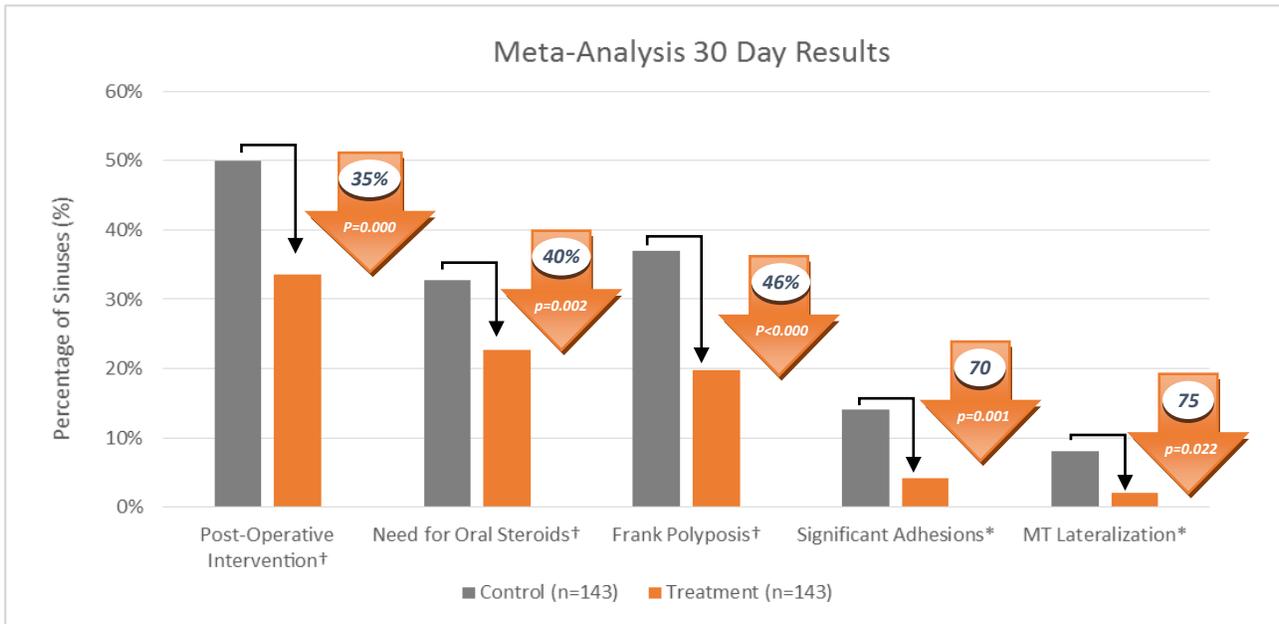


PROPEL Clinical Evidence Summary

PROPEL implants are the first and only sinus surgery products clinically proven with Level 1-A evidence to improve the outcomes of sinus surgery.¹

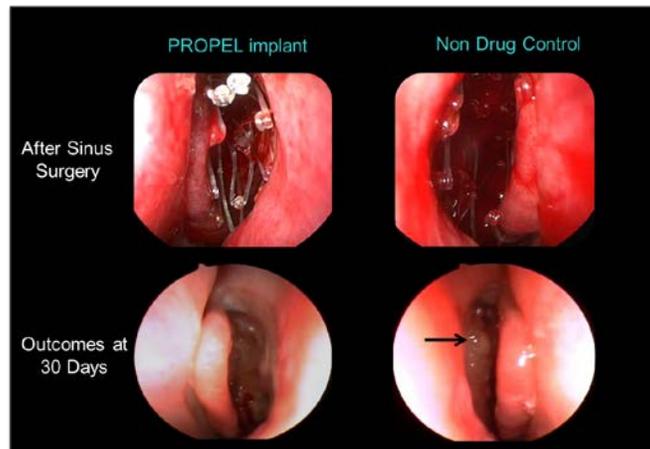
PROPEL Meta-Analysis: Efficacy when placed Following Ethmoid Sinus Surgery

Clinically proven to improve surgical outcomes compared to spacing alone.



N=143 in ITT population, with N=128 evaluable patients for composite endpoint. †Judged by Independent panel. *Judged by on-site clinical investigators. All numbers indicate relative reduction 30 days following treatment. *P-values for secondary endpoints were not adjusted for multiplicity.

