	126 (15.4%)	143 (17.5%)	127 (14.3%)	159 (17.9%)	253 (14.8%)	303 (17.7%)
2016	209 (25.5%)	207 (25.3%)	275 (30.9%)	231 (26.0%)	484 (28.3%)	435 (25.5%)
2017	212 (25.9%)	192 (23.4%)	199 (22.4%)	210 (23.6%)	411 (24.0%)	402 (23.5%)
2018	193 (23.6%)	166 (20.3%)	191 (21.5%)	189 (21.2%)	384 (22.5%)	351 (20.5%)
2019	79 (9.6%)	111 (13.6%)	98 (11.0%)	101 (11.3%)	177 (10.4%)	218 (12.8%)
Index surgery facility type[c]						
Outpatient	808 (98.7%)	792 (96.7%)	882 (99.1%)	866 (97.3%)	1690 (98.9%)	1659 (97.1%)
Inpatient	3 (0.4%)	6 (0.7%)	0 (0.0%)	6 (0.7%)	3 (0.2%)	11 (0.6%)
Unknown	8 (1.0%)	21 (2.6%)	8 (0.9%)	18 (2.0%)	16 (0.9%)	39 (2.3%)

Abbreviations. CPT, Current Procedural Terminology; CRSsNP, chronic rhinosinusitis without nasal polyps; CRSwNP, chronic rhinosinusitis with nasal polyps; SD, standard deviation.
[a]Due to the propensity score re-matching done within the CRSsNP and CRSwNP subgroups, numbers in the implant and non-implant cohorts across subgroups may not sum to the implant and non-implant cohorts in the overall study population.
[b]The OM1 Real-World Data Cloud provides data on the type of sinuses treated, but not on the specific sinus location of implant placement or the type of implant used. None of the studied implants are approved for placement in the sphenoid sinuses.
[c]Outpatient facility included day surgery and ambulatory services.

Table 5. Repeat sinus surgery during the 24 months following index sinus surgery by subgroup and cohort.

	CRSwNP[a]			CRSsNP[a]			Overall		
	Implant $N = 819$	Non-implant $N = 819$	*p*-value	Implant $N = 890$	Non-implant $N = 890$	*p*-value	Implant $N = 1709$	Non-implant $N = 1709$	*p*-value
Repeat sinus surgery (*N*, %)	31 (3.8%)	49 (6.0%)	.039	32 (3.6%)	37 (4.2%)	.539	63 (3.7%)	88 (5.1%)	.037
(% of repeat surgery patients)									
Implant[b]	7 (22.6%)	0 (0.0%)	–	7 (21.9%)	1 (2.7%)	–	14 (22.2%)	1 (1.1%)	–
Repeat surgery by sinus type									
Maxillary	22 (71.0%)	37 (75.5%)	–	18 (56.3%)	27 (73.0%)	–	40 (63.5%)	66 (75.0%)	–
Ethmoid	21 (67.7%)	43 (87.8%)	–	25 (78.1%)	23 (62.2%)	–	46 (73.0%)	68 (77.3%)	–
Frontal	20 (64.5%)	32 (65.3%)	–	15 (46.9%)	15 (40.5%)	–	35 (55.6%)	48 (54.5%)	–
Sphenoid	16 (51.6%)	31 (63.3%)	–	12 (37.5%)	13 (35.1%)	–	28 (44.4%)	45 (51.1%)	–
(% of total patients)									
Implant[b]	7 (0.9%)	0 (0.0%)	–	7 (0.8%)	1 (0.1%)	–	14 (0.8%)	1 (0.1%)	–
Repeat surgery by sinus type									
Maxillary	22 (2.7%)	37 (4.5%)	–	18 (2.0%)	27 (3.0%)	–	40 (2.3%)	66 (3.9%)	–
Ethmoid	21 (2.6%)	43 (5.3%)	–	25 (2.8%)	23 (2.6%)	–	46 (2.7%)	68 (4.0%)	–
Frontal	20 (2.4%)	32 (3.9%)	–	15 (1.7%)	15 (1.7%)	–	35 (2.0%)	48 (2.8%)	–
Sphenoid	16 (2.0%)	31 (3.8%)	–	12 (1.3%)	13 (1.5%)	–	28 (1.6%)	45 (2.6%)	–

