Technology Brief

Balloon Sinuplasty for Chronic Rhinosinusitis

February 2012
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This brief was prepared by Dr Vicki Foerster and Dr Prema Thavaneswaran from ASERNIP-S.
**TECHNOLOGY BRIEF**

<table>
<thead>
<tr>
<th>REGISTER ID</th>
<th>WP060</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NAME OF TECHNOLOGY</strong></td>
<td>Balloon sinuplasty</td>
</tr>
<tr>
<td><strong>PURPOSE AND TARGET GROUP</strong></td>
<td>To dilate obstructed sinus openings in a minimally invasive manner in patients with chronic rhinosinusitis</td>
</tr>
</tbody>
</table>

### Stage of Development in Australia

- [ ] Yet to emerge
- [ ] Established
- [ ] Experimental
- [ ] Established but changed indication or modification of technique
- [ ] Investigational
- [ ] Should be taken out of use
- [x] Nearly established

### Australian Therapeutic Goods Administration Approval

- [x] Yes
- [ ] No
- [ ] Not applicable

**ARTG number:** 168057, 178372 and 181941

### International Utilisation

<table>
<thead>
<tr>
<th>Country</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Canada</td>
<td>✓</td>
<td>Presumed in use but rate of diffusion unknown</td>
<td></td>
</tr>
<tr>
<td>Australia and New Zealand</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Europe (Austria, Denmark, Finland, Germany, Greece, Ireland, Italy, Poland, Spain, UK)</td>
<td>--</td>
<td>Presumed in use but rate of diffusion unknown</td>
<td></td>
</tr>
<tr>
<td>Central / S. America (Brazil, Chile, Mexico, Venezuela)</td>
<td>--</td>
<td>Presumed in use but rate of diffusion unknown</td>
<td></td>
</tr>
<tr>
<td>Asia (Brunei, India, Malaysia, Singapore, Thailand, Turkey)</td>
<td>✓</td>
<td>Presumed in use but rate of diffusion unknown</td>
<td></td>
</tr>
<tr>
<td>Middle East (Israel, Saudi Arabia, United Arab Emirates)</td>
<td>--</td>
<td>Presumed in use but rate of diffusion unknown</td>
<td></td>
</tr>
</tbody>
</table>
**IMPACT SUMMARY**

Chronic rhinosinusitis (CRS) is estimated to affect about 9 per cent of the Australian population. Several manufacturers provide balloon sinuplasty (BSP) systems (e.g. Relieva™ by Acclarent; FinESS™ by Entellus Medical Inc) for the minimally invasive treatment of CRS that is unresponsive to medical management. The technology would be made available through otolaryngology surgeons for adults and possibly children (≥ 2 years) with CRS.

The current surgical approach to unresponsive CRS is functional endoscopic sinus surgery (FESS), a procedure that involves endoscopic removal of tissue and bone to dilate narrowed sinus passageways. This procedure can be complex and time-consuming. Four relatively small low-quality studies assessed the safety and efficacy of BSP devices, reporting results that are at least as favourable as those achieved with FESS.

BSP devices have been approved for marketing in many countries including Australia. It appears that uptake of the device has been broad, particularly in the United States (USA) where >100,000 patients have been treated; worldwide, >5600 physicians have been trained by the manufacturers of BSP systems and training in Australia is slated for April 2012.

**BACKGROUND**

CRS is the inflammation of the lining of one or more of the sinuses, which occurs due to nasal mucus membrane swelling, excessive mucus production or an anatomical abnormality, blocking the drainage of the sinuses. The obstruction can lead to bacterial infection and further inflammation. Symptoms include pressure-like pain on the forehead, temples, cheeks, nose, or around the eyes; difficulty breathing through the nose; abnormal nasal drainage; and reduced sense of smell or taste. By definition, CRS lasts for more than 2-3 months and recurrent sinusitis involves ≥ 3 episodes a year (AIHW 2010).

