NICE advice

# PROPEL sinus implants for maintaining sinus patency after surgery

Medtech innovation briefing
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## Summary

- The **technology** described in this briefing is PROPEL. It is used to maintain patency of the ethmoid or frontal sinus opening after sinus surgery for chronic rhinosinusitis.
- The **innovative aspects** are that it keeps the sinus open and delivers corticosteroids directly to the sinus mucosa while gradually dissolving.
- The intended **place in therapy** would be as an alternative to topical corticosteroids and spacers or nasal packing in adults with chronic sinusitis after sinus surgery. The procedure used to insert PROPEL is covered by NICE's interventional procedures guidance on corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis, which recommends that corticosteroid-eluting bioabsorbable stents or spacers should only be used with special arrangements for clinical governance, consent, and audit or research.

- The **main points from the evidence** summarised in this briefing are from 3 randomised studies including a total of 266 adult patients in surgical centres in the US. They show that PROPEL is more effective than a stent alone in people with chronic rhinosinusitis who have had sinus surgery.
- **Key uncertainties** around the evidence or technology are that all the evidence is from the US, and the comparators are limited and do not fully reflect treatments available in the NHS.
- **Safety issues** identified are fungal infections and the stents migrating or being expelled after placement.
- The **cost** of PROPEL is £580 per unit (excluding VAT). The **resource impact** would be greater than standard care, which is around £60 (excluding VAT).

# The technology

PROPEL (Intersect ENT) sinus implants are designed to keep the sinus open and deliver steroids directly to the sinus mucosa after sinus surgery. It's made of a synthetic bioabsorbable co-polymer with a matrix-like structure. It's also impregnated with 370 micrograms of mometasone furoate, an anti-inflammatory drug, which it releases gradually into the sinus mucosa over a 30-day period.

There are 3 versions of PROPEL: PROPEL for the ethmoid sinus, PROPEL Mini for the ethmoid sinus and frontal sinus opening, and PROPEL Contour for the frontal and maxillary sinus ostia. All of them have a syringe-style delivery mechanism, a sheath and distal tip. The sheath and distal tip vary in length depending on the different anatomies of sinus sites where they are used. Additional tools may be provided depending on the variant. The sinus implant is delivered to the sinus site through the nostrils and opens out once it's in place. The implant itself is designed to dissolve within 30 to 45 days.

## Innovations

The innovative aspects of the technology are that it is both a spacer and an inflammatory drug delivery device. The company claims this helps reduce the need for postoperative intervention, including surgery and oral corticosteroids, by reducing inflammation, polyposis and middle turbinate lateralisation.

# Current care pathway

Current guidance concentrates on surgery and treatments before surgery. There are no guidelines on post-surgical interventions.

Maintenance therapies maintain the sinus opening created by surgery. They include nasal irrigation with a saline solution and intranasal corticosteroids (for example, mometasone or fluticasone) for up to 3 months.

Follow up should be tailored to individual patient needs and may be influenced by other factors such as allergies and comorbidities. There is no significant evidence to support frequent postoperative debridement of sinus cavities.

The following publications have been identified as relevant to this care pathway:

- NICE's medical technologies guidance on XprESS multi sinus dilation system for treating chronic sinusitis
- NICE's interventional procedures guidance on corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis
- NICE's interventional procedures guidance on balloon catheter dilation of paranasal sinus ostia for chronic sinusitis
- ENT UK and the Royal College of Surgeons' commissioning guide on chronic rhinosinusitis.

# Population, setting and intended user

The technology would be used by surgeons for people with chronic rhinosinusitis, immediately after endoscopic sinus surgery.

Chronic sinusitis is a common condition estimated to affect around 10% of adults. Prevalence increases with age, and it's more common in women, and people with asthma, chronic obstructive pulmonary disease, or a history of allergies. The company estimates that in England 30,000 people (60,000 implants) could benefit from the procedure each year.

# Costs

## Technology costs

PROPEL costs £580 per implanted unit.

## Costs of standard care

The cost of a non-drug-eluting spacer was estimated by the company to be £62.50 for a pair (NasoPore) and £26 for a 3-day supply of corticosteroids.