Abbreviations. CPT, Current Procedural Terminology; CRSsNP, chronic rhinosinusitis without nasal polyps; CRSwNP, chronic rhinosinusitis with nasal polyps.
[a]Due to the propensity score re-matching done within the CRSsNP and CRSwNP subgroups, numbers in the implant and non-implant cohorts across subgroups may not sum to the implant and non-implant cohorts in the overall study population.
[b]Represents patients who underwent repeat sinus surgery with placement of a steroid-eluting sinus implant. Data on specific sinus location of implant placement and the type of implant used are not available in the OM1 Real-World Data Cloud. None of the studied implants are approved for placement in the sphenoid sinus.

patients who underwent endoscopic sinus surgery with steroid-eluting implants compared to a matched cohort that underwent sinus surgery alone. A lower percentage of the patients who received implants required all-cause outpatient and all-cause otolaryngologist visits. Patients who received implants were also observed to experience fewer sinus-related endoscopy and fewer sinus-related debridement procedures. Despite a greater burden of disease and more extensive surgery in nasal polyp patients[1], the reductions in HCRU outcomes observed in the CRSsNP patients and the overall study population were also seen in the CRSwNP subgroup.

Patients in the CRSwNP subgroup who received implants had the greatest reduction in revision surgery during the 24-month study period. While not statistically significant, patients in the CRSsNP subgroup showed a consistent trend toward reduced revision surgery after implant placement. Although the study followed patients for 24 months postoperatively, the study period may nevertheless be insufficient to capture a statistically significant difference in revision surgery in CRSsNP patients between implant and non-implant cohorts.

These observations of reduced revision surgery in CRSwNP patients after implant use are particularly compelling given that such patients are known to be more prone to disease recurrence and revision surgery[6]. Further investigation may be warranted to confirm these findings.

Within the CRSwNP subgroup, revision surgery was less common in the implant cohort than in the non-implant

Table 6. Healthcare resource utilization during 24 months following index sinus surgery by subgroup and cohort.

	CRSwNP[a]			CRSsNP[a]			Overall		
	Implant $N = 819$	Non-implant $N = 819$	*p*-value	Implant $N = 890$	Non-implant $N = 890$	p-value	Implant $N = 1709$	Non-implant $N = 1709$	*p*-value
Healthcare visits (*N*, %)									
All-cause outpatient	737 (90.0%)	769 (93.9%)	.004	791 (88.9%)	838 (94.2%)	<.001	1528 (89.4%)	1606 (94.0%)	<.001
All-cause otolaryngologist	527 (64.3%)	626 (76.4%)	<.001	476 (53.5%)	662 (74.4%)	<.001	1003 (58.7%)	1289 (75.4%)	<.001
All-cause ER/urgent care	224 (27.4%)	255 (31.1%)	.092	257 (28.9%)	246 (27.6%)	.563	481 (28.1%)	500 (29.3%)	.472
Sinus procedures performed (N, %)									
Endoscopy	332 (40.5%)	388 (47.4%)	.005	283 (31.8%)	371 (41.7%)	<.001	615 (36.0%)	763 (44.6%)	<.001
Debridement	400 (48.8%)	455 (55.6%)	.007	327 (36.7%)	475 (53.4%)	<.001	727 (42.5%)	932 (54.5%)	<.001
Polypectomy	1 (0.1%)	5 (0.6%)	.102	0 (0.0%)	0 (0.0%)	–	1 (0.1%)	5 (0.3%)	.102
Sinus-related imaging (*N*, %)									
CT	61 (7.4%)	70 (8.5%)	.412	97 (10.9%)	84 (9.4%)	.308	158 (9.2%)	156 (9.1%)	.906
MRI	12 (1.5%)	16 (2.0%)	.446	18 (2.0%)	7 (0.8%)	.027	30 (1.8%)	24 (1.4%)	.410

Abbreviations. CT, computed tomography scans, ER, emergency room; MRI, magnetic resonance imaging; SD, standard deviation.
[a]Due to the propensity score re-matching done within the CRSsNP and CRSwNP subgroups, numbers in the implant and non-implant cohorts across subgroups may not sum to the implant and non-implant cohorts in the overall study population.

cohort for all sinus types. In CRSsNP patients, maxillary revision surgery was less common in the implant cohort, while ethmoid, frontal, and sphenoid revision surgery was less common in the non-implant cohort. The overall revision surgery percentages of 3.6–6.0% noted in this study are consistent with the revision sinus surgery rates seen at 2 years in other studies[19], but well below the long term estimated revision sinus surgery rate of 15% over 10 years[20].