In most patients diagnosed with CRS, symptoms are successfully managed with decongestants, analgesics, antibiotics, topical steroids or nasal/sinus irrigation. However, for those patients who do not respond to medical management, surgical treatment may be required. FESS is currently the standard surgical treatment for CRS. This procedure aims to open the sinus ostia in order to return mucosa to their normal state and improve aeration and drainage; however, long-term, surgical procedures may be ineffective, due to the development of adhesions and scarring around the ostium of the sinus.

The BSP system was introduced in 2005 as a minimally invasive tool to treat CRS. The system follows the principles of over-the-wire, catheter-based balloon dilatation, such as that used in interventional cardiology. The balloon is advanced under fluoroscopic...
guidance to a narrowed segment in a sinus opening and then inflated under high pressure, dilating the passageway by creating microfractures and moulding the bone (Friedman et al 2008; Levine & Rabago 2011). Unlike the traditional surgical approach, tissue and bone are not removed. The National Institute of Health and Clinical Excellence (NICE) in the United Kingdom (UK) suggests that BSP may be offered as a routine treatment option for patients with chronic sinusitis, provided that doctors are certain that (i) the patient understands what is involved and agrees to the treatment, and (ii) the results of the procedure are monitored (NICE 2008).

Studies have assessed the safety and utility of BSP alone, in combination with FESS, and in combination with adenoidectomy in children. Common outcome measures used to assess patients suffering from CRS include:

- Sino-Nasal Outcome Test (SNOT-20) scores: symptom severity over the previous 2 weeks in 20 categories is measured using a 1 to 6 scale (0=no problem, 6=bad as it can be); pre- and post-operative scores are compared (Weiss et al 2008).
- Degree of sinus opacity on computed tomography (CT) using the Lund-McKay score: measures the degree of opacification of a sinus: 0=none, 1=partial, 2=total; 6 sinuses are scored on each side for a possible maximum score of 24 (Lund & Kennedy 1995).

**Clinical Need and Burden of Disease**

About 1.8 million Australians (9.2%) reported having CRS in 2004/05,¹ making it one of the most frequently reported health conditions. Prevalence was higher among females (10.9%) than males (7.5%). The peak age in females was 70-74 years versus peaks in males at 55-59 and 75-79 (Figure 1).

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¹ Similar data for New Zealand were not located.
It is currently unclear what proportions of CRS patients in Australia would be eligible for BSP procedures; however, the published literature suggests that approximately 20 per cent of patients suffering from CRS are refractory to medical treatment and may require surgery (Cummings et al 2009).

The disorder is associated with genetic susceptibility and infectious diseases as risk factors, and smoking, air pollution, and occupational exposure are trigger factors. Associations with asthma and hay fever are common; about 300,000 people in Australia had all three conditions. In addition to local sinonasal symptoms, CRS also has a significant negative impact on the energy levels, mood and physical and social functioning of sufferers. However, deaths are very rare – fewer than 10 annually (AIHW 2010).

In Australia, acute and chronic sinusitis is the primary reason for 1.3 per cent of general practitioner (GP) consultations, accounting for 1.5 million GP visits each year (Britt et al 2010). Australian Institute of Health and Welfare (AIHW) health services data for CRS and hayfever2 in 2006/07 (AIHW 2010):

- Principal diagnosis for 11,117 hospitalisations; average length of stay 1.3 days
- Hospital separation rates increase with age until 60–64 years, and then fall progressively
- Related surgical cases:
  - Intranasal maxillary antrostomy (7,535 cases): surgical creation of a hole between the nasal passages and the maxillary sinuses to ease mucous drainage.
  - Sinoscopy (6,003 cases): examination of the sinuses via magnifying lenses.
  - Ethmoidectomy (5,558 cases): surgical enlargement of holes between ethmoid cavities, polyp removal, and mucous drainage.
  - Septoplasty (3,308 cases): straightening of the nasal septum.