# Resource consequences

Three studies reporting economic outcomes related to PROPEL were identified in searches and by the company. Javanbakht et al. (2020) is a cost-effectiveness analysis undertaken using a UK NHS perspective, but with the clinical parameters taken from a study that was conducted in the US (Han et al. 2012). Rizzo et al. (2016) and Rudmik and Smith (2014) use a US healthcare perspective and report outcomes related to budget impact and cost effectiveness. These studies provide some evidence that over time PROPEL may be associated with similar costs compared to current practice.

# Regulatory information

PROPEL is a CE marked class III medical device.

Thirty-four alerts were identified on the MAUDE database. A number appear to be duplicate reports for the same intervention, and not all could be clearly attributed to the device. The most common issue reported was migration or expulsion of the device, in 2 instances into the throat. There were also multiple reports of fungal infections and fungus on the device.

# Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were identified.

# Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

## Published evidence

Three studies are summarised in this briefing.

All of the studies use an intraoperative study design, meaning that the patient acted as their own control, with the study intervention in one sinus and the control intervention in the other. In 2 studies (Murr et al. 2011 and Han et al. 2012) the control was a PROPEL stent alone in the contralateral and in 1 (Smith et al. 2016) it was surgery alone. These studies suggest that the gradual release of mometasone furoate into the sinus cavity through its impregnation in a stent provides better clinical outcomes than a stent alone.

## Overall assessment of the evidence

The evidence seen was of a good standard. However, a number of limitations were identified for which further research and evidence would be useful for decision makers. No evidence from a UK perspective was identified, with all the studies taking place in the US. There is little evidence comparing PROPEL to alternative stents, nasal packaging, and corticosteroids. Follow-up periods were relatively short and would benefit from research with longer follow up looking at the need for repeat surgery, stents and other interventions, and longer-term quality of life.

### Murr et al. (2011)

#### Study size, design and location

Intraoperative double-blind randomised trial of 43 adults (86 sinuses) with chronic

rhinosinusitis. Patients received the intervention in one nostril and the comparator in the other. Patients were scheduled to have primary or revision endoscopic sinus surgery (ESS) and sinus stents were deemed feasible and appropriate for them. They were recruited prospectively in 4 otolaryngology–head and neck surgery centres in the US.

All interventions were in the ethmoid sinus.

### Intervention and comparator(s)

Intervention: PROPEL.

Comparator: non-drug-eluting spacer, a further small subset (non-randomised, n=5) received bilateral drug-eluting stents to assess systemic safety.

### Key outcomes

Compared with the control, PROPEL produced a statistically significant reduction in inflammation at days 21 to 45 ($p<0.003$), frequency of polyp formation ($p=0.0391$), and frequency of significant adhesion ($p=0.0313$). Inflammation scores were higher in the PROPEL group at 7 days, and lower (but not by a statistically significant amount: $p>0.05$) at days 14 and 60. There was also a reduced frequency of middle turbinate lateralisation, but this was not statistically significant. All stents were successfully deployed. There were no device-related adverse events.

### Strengths and limitations

The comparator was the PROPEL stent, so it is possible to see the additional benefits from the addition of mometasone furoate. A non-randomised cohort of 5 people was also included to assess the systemic safety of the stent and mometasone furoate. The size of this population was not based on any power calculations but on clinical judgement and previous animal studies.

## Han et al. (2012)

### Study size, design and location

Meta-analysis of 143 adults having endoscopic sinus surgery refractory to medical management. They were enrolled onto 2 trials: a pilot study (Murr et al. 2011) and the

ADVANCE II study (Marple et al. 2012) involving 7 and 11 centres respectively in the US.

The trials were intraoperative (patients received intervention in 1 nostril and comparator in the other) double-blind randomised trials.

### Intervention and comparator(s)

Intervention: PROPEL.

Comparator: non-drug releasing spacer.

### Key outcomes

Significant adhesions, defined as dense or severe by clinical investigators, which are a measure of need for surgical lysis, were present in 4.2% of patients treated with PROPEL and 14.1% of patients treated with the control (p=0.0013). Middle turbinate lateralisation occurred in 2.1% of the sides treated with PROPEL and 8.4% in the control (p=0.0225). Need for postoperative intervention was 32.8% for PROPEL and 50.8% for the control (p=0.0008). PROPEL was similarly effective on this measure when compared by polyp and non-polyp. The rate of surgical interventions for adhesion was 14.2% for PROPEL and 29.1% for the control (p=0.0016). The need for steroid intervention for recurrent inflammation was 22.1% for PROPEL and 37.2% for control (p=0.0023). The rate of frank polyposis was 19.8% for PROPEL and 36.9% for control (p<0.0001).