The findings of this study reinforce the results of clinical trials that demonstrated the efficacy of steroid-eluting implants in improving sinus surgery postoperative outcomes through postoperative day 30 and they extend the observations of previous RWE studies to 24 months postoperatively. The reduction in HCRU seen in this study further corroborates the cost-effectiveness of steroid-eluting implants observed by others[2,11,12,14].

Strengths of this study include the addition of data from the Reg-ENT registry, previously unavailable, which yielded greater availability of all-cause ENT and urgent care visits, as well as postoperative sinus debridement. The study period was a full 24 months postoperatively. Inclusion criteria were refined to restrict the clinical diagnosis of CRS to ICD codes only and ESS to CPT codes only, consistent with contemporary research in the field[20]. To establish a more uniform set of CRS patients, patients who underwent an index surgery consisting of balloon sinus dilation only as well as those with a prior history of ESS were excluded from the dataset. The study design provided for a direct comparison of HCRU outcomes in CRSwNP and CRSsNP subgroups. Confounding by baseline characteristics was controlled through PS-matching at the cohort level and matching on the PS was repeated for the CRSwNP and CRSsNP subgroups.

Caution is always warranted when interpreting results of studies of this nature. Although the matched implant and non-implant cohorts were well-balanced on measured baseline characteristics, residual confounding by unmeasured characteristics remains possible. The PS matching relied on data available in EMR and claims records, and may not remove all confounding, particularly for unmeasured variables, such as disease and/or nasal polyp severity. There remains an implicit assumption that clinical practices between the cohorts differ only in the use of steroid-eluting sinus implants, yet patients receiving implants may also receive more thorough surgery and more meticulous postoperative care. These considerations may affect HCRU and warrant further investigation.

Limitations

There are limitations inherent in retrospective study designs and the secondary use of data. While the sinus types operated on during the index surgery and revision surgeries are reported, the dataset did not allow for determination of the specific sinuses where implants were placed, nor of the number of implants placed. Since the non-implant cohort was matched to the patients in the implant cohort, the revision surgery rates and HCRU observed in the non-implant cohort may not be generalizable to a larger population of less severely diseased CRS patients who do not receive implants during sinus surgery. Despite the multi-source nature of the dataset, incomplete data capture may have occurred: only 53.5–76.4% of patients had an otolaryngology visit during the 24-month study period. The COVID-19 pandemic may have restricted access to both office visits and elective procedures in 2020 and 2021, yet the percentage of patients with these encounters would be expected to be higher in most clinical practices, suggesting incomplete data capture. The HCRU observed in the dataset may underestimate total HCRU as services paid for out-of-pocket or otherwise are not captured in the claims or EMR data; however, this would not be expected to bias the findings as it should apply to both groups of patients. The study did not assess differences in postoperative medication use such as inhaled nasal corticosteroids, saline rinses, antibiotics or oral steroids as these therapies are low cost, frequent components of the postoperative standard of care[9] and would be expected to be similar regardless of implant status. Chances of statistically significant findings due to multiple comparisons also cannot be ruled out.

Conclusions

In this retrospective, observational RWE study, CRSwNP and CRSsNP patients who received steroid-eluting sinus implants after ESS had significantly lower HCRU over 24 months compared to patients who underwent ESS alone. Revision surgery over 24 months was significantly reduced in implant patients in the CRSwNP subgroup. These findings provide additional evidence that long-term reductions in HCRU may be achieved with steroid-eluting sinus implant use during sinus surgery in the challenging CRSwNP population as well as in CRSsNP patients.

Note

i. PROPEL family of sinus implants (PROPEL, PROPEL Mini and PROPEL Contour), Intersect ENT, Inc., Menlo Park, CA, USA. PROPEL is indicated following ethmoid sinus surgery, PROPEL Contour is indicated following frontal and maxillary sinus surgery, and PROPEL Mini is indicated following ethmoid and frontal sinus surgery.

Transparency

Declaration of funding

Intersect ENT, Inc. (now Medtronic) engaged and provided funding to OM1, Inc. to conduct this study.

Declaration of financial/other relationships

VH, KM, and IT are employees of OM1, Inc. AKG is a former employee of Intersect ENT, Inc. JEK was a paid consultant to Intersect ENT, Inc. Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

Author contributions

Conception/design of the study: VH, IT, AG, JEK; Acquisition/analysis of the data: VH, KM, IT; Interpretation of the data: All authors; Drafting of the paper or revising it critically for intellectual content: All authors; Final approval of the version to be published: All authors. All authors agree to be accountable for all aspects of the work.

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