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2 Utilisation data for hayfever and chronic sinusitis are combined (AIHW 2010).
DIFFUSION OF TECHNOLOGY

Australia

Three BSP technologies are listed on the Australian Register of Therapeutic Goods (ARTG, 2011):

- 168057: Acclarent Inc (USA); sponsored by Johnson & Johnson Medical Pty Ltd, NSW, Australia. Effective date January 15, 2010.
- 178372: Karl Storz GmbH & Co KG (Germany); sponsored by Karl Storz Endoscopy Australia Pty Ltd, NSW, Australia. Effective date December 15, 2010.
- 181941: Joline GmbH & Co (Germany); sponsored by Endocorp Pty Ltd, NSW, Australia. Effective date April 7, 2011.

According to a press release from the Department of Human Services in Victoria, the first pilot project in the world on this technology was completed in 10 patients at The Alfred Hospital in Melbourne by Dr. Christopher Brown, and a larger trial including six USA sites was planned (DHS 2006).³

It was not readily apparent how widely diffused BSP is in Australia, but the website of device manufacturer Acclarent lists physicians trained in the use of the technology; seven are listed in Australia covering New South Wales (1), Queensland (2), South Australia (1), and Victoria (3), and four in New Zealand (Acclarent 2011).

The 2012 Scientific Meeting of the Australian Society of Otolaryngology Head & Neck Surgery (ASOHNS) in late March in Adelaide will cover the topic of balloons in otolaryngology, including a full day post-meeting satellite workshop (April 4) titled ‘Balloon dilatation technology and its application in ENT: sinuses, airway and oesophagus’; the workshop includes hands-on experience with BSP using cadavers (ASOHNS 2011).

USA

The Food & Drug Administration (FDA) approved the Relieva™ Sinus Balloon Dilation Catheter as a Class I device on April 5, 2005. The approved indication was to ‘dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures’ (US FDA 2005). Since then, variations of this catheter have also been approved, for example the Relieva Acella™ catheter (US FDA 2008a).

Other manufacturers produce similar technologies, for example the FinESS which is marketed by Entellus Medical (Maple Grove, Minnesota) for treatment of the ethmoid infundibulum and maxillary ostium (US FDA 2008b). The latter is a ‘minimally invasive option for treating patients in an office setting [using local anaesthesia]’ (Entellus Medical 2011).

³ The planned multicentre trial is likely Bolger et al (2007), an early publication on the safety and efficacy of BSP with authors from nine USA sites plus Dr. Brown from Melbourne.
Two professional organisations in the USA have issued position statements on BSP, the American Academy of Otolaryngologists – Head & Neck Surgeons (AAO-HNS) and the American Rhinologic Society (ARS):

- AAO-HNS: ‘Sinus ostial dilation (e.g. balloon ostial dilation) is an appropriate therapeutic option for selected patients with sinusitis. This approach may be used alone to dilate a sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments (e.g. microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.’ (AAO-HNS 2010) (Note that there are no references supporting this statement.)

- ARS: The position statement briefly reviews three studies from 2006 (one is on cadavers and one is very small), sets out the organisation’s position, and also endorses the position statement of the AAO-HNS (ARS 2011):
  o Based on currently available scientific medical evidence, endoscopic balloon dilation technology is acceptable and safe for use in the management of sinus disease.
  o Endoscopic balloon dilation technology is a tool, not a procedure, available to the operating surgeon at his/her discretion for the surgical management of sinus disease.
  o Patients who are treated with this technology may require concurrent conventional endoscopic sinus surgery especially in the ethmoid sinuses much like any surgical instrument that may be used in some parts of the sinus and not others or in combination with other technologies.
  o In a group of selected patients, the use of balloon catheter dilation technology alone may eliminate the need for other surgical techniques.
  o Endoscopic balloon catheter dilation as a tool for dilating the opening of the maxillary sphenoid, and frontal sinuses is not investigational or experimental and should not be viewed as such.

