Mometasone-Eluting Sinus Implants in the Management Of Chronic Rhinosinusitis: A Comprehensive Review

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Abstract:
Chronic rhinosinusitis (CRS) is recognized as a persistent inflammatory disorder of the paranasal sinuses, frequently resistant to conventional medical therapy and often necessitating surgical intervention. Functional endoscopic sinus surgery (FESS) has been widely adopted to restore sinus ventilation and drainage; however, postoperative recurrence and inflammation remain prevalent. To address these challenges, a bioabsorbable, mometasone furoate–eluting sinus implant (Propel®, Intersect ENT, Palo Alto, CA) has been developed and FDA-approved for placement following ethmoid sinus surgery. The implant is designed to provide mechanical support and sustained, localized corticosteroid delivery directly to inflamed tissue for up to 30 days. Its efficacy and safety have been demonstrated in multiple clinical trials, including randomized controlled studies, where reductions in postoperative polyposis, adhesions, inflammation, and need for further interventions were reported. Minimal systemic absorption and a favorable safety profile have been consistently observed. Despite promising outcomes, limitations such as short follow-up periods and the absence of long-term data have been identified. Future directions may include the development of smart drug-delivery systems, multi-drug platforms, and expanded applications to other sinus regions. The Propel implant has been shown to enhance postoperative healing, reduce recurrence, and minimize the need for systemic corticosteroids, positioning it as a valuable adjunct in the management of CRS.

I. Introduction

Chronic rhinosinusitis (CRS) is a widespread inflammatory condition of the nasal and paranasal sinus mucosa, affecting up to 12% of the adult population and significantly impairing quality of life and productivity. It is characterized by persistent symptoms such as nasal congestion, facial pain or pressure, nasal discharge, and reduced sense of smell lasting for more than 12 weeks.

Although the precise pathophysiology of CRS remains unclear, several contributing factors have been proposed, including environmental and genetic predisposition, anatomic variations, microbial colonization, superantigen effects, biofilm formation, fungal elements, allergic responses, immune dysfunction, and impaired mucociliary clearance. Regardless of the initial cause, the disease is often exacerbated by bacterial or fungal contamination of the sinuses.

Functional endoscopic sinus surgery (FESS) is widely used to restore ventilation and drainage by removing obstructions and preserving mucosal integrity. In addition to mechanical restoration, FESS enhances the efficacy of topical therapies such as saline irrigation, antibiotics, and corticosteroids by improving access to inflamed mucosa. However, despite surgical intervention, CRS frequently recurs, necessitating continued medical therapy. Surgery alone does not address the

underlying inflammatory pathways or etiologic factors responsible for chronic disease.

Topical corticosteroids, administered primarily via nasal sprays, are a mainstay in the management of CRS and are favored for their low systemic absorption. However, conventional sprays often have limited access to the middle meatus and sinus cavities, especially postoperatively due to edema, crusting, or poor patient compliance. Systemic corticosteroids are more potent but carry significant adverse effects including osteonecrosis, osteoporosis, cataracts, mood disturbances, and hyperglycemia. Given these limitations, there is an ongoing need for targeted, sustained-release drug delivery methods that provide therapeutic benefits while minimizing systemic exposure.

The Propel mometasone furoate–eluting sinus implant (Intersect ENT, Palo Alto, CA) is the first FDA-approved bioabsorbable drug-eluting stent designed to release corticosteroids directly into the ethmoid sinus cavity post-FESS. This device offers localized, controlled steroid delivery for up to 30 days, reducing inflammation, preventing polyp recurrence, and supporting mucosal healing.

This review aims to provide a comprehensive evaluation of the Propel implant, focusing on its design, mechanism of action, clinical efficacy, surgical integration, patient outcomes, safety, limitations, and potential future directions. By synthesizing existing evidence, this article highlights the current role of the Propel device in CRS management and explores innovations in localized steroid therapy.

II. Main Body

2.1. Pathophysiology / Disease Background

Chronic rhinosinusitis (CRS) is a persistent inflammatory condition of the paranasal sinuses, often lasting more than 12 weeks despite appropriate medical therapy. Although its precise pathophysiology is not fully understood, various contributing factors have been identified. These include anatomical variations, environmental exposures, microbial colonization, superantigens, biofilms, fungi, immunodeficiency, atopy, and mucociliary dysfunction [1,2]. A key component of CRS is persistent inflammation exacerbated by bacterial and fungal contamination [3]. Standard treatments include topical saline irrigation, intranasal corticosteroids, antibiotics, and in severe cases, systemic steroids or endoscopic sinus surgery (ESS) [4]. Despite surgery, long-term management remains necessary due to persistent inflammatory triggers, necessitating integrated postoperative medical therapies, especially corticosteroids [5].