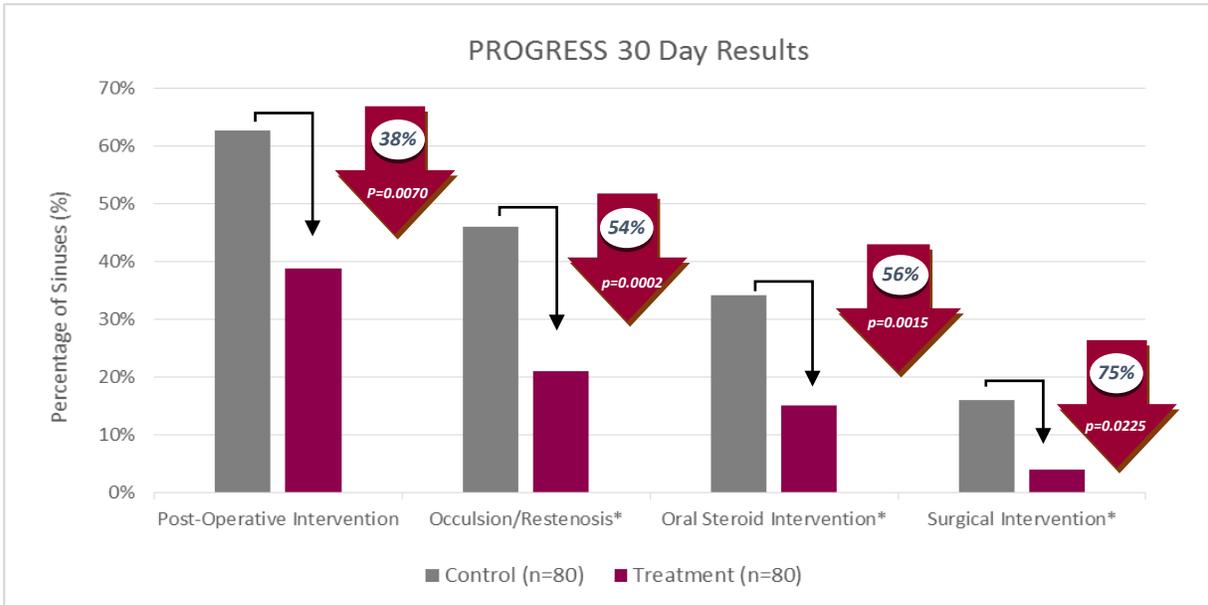
PILOT Study: Example Patient Outcome Following Ethmoid Surgery with PROPEL²



Case represents one patient experience. Results may vary.

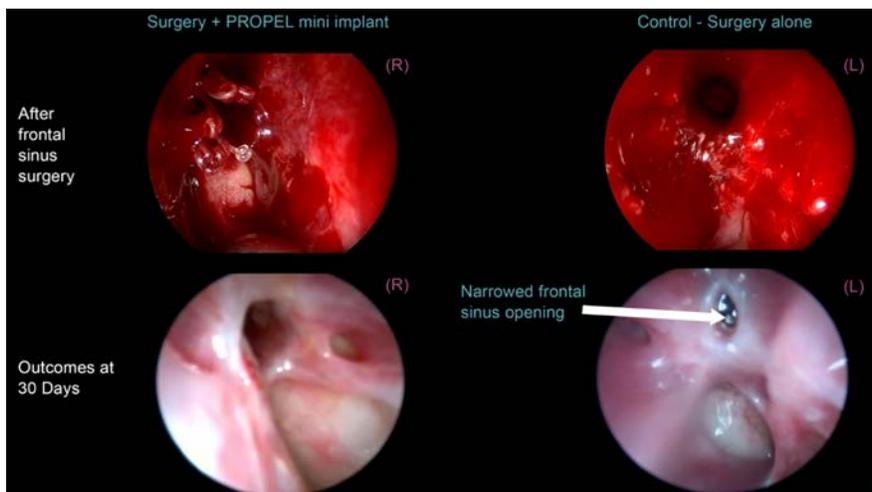
PROGRESS Study³: Safety and Efficacy of PROPEL Mini Following Frontal Sinus Surgery

An 80 patient randomized, controlled, blinded clinical trial, that evaluated outcomes of frontal surgery (using balloons and/or traditional instruments) with PROPEL mini placement, compared to the surgery alone with standard post-operative care.³



N=80 in ITT population, with N=67 evaluable patients where both sinuses available for composite endpoint. Judged by Independent panel. *Judged by clinical investigators. All numbers indicate relative reduction 30 days following treatment. *P-values for secondary endpoints were not adjusted for multiplicity.