Europe & beyond:
CE Mark clearance in Europe was granted in February 2006 and international sales commenced a year later. According to marketing materials, BSP devices are marketed and sold in more than 30 international markets (EDGAR Online 2008) and 5,600 physicians have been trained in their use as of 2010 (Acclarent 2010). Acclarent provides training for physicians and includes physician names on their website (Acclarent 2011). The list of 26 countries (outside the USA) with links to physician contact information covers: Europe (10 countries), Americas (5), Asia (6) and the Middle East (3), in addition to physicians in Australia and New Zealand.
COMPARATORS
The current reference standard for the surgical treatment of CRS that is non-responsive to medical management is FESS, which was introduced in the USA in 1985. FESS is constantly evolving (e.g. through-cutting forceps, powered instrumentation, and image guidance), and is associated with success rates of between 75 and 95 per cent (Bolger et al 2007; Levine et al 2008; Stankiewicz et al 2008).

In the USA, FESS is the leading driver of litigation among otolaryngology procedures with a mean settlement of about US $750,000. Incidence of major adverse events (AEs) is low but includes death, cerebrospinal fluid leak, blindness and major bleeding in about one per cent of cases; minor AEs such as minor bleeding, infection, periorbital swelling and bruising occur in more than five per cent of cases (Levine et al 2008).

SAFETY AND EFFECTIVENESS ISSUES
Study description
A total of four studies assessing the safety and efficacy of BSP for chronic rhinosinusitis were included in this brief, three in adults and one in children (Table 1). All studies were conducted primarily in the USA. Two studies involved comparisons between study arms where patients were given a choice between procedures, and blinding was not employed (Freidman et al 2008 and Ramadan et al 2010) (level III-2 intervention evidence). The two other studies were case series of patients receiving BSP (Bolger et al 2007 updated in Weiss et al 2008 and Stankiewicz et al 2009) (level IV intervention evidence).
### Table 1: Overview of included studies

<table>
<thead>
<tr>
<th>Authors (Year); Location</th>
<th>Study Type &amp; Level of Evidence (See Appendix)</th>
<th>Study Arms</th>
<th>Patient Enrollment (# Sinuses)</th>
<th>Outcomes Assessed</th>
<th>Length of Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolger et al (2007) &amp; Weiss et al (2008); multiple sites in the USA *</td>
<td>Prospective, multi-centre case series; level IV evidence</td>
<td>One arm: Patients received BSP using the Relieva System</td>
<td>n=115 adults (307 sinuses) at 6 months; 65 adults (195 sinuses) at 24 months</td>
<td>- Sinus ostium patency assessed by endoscopy (6 months) or CT (2 years) - SNOT-20 scores - Rate of revision surgery</td>
<td>6 months (Bolger et al 2007) &amp; 24 months (Weiss et al 2008)</td>
</tr>
<tr>
<td>Freidman et al (2008); USA (Chicago)</td>
<td>Retrospective review of prospectively collected data; two parallel groups; level III-2 evidence</td>
<td>Two arms: Patients given the choice of BSP Relieva System or FESS</td>
<td>n=70 adults; 35 in each group (208 sinuses)</td>
<td>- SNOT-20 scores - Patient satisfaction - Narcotic use - Cost</td>
<td>Minimum 3 months</td>
</tr>
<tr>
<td>Stankiewicz et al (2009); USA (3 sites) 'BREATHE I' study</td>
<td>Prospective, multi-centre case series; level IV evidence</td>
<td>One arm: Patients received BSP using the FinESS System</td>
<td>n=30 adults (58 sinuses)</td>
<td>- Sinus ostium patency via CT scanning - SNOT-20 scores</td>
<td>6 months</td>
</tr>
<tr>
<td>Ramadan &amp; Terrell (2010); USA (W. Virginia)</td>
<td>Prospective, controlled, non-randomised; two parallel groups; level III-2 evidence</td>
<td>Two arms: Patients referred for adenoectomy &amp; offered BSP ± adenoectomy if required, as an alternative</td>
<td>n= 49 children ages 2-11 years; 30 BSP± adenoectomy if required, 19 adenoectomy alone</td>
<td>- SN-5 scores - Rate of revision surgery</td>
<td>12 ± 2 months</td>
</tr>
</tbody>
</table>

