Health Policy Advisory Committee on Technology

Technology Brief Update

Balloon Sinuplasty for Chronic Rhinosinusitis

February 2014
TECHNOLOGY BRIEF UPDATE 2014

Technology, Company and Licensing

Register ID: WP060
Technology name: Balloon Sinuplasty
Patient indication: For patients with chronic rhinosinusitis

Stage of development in Australia

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

Australian Therapeutic Goods Administration approval

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

ARTG number (s): 203853, 168057, 178372, 197043, 215963, 215961

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>Australia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Austria</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turkey</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States of America</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2014 Evidence and Policy

It should be noted that hybrid procedures are sometimes referred to as balloon sinuplasty; therefore, the term balloon sinus dilation has been used in the update to avoid confusion.
2014 Safety and effectiveness

One systematic review (BlueCross Blue Shield) (level I Intervention evidence) (1) and two randomised controlled trials (RCTs) (level II Intervention evidence) (2, 3) evaluating balloon sinus dilation for chronic rhinosinusitis were included in this update.

The systematic review summarised all available evidence up to December 2012 evaluating balloon sinus dilation for chronic rhinosinusitis. The two additional RCTs were published after the literature review and compared the safety and efficacy of balloon sinus dilation with functional endoscopic sinus surgery (FESS) in a total of 107 patients. The primary outcome of both RCTs was improvement in the 20-item Sinonasal Outcome Test (SNOT-20), a quality of life measure for patients with rhinosinusitis. However, the other reported outcomes differed between the studies. Achar et al (2) reported the average postoperative recovery time and saccharin clearance time (SCT) (an indication muco-ciliary clearance time). By contrast, Cutler et al (3) reported post-discharge nausea, nasal bleeding, duration of analgesic use, recovery time, short-term improvement in sinus symptoms, complications and revision rate. A summary of the included studies is outlined in Table 1.

Table 1 Characteristics of included studies evaluating balloon sinus dilation

<table>
<thead>
<tr>
<th>Study</th>
<th>BlueCross BlueShield 2013</th>
<th>Cutler et al. 2013</th>
<th>Achar et al. 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design (evidence level)</td>
<td>Systematic review (includes II – IV)</td>
<td>Randomised controlled trial (II)</td>
<td>Randomised controlled trial (