PROGRESS Study: Example Patient Outcome Following Frontal Sinus Surgery with PROPEL mini²



Case represents one patient experience. Results may vary.

The PROPEL sinus implant is intended for use following ethmoid sinus surgery to maintain patency. PROPEL mini is intended for use following ethmoid or frontal sinus surgery to maintain patency. The implants are intended for use in patients ≥18 years of age. Contraindications include patients with intolerance to mometasone furoate (MF) or a hypersensitivity to bioabsorbable polymers. Safety and effectiveness of the implant in pregnant or nursing females has not been studied. Risks may include pain/pressure, displacement of implant, and possible side effects of intranasal MF. The most common adverse events in clinical studies were sinusitis, headache, epistaxis and bronchitis. For complete prescribing information see IFU at www.PROPELOPENS.com. Rx only.

Safety & Efficacy – PROPEL implants have been studied in 4 prospective clinical trials totaling 285 patients

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|----------|--|
| 1 | PROGRESS³: A randomized, controlled, blinded clinical trial evaluating the safety and efficacy of PROPEL Mini when used following frontal sinus surgery. Study demonstrated statistically significant reduction in need for post-operative interventions and other endoscopic outcomes, compared to surgery alone with standard post-operative care. |
| 2 | Pilot Study²: A randomized, controlled, double blind clinical trial comparing PROPEL to a non-steroid eluting implant. Study demonstrated significant improvement in need for post-operative interventions, and other endoscopic outcomes, following the use of PROPEL. |
| 3 | ADVANCE II⁴: A randomized, controlled, double-blind clinical trial evaluating the safety and efficacy of PROPEL when used following ethmoid sinus surgery. Study demonstrated statistically significant reduction in need for post-operative interventions and other endoscopic outcomes, as well as ocular safety. |
| 4 | ADVANCE Study⁵: A single-cohort study to assess the safety, endoscopic outcomes and patient symptom scores following the use of PROPEL in ethmoid sinus surgery out to six months. Study demonstrated significant symptom relief through 6 months. |

All trials assessed the safety and efficacy of controlled delivery of mometasone furoate to the ethmoid or frontal sinus mucosa via dissolvable implants in chronic rhinosinusitis (CRS) patients undergoing functional endoscopic sinus surgery (FESS).

Safety Established in Clinical Studies:

- Ocular safety demonstrated: No clinically significant changes from baseline in intraocular pressure or lens opacities occurred⁴.
- Systemic safety demonstrated: No evidence of systemic steroid exposure or adrenal-pituitary axis suppression².

Summary of Clinical Publications

The PROGRESS Study³

Smith TL, Singh A, Luong A et al., Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. 2016; ePub on July 1, 2016.

- *First and only product clinically proven to improve the outcomes of frontal sinus surgery.*
- *PROPEL mini improves frontal sinus surgery outcomes: 38% reduction in need for post-operative interventions at 30 days was maintained through 90 days (p=0.0129), demonstrating a sustained treatment effect.*
- *Localized controlled steroid delivery confers meaningful benefits: Reduces inflammation and occlusion/restenosis and greater diameter Frontal Sinus Opening (FSO).*
- *Preserves frontal patency by reducing (relative reduction) frontal occlusion/restenosis by 54%, a meaningful benefit of scaffolding and sustained, localized steroid release.*

Meta-Analysis of 143 Pilot Study and ADVANCE II Patients¹

Han JK, Marple BF, Smith TL et al. Int Forum Allergy Rhinol. 2012; 2(4) 271-279.

- *First and only Level 1-A evidence in support of an ENT product used in sinus surgery.*

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- The Meta-analysis pooled efficacy data for the 143 patients from the two prospective, controlled, randomized, double-blind, multi-center trials with similar entry criteria and endpoints.
- *Localized controlled steroid delivery confers meaningful benefits:* Reduces scarring, inflammation, polyposis and middle turbinate lateralization.
- *PROPEL improves surgical outcomes:* 35% reduction in need for post-operative medical/surgical interventions.
- Reduces need for oral steroids by 40%, a meaningful benefit of sustained, localized steroid release.