BSP: balloon sinuplasty; CT: computed tomography; FESS: functional endoscopic sinus surgery; SNOT: Sino-Nasal Outcome Test

* An Australian site (Melbourne) appears to have been included in the first publication but not the second

For the four included studies, further (selected) study detail, including inclusion and exclusion criteria and the medical/surgical treatment methods used are outlined in Table 2. All studies enrolled patients with CRS who had failed medical management. Generally, more ‘complex’ patients, such as those with severe disease, a Lund-McKay score >12, or significant nasal polyposis, were excluded. One study excluded patients with previous sinus surgery (Ramadan et al 2010); however, three studies included patients who were undergoing revision surgery (Friedman et al 2008; Stankiewicz et al 2009; Weiss et al 2008).
Table 2  Inclusion and exclusion criteria and surgical methods used in the included studies

<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Type</th>
<th>Selected Inclusion &amp; Exclusion Criteria</th>
<th>Selected Details about Medical and Surgical Treatment of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolger et al (2007) &amp; Weiss et al (2008)</td>
<td>Prospective, multi-centre case series</td>
<td>• Included: Consecutive adults with CRS, no response to medical Rx, slated for FESS, April-Dec 2005&lt;br&gt;• Excluded: Extensive nasal polyposis, extensive previous sinus surgery or osteoneogenesis, CF, tumour, facial trauma, ciliary dysfunction, pregnancy</td>
<td>• Patients were prepared for surgery and treated post-op as for FESS&lt;br&gt;• All patients booked for FESS were offered BSP and all accepted</td>
</tr>
<tr>
<td>Friedman et al (2008)</td>
<td>Retrospective review of prospectively collected data; two parallel groups</td>
<td>• Included: Adults with CRS, lack of response to medical Rx &amp; who had BSP or FESS between Dec 2005 &amp; May 2006&lt;br&gt;• Excluded: Severe disease, Lund-McKay score &gt;12, significant nasal polyposis, sinus osteoneogenesis, systemic disease, Rx with BSP &amp; FESS combined</td>
<td>• Relieva System Rx under local anaesthesia alone (9%), local with sedation, (23%) or general anaesthesia (69%) OR FESS Rx under general anaesthesia (100%)&lt;br&gt;• All surgery was performed by one surgeon</td>
</tr>
<tr>
<td>Stankiewicz et al (2009); 'BREATHE I' study</td>
<td>Prospective, multi-centre case series</td>
<td>• Included: Adults with a Dx of CRS in maxillary ± anterior ethmoid sinuses &amp; abnormal sinus CT after medical Rx from Sept 2007 to March 2008&lt;br&gt;• Excluded: CRS posterior ethmoid, frontal or sphenoid / evidence of fungal sinusitis</td>
<td>• 1-3 weeks of antibiotic Rx pre-surgery&lt;br&gt;• FinESS Rx of sinuses under local (73%) or general (27%) anaesthesia&lt;br&gt;• All surgery was performed by one surgeon</td>
</tr>
<tr>
<td>Ramadan &amp; Terrell (2010)</td>
<td>Prospective, controlled, non-randomised; parallel groups</td>
<td>• Included: Children ages 2-12 with CRS (medical Rx 3-6 months) deemed to be surgical candidates between Feb 2006 and May 2008&lt;br&gt;• Excluded: Positive cilia biopsy, extensive previous sinus surgery or osteoneogenesis, CF, tumour or other obstruction, facial trauma</td>
<td>• After pre-op evaluation, patients were offered BSP at the time of adenoidectomy:&lt;br&gt; o 17 (35%) had BSP + adenoidectomy&lt;br&gt; o 13 (26%) had only BSP (previous adenoidectomy or little tissue present)&lt;br&gt; o 19 (39%) had only adenoidectomy&lt;br&gt; • All had general anaesthesia</td>
</tr>
</tbody>
</table>

BSP: balloon sinuplasty; CF: cystic fibrosis; CRS: chronic rhinosinusitis; CT: computed tomography; Dx: diagnosis; FESS: functional endoscopic sinus surgery; Rx: treatment; SNOT: Sino-Nasal Outcome Test

Safety

Three of the four included studies reported safety outcomes (Bolger et al 2007 updated in Weiss et al 2008, Stankiewicz et al 2009 and Friedman et al 2008) (Table 3). Where the rate of AEs following BSP and FESS were compared, no significant differences were observed.
Efficacy

The key efficacy outcomes reported in the four included studies are summarised in Table 4.
Table 4  Efficacy outcomes reported in included studies

<table>
<thead>
<tr>
<th>Authors (Year)</th>
<th>n=# Sinuses; F/u Period</th>
<th>Sinus Patency</th>
<th>SNOT-20 Scores * (SN-5 for children) **</th>
<th>Rate of Revision Surgery</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolger et al (2007) &amp; Weiss et al (2008) – only Weiss 24-month data are presented here</td>
<td>n=195 sinuses; 24 month f/u</td>
<td>Of the 65 patients, 34 had BSP only; 31 had 'hybrid' = BSP + FESS</td>
<td>BSP &amp; hybrid: Significant improvement over baseline in both groups (0.9 vs 2.1; p&lt;0.001)</td>
<td>Overall required in 4% of sinuses in 9% of patients</td>
<td>Improvement in symptoms: 85% better, 15% same, 0% worse</td>
</tr>
<tr>
<td>Freidman et al (2008)</td>
<td>n=208 sinuses; minimum 3 month f/u</td>
<td>--</td>
<td>BSP &amp; FESS: Significant improvement over baseline (p&lt;0.001)</td>
<td>1 patient in the BSP group; 0 in the FESS group (but short f/u period)</td>
<td>Patient satisfaction: Overall experience**: BSP +3.71 ± 1.20 vs FESS +2.94 ± 1.39; p=0.016</td>
</tr>
<tr>
<td>Stankiewicz et al (2009)</td>
<td>n=58 sinuses; 6 month f/u</td>
<td>CT patency at 3 months: 96%</td>
<td>Mean change in scores at 6 months = 2.1 (from 2.9 ± 1.0 pre-op to 0.8 ± 0.8; p&lt;0.001)</td>
<td>--</td>
<td>Recovery time (discharge to normal activities): 47% w/in 24 hours, 43% w/in 24-48 hours</td>
</tr>
<tr>
<td>Ramadan &amp; Terrell (2010)</td>
<td>n=57 sinuses; 12 month f/u</td>
<td>--</td>
<td>Significant change in SN-5 scores from pre- to post-op (mean score of 4.1 dropped to 2.9; p&lt;0.0001) • BSP: 4.2 → 3.0; p=0.0001 • Adenoidectomy alone: 3.8 → 2.9; p&lt;0.01</td>
<td>• BSP alone = 2/13 (15%) • Adenoidectomy alone = 3/19 (15%) • BSP + adenoidectomy = 4/17 (24%)</td>
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</tr>
</tbody>
</table>

BSP: balloon sinuplasty; FESS: functional endoscopic sinus surgery; f/u: follow-up; Rx: treatment; w/in: within
* Difference between pre- and post-op scores calculated; change > 0.6 is considered clinically significant
** SN-5 score measures health-related quality of life in children with persistent sinonasal symptoms; a decrease ≥0.5 is considered clinically significant (Ramadan & Terrell, 2010).
*** Rated from -5 (worst I could have expected) to +5 (best I could have expected).

Bolger et al (2007) & Weiss et al (2008): From one report to the next, study sites dropped from nine (including Melbourne) to six and patient numbers dropped from 115 to 65. Longer-term (24-month) data showed improvement in symptoms for 85 per cent of patients (15% unchanged) and a clinically significant decrease in SNOT-20 scores and sinus opacity as assessed on CT. Revision surgery was required in four per cent of sinuses in 9 per cent of patients.