2.2. Device Description & Mechanism of Action

The Propel sinus implant (Intersect ENT, Palo Alto, CA) is the first FDA-approved device for delivering corticosteroids directly into the ethmoid sinus cavity following ESS [6]. The implant is composed of a bioabsorbable lattice structure made of polylactide-co-glycolide, embedded with 370 mcg of mometasone furoate, a potent topical corticosteroid [7,8]. Its spring-like structure allows it to expand and conform to the anatomy of the ethmoid sinus, ensuring stable placement and optimal drug delivery [9]. The device provides both mechanical support—preventing synechiae and maintaining middle turbinate positioning—and sustained local steroid release for up to 30 days [10]. Bioabsorption is predictable, with less than 0.2% of the material remaining after 60 days [11].

2.3. Clinical Evidence

Three key studies have demonstrated the safety and efficacy of the Propel implant. In a randomized, double-blind pilot study by Marple et al., patients with CRS undergoing ESS received a steroid-releasing implant in one ethmoid cavity and a non-eluting implant in the contralateral side [12]. The study demonstrated significant reductions in postoperative inflammation, polyp formation ($p=0.0391$), and adhesions ($p=0.0313$) between days 21–45.

The ADVANCE trial, a prospective, multicenter, single-cohort study, involved 50 patients and 90 sinuses implanted with the device postoperatively. The results confirmed low rates of inflammation, polyposis, and adhesions comparable to the initial pilot study, with statistically significant improvements in patient-reported outcomes using the Rhinosinusitis Disability Index (RSDI) and Sinonasal Outcome Test-22 (SNOT-22) [13].

The ADVANCE II trial, a double-blind, randomized, controlled study involving 105 patients, demonstrated a 29% reduction in postoperative interventions ($p=0.028$), a 52% decrease in adhesions ($p=0.005$), and a 44.9%

reduction in polyposis (p=0.002) on the treated side compared to the control [14].

2.4. Surgical Technique & Use in Practice

The Propel implant is placed intraoperatively under endoscopic visualization using a one-handed delivery system. It expands upon deployment to conform to the ethmoid cavity, holding the middle turbinate in a medial position, thereby reducing the likelihood of lateralization and synechiae [15]. Though no cadaveric studies have examined skull base impact, no cases of cerebrospinal fluid (CSF) leak or skull base violation have been reported [16].

2.5. Patient Outcomes & Safety Profile

Patients receiving the implant demonstrated substantial improvements in symptoms and quality of life scores, as evidenced by RSDI and SNOT-22 assessments through 6 months post-surgery [13,14]. Safety profiles from the three major studies report only three adverse events, none of which were device-related [12-14].

Systemic absorption of mometasone is minimal. Plasma levels of mometasone remained below detection limits, and cortisol levels stayed within the normal range, indicating no adrenal suppression [17]. Mometasone furoate's safety in children over a year of daily use has also been demonstrated without growth retardation or hypothalamic-pituitary-adrenal (HPA) axis suppression [18].

The ophthalmic safety of the implant was assessed in ADVANCE and ADVANCE II trials. No significant changes were found in intraocular pressure or lens opacity, and no clinically meaningful posterior subcapsular cataracts were observed up to day 90 post-implantation [19,20].

2.6. Limitations and Controversies

While the clinical trials show strong evidence of efficacy, the studies rely heavily on intrapatient control designs, which may introduce bias. Additionally, limited long-term data beyond six months restricts understanding of chronic safety outcomes [21]. The absence of patient preference studies limits insight into acceptability and adherence compared to traditional post-surgical therapies [22]. Cost-effectiveness evaluations are also lacking.

2.7. Future Perspectives

Future improvements in device design could include smart implants capable of monitoring inflammation markers or delivering combination therapies. Expansion of localized drug-delivery stents for other sinonasal and respiratory conditions such as allergic fungal rhinosinusitis, nasal polyposis, and even non-ENT disorders is currently being explored [23-25].

III. Conclusion

Current evidence suggests that the mometasone-eluting sinus implant is effective in reducing postoperative inflammation, polyposis, mucosal adhesions, and middle turbinate lateralization following endoscopic sinus surgery. Reported adverse effects are limited, primarily including infection and crusting that occasionally necessitate implant removal. The implant aids in maintaining surgical outcomes and reduces reliance on systemic corticosteroids and extensive postoperative debridement.The mometasone implant provides a localized, sustained-release corticosteroid therapy that enhances healing within the ethmoid cavity after sinus surgery. It significantly improves patient-reported outcomes, reduces the need for oral steroids, and may lower the risk of postoperative complications such as scarring and adhesion formation. Its current role in clinical practice offers a valuable adjunct to improve recovery and reduce recurrence in chronic rhinosinusitis.Further research is warranted to evaluate the long-term safety and efficacy of the mometasone-eluting implant across a broader patient population. Innovations may focus on developing implants tailored for the frontal, maxillary, and sphenoid sinuses, as well as exploring multi-drug platforms incorporating antibiotics or alternative anti-inflammatory agents. Additionally, combining steroid-eluting implants with balloon sinus dilation represents a promising, minimally invasive approach that may offer dual benefits of mechanical and pharmacological intervention in chronic rhinosinusitis management.

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