The ADVANCE II Study⁴

Marples BF, Smith TL, Han JK et al. *Otolaryngol Head Neck Surg.* 2012; 146(6) 1004-1011.

- Primary efficacy endpoint in this prospective, multicenter, randomized, double-blind trial was evaluated by an independent, blinded panel of 3 surgeons (n=105).
- *PROPEL Sustained Steroid Release provides clinically meaningful benefits to patients:* Reduces the need for surgical intervention and oral steroids.
- *PROPEL maintains sinus patency:* Reduces inflammation, adhesions and polyposis. Reducing such scarring and inflammation is essential to improve long-term outcomes and reduce the need for revision surgery.^{6,7}

Pilot Study²

Murr AH, Smith TL, Hwang PH, et al. *Int Forum Allergy Rhinol.* 2011; 1:23–32.

- Prospective, multi-center, randomized, double-blind trial comparing PROPEL to a non-steroid eluting implant (n=50).
- Broad patient population: 70% polyp patients, 37% prior sinus/nasal surgery, mean Lund-MacKay CT stage = 13.4.
- Statistically significant reductions in adhesions, inflammation and polyposis, which are often associated with surgical failure⁶.

The ADVANCE Study⁵

Forwith KD, Chandra RK, Yun PT, et al. *Laryngoscope.* 2011; 121(11): 2473–2480.

- Real world study design: Single-cohort, open-label study (n=50).
- Broad patient population: 66% polyp patients, 28% prior sinus/nasal surgery patients, mean Lund-MacKay CT stage = 11.2
- FESS + Implants resulted in significant symptom reduction through 6 months using SNOT-22 & RSDI

Additional Publications

Lee JT, Han JK. Sinus Implants for chronic rhinosinusitis: technology evaluation. *Expert Opin. Drug Deliv.* 2013; 10(12): 1735–1748.

Wei CC, Kennedy DW. Mometasone implant for chronic rhinosinusitis. *Medical Devices: Evidence and Research.* 2012; 5:75-80.

Kennedy DW. The PROPEL steroid releasing bioabsorbable implant to improve outcomes of sinus surgery. *Expert Review of Respiratory Medicine.* 2012; 6(5):493-498.

Ramakrishnan VR, Kennedy DW. Advances in the surgical management of chronic sinusitis and nasal polyps. *Current Allergy and Asthma Reports.* 2011; 11(3): 220-229.

Li PF, Downie D, Hwang PH. Controlled steroid delivery via bioabsorbable stent: Safety and performance in a rabbit model. *American Journal of Rhinology & Allergy.* 2009; 23(6): 591-596.

Janisiewicz, A, Jivianne T. Lee. In-office use of a steroid-eluting implant for maintenance of frontal ostial patency after revision sinus surgery. *Allergy Rhinol.* 2015; 6(1): e68-75.

Matheny K., Kenny C. Safety, feasibility and efficacy of placement of steroid-eluting bioabsorbable sinus implants in the office setting: a prospective case series. *International Forum of Allergy & Rhinology,* 2014; 4(10):808-815.

Rudmik L, Smith TL. Economic Evaluation of a Steroid-Eluting Sinus Implant following Endoscopic Sinus Surgery for Chronic Rhinosinusitis. *Otolaryngology–Head & Neck Surgery.* 2014; 151(2): 359-366.

Rizzo J., et al. Budget impact analysis of bioabsorbable drug-eluting sinus implants following endoscopic sinus surgery. *Journal of Medical Economics.* 2016 4 (3)

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1. Han JK, Marple BF, Smith TL et al. Int Forum Allergy Rhinol. 2012 ; 2 :271-279.
 2. Murr AH, Smith TL, Hwang PH, et al. Int Forum Allergy Rhinol. 2011;1:23–32.
 3. Smith TL, Singh A, Luong A et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. 2016; ePub on July 1, 2016.
 4. Marple BF, Smith TL, Han JK et al. Otolaryngol Head Neck Surg. 2012; 146(6) 1004-1011.
 5. Forwith KD, Chandra RK, Yun PT, Miller SK, Jampel HD. Laryngoscope. 2011;121:2473–2480.
 6. Kennedy DW, Wright ED, Goldberg AN. Laryngoscope. 2000;110:29–31.
 7. Kennedy DW. Expert Review of Respiratory Medicine. 2012; 6(5):493-498.

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