Freidman et al (2008): Revision surgery was performed in 36 per cent of patients and local anaesthesia was employed for 31 per cent of those with BSP (0% for FESS). Changes in SNOT-20 scores showed that patients in both groups had clinically
meaningful clinical responses. Patient satisfaction was higher and post-operative narcotic use lower for those in the BSP group. The one patient requiring revision surgery was in the BSP group.

*Stankiewicz et al (2009):* All patients but one were able to undergo the procedure with local anaesthetic, with (76%) or without (24%) intravenous sedation. The procedural completion rate was 95 per cent, CT-assessed sinus ostial patency at 3-months was 96 per cent, and overall SNOT-20 scores dropped significantly as assessed 1 week post-operatively (from 2.9 to 0.8; *p*<0.0001) with the favourable score sustained at 3 and 6 months. Recovery time (discharge to normal activities) was rapid (47% in 24 hours, another 43% in 48 hours) and the mean duration of post-operative analgesia was short (1.4 ± 1.3 days; range, 0-6).

*Ramadan & Terrell (2010):* All children had general anaesthesia. Guardians completed SN-5 questionnaires to assess health-related quality of life. Results were superior for BSP (± adenoidectomy) versus adenoidectomy alone: 80 versus 53 per cent improvement in symptoms. Two children in the BSP group required FESS revision surgery, whereas three children in the adenoidectomy alone group required BSP treatment. Multivariate logistic regression showed no effect on surgical success due to age, gender, pre-operative CT score, prior adenoidectomy, asthma or allergies.

**Other evidence:** registry of study data 2005-2007

A registry report was also located (Levine et al 2008); this is presumed to include some of the data from the four studies in the brief. Information from December 2005 to May 2007 was gathered by chart review from 27 centres in the USA employing BSP (n=1036 patients). Data collection and analysis were funded by Acclarent Inc. Balloon catheters were used in 3,276 sinus procedures with a mean of 3.2 per patient. The revision rate was 1.3 per cent after a mean follow-up of 40 weeks. Sinus symptoms improved for 95 per cent of patients, were unchanged for 4 per cent and were worse for 1 per cent. These results were consistent across patient categories including BSP-only and revisions. No major AEs were reported in this registry study.

**Cost Impact**

The economic impact of sinusitis in the USA has been evaluated (Ray et al 1999). This study which was conducted in 1996, estimated the direct and indirect health expenditure due to sinusitis. The total health expenditure attributed to sinusitis was $5.8 billion, of which $3.4 billion was for the primary diagnosis of acute and chronic sinusitis. These costs were associated with 26.7 million outpatient visits, the majority of which were for the primary diagnosis of acute or chronic sinusitis, and the 46.9 million medications ordered at these visits. Additionally, there were 45,000 hospital discharges and 156,000 hospital days that were attributed to sinusitis.
The cost of Relieva™ BSP devices (including the balloon catheter and various consumables) per procedure in Australia, provided by the Sponsor (Johnson & Johnson Medical Pty Ltd), is $2,104. However, in a field evaluation funded by the Victorian Department of Health and conducted at the Royal Victorian Eye and Ear Hospital in Melbourne, the cost of BSP devices per procedure was $1,250.

A US study by Friedman et al (2008) compared the cost of BSP with that of FESS. This retrospective review examined 2005-2006 data for patients who received BSP under local anaesthesia (n=35) versus those who had classic FESS under general anaesthesia (n=35). Both primary surgeries and revisions (about 20% of cases) were included.

The costs for time and equipment proved to be similar for primary procedures; however, for revision procedures, costs were lower for BSP. In particular:

- **Primary:** BSP = $14,022 ± $2,200 versus FESS = $13,574 ± $2,795; \( p=0.56 \).
- **Revision:** BSP = $10,346 ± $3,324 versus FESS = $16,190 ± $1,653; \( p<0.0001 \).
- **Equipment charges:** Higher for BSP, e.g. BSP set ($1,500), C-arm ($500-1,000) versus FESS which sometimes used a microdebrider and blades ($500) and image-guided system ($500).
- **Time charges:** Due to use of local anaesthesia, BSP required less operating room time ($600 per 15 minutes) and post-anaesthesia recovery time ($300 per 15 minutes).