### Strengths and limitations

Most outcomes were based on the judgements of an independent panel. Because both nostrils received a stent it is possible to see the impact of mometasone furoate. However, it is not possible to compare the effects against no treatment or topical application of anti-inflammatories. A number of the authors in the original trials were employees of the company.

## Smith et al. (2016)

### Study size, design and location

Prospective, randomised, blinded trial using an intrapatient control design of 80 adults. Participants were scheduled to have primary or revision bilateral ESS and had evidence of

bilateral frontal sinus disease based on computed tomography in 11 investigation centres in the US.

### Intervention and comparator(s)

Intervention: PROPEL.

Control: surgery alone (in contralateral side).

### Key outcomes

The primary outcome of the study was the need for postoperative intervention in the frontal sinus opening (including debridement and steroid intervention) at 30 days assessed by an independent blinded reviewer. This was 38.8% for PROPEL and 62.7% for the control (p=0.007). When this result was adjusted for a potential confounding effect of 3 people who received oral steroids before the 30-day follow up the differences remained statistically significant (p=0.0107). Need for postoperative interventions at 30 days on the treatment side based on clinical investigator assessment was 16.5% for PROPEL and 41.8% for the control (p<0.0001). The differences remained significant at 90 days (p=0.0129). The need for oral steroid interventions and surgical intervention (based on clinical observation) were also significantly lower for the PROPEL side (p=0.0015 and p=0.0225 respectively).

### Strengths and limitations

This was a reasonably large study that provides a useful comparison to sinus surgery alone. The design makes it difficult to determine to what extent the improvement in outcomes were due to the stent, or to slow release of corticosteroids. However, intranasal steroid sprays were allowed from 14 days post surgery. The company provided funding for the study and a number of the authors were consultants for the company.

## Sustainability

PROPEL is made from bioabsorbable materials so there is no waste from the product itself. The packaging for the product is recyclable.

## Recent and ongoing studies

No ongoing or in-development trials were identified.

# Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 experts were familiar with or had used this technology before.

## Level of innovation

Two experts considered the technology to be novel. The other expert considered it a minor variation which is unlikely to alter the procedure's safety and efficacy. One of those who considered it novel identified Acclarent as its closest comparative treatment, but noted this had been withdrawn from the UK.

## Potential patient impact

The experts identified potential patient benefits as less:

- sinus stenosis
- need for postoperative local care
- development of early postoperative recurrent polyposis in people with polyps
- revision surgery.

Patients with rapidly recurring polyps, recurrent chronic sinus disease, and severe eosinophilic chronic sinusitis were identified as subgroups who would particularly benefit from this technology.

## Potential system impact

Fewer hospital visits and less revision surgery, and enabling a shift to tertiary centres were identified as potential system benefits.

## General comments

When asked about the cost consequences of adopting the technology 1 expert noted that it would cost more initially. The other experts said that it could save more or be cost neutral, but this was based on projections with uncertainties. There were mixed estimates of the population in whom the technology would be used ranging from 5% up to 30% of those with chronic sinusitis who need surgery. The experts said training was needed to use PROPEL but this was minimal. They noted that no additional facilities were needed to use PROPEL. In terms of safety they noted the adverse events reported in the papers: migration of the device, fungal infections and adverse reactions to corticosteroid. The experts said that uncertainties and concerns were: cost, efficacy compared with absorbable packing soaked in steroids, stability of fixation of the implant and potential for misplacement.

# Expert commentators

The following clinicians contributed to this briefing:

- Professor Carl Philpott, professor of rhinology and olfactology, University of East Anglia; head of rhinology and ear, nose and throat (ENT) research group professionalism lead; did not declare any interests.
- Professor Paul Chatrath, consultant ENT surgeon and rhinologist; did not declare any interests.
- Professor Hesham Saleh, consultant rhinologist and facial plastic surgeon at Imperial College Healthcare NHS Trust; professor of practice in rhinology at Imperial College. He has received samples of the device, been involved in publications on the device, and gave a lecture in a webinar organised for the company for which the rhinology research fund received a payment.

# Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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