**Ethical, Cultural or Religious Considerations**

No issues were identified from the retrieved material.

**Other Issues**

**Upcoming clinical trials:**

- **NCT01319305 (‘BREATHE’):** This long-term (24 month) US study is a case series (n=70) exploring BSP technology using FinESS™ and is a follow-up to BREATHE I (n=30), a feasibility and 6-month safety assessment of BSP under local anaesthesia (Stankiewicz et al 2009). Outcomes are SNOT-20 scores and results of work productivity assessment questionnaires. According to clinicaltrials.gov the study is complete but no publications were located.

- **NCT00939393 (‘ORIOS’):** This Acclarent-sponsored open-label parallel US study has a focus on costs, comparing those for use of the Relieva™ System in an office setting with those in the operating room where the BSP system may or may not be a component of FESS. Safety and efficacy are secondary outcomes. Estimated enrollment was 100 adults. The study commenced in April 2008 and was to end in September 2011.

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\( ^4 \) Information from [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
• NCT01107379 (“ORIOS2“): Also Acclarent-sponsored, this prospective, single-arm, multi-centre, 6-month, post-market study in aimed to enrol 100 adult patients with CRS who were treated with the Relieva™ System under local anaesthetic in an office setting. The US study was to cease in December 2011 with final data collection in April 2011. Primary outcomes are changes on CT and SNOT-20 scores. Patient tolerability and pain scores are secondary outcomes.

• NCT01455948: A 6-month, randomised, single blind study of FESS using specialised cannulating probes and small resection forceps versus the Relieva™ System is planned in Toronto, Canada. The study aims to recruit 200 otherwise healthy working adults (ages 18 to 65) with CRS unresponsive to medical treatment. Data collection is expected to stop in mid-2013 and study completion is scheduled for late 2013. The main outcome measures are economic, i.e. direct and indirect costs of treatment. Secondary outcomes include health status (EQ-5D questionnaire) and symptom relief (SNOT-20).

Conflict of interest of study authors:
In most of the included studies, one or more authors received compensation from BSP device manufacturers in the form of remuneration or stock options (Ramadan et al 2010, Stankiewicz et al 2009, Levine et al 2008, Weiss et al 2008 and Bolger et al 2007). The study by Freidman et al (2008) was an exception, as it was funded entirely by the first author, and reported that there were no financial relationships to disclose with the device manufacturer.

SUMMARY OF FINDINGS
Based on a few small low-quality studies, BSP appears to be at least comparable in efficacy to the conventional, more invasive FESS procedure, while offering several advantages, such as the ability to deliver care under local anaesthesia, as well as high levels of patient symptom relief and satisfaction. In addition, BSP is associated with a low rate of AEs. However, it is a technology that appears to have diffused widely before extensive high-quality research has established safety and effectiveness, and it is unclear whether high-quality studies (e.g. randomised, blinded, comparative) are now possible. More than 100,000 patients have been treated in the USA since 2005, but it is less clear how widely the technology has diffused in Australia and New Zealand.

HEALTHPACT ASSESSMENT:
In Australia, at least three BSP devices have received ARTG approval, physicians have been trained in its use, and a 2012 Australian otolaryngology conference has included this technology as a topic theme and is devoting a day to hands-on instruction. In addition, a number of clinical trials and field evaluations, the results of which will provide valuable information about the utility of BSP, are currently ongoing. Therefore, due to the wide diffusion of BSP technology in other countries, and an apparent interest
in Australia, HealthPACT wish to monitor the technology, which will be reviewed in 24 months time.

**NUMBER OF STUDIES INCLUDED**

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the following link on the HealthPACT web site.

Total number of studies 4
Total number of Level III-2 studies 2
Total number of Level IV studies 2

**REFERENCES**


**SEARCH CRITERIA TO BE USED**

Balloon catheter OR Sinuplasty OR Sinusotomy; Chronic rhinosinusitis OR Rhinosinusitis OR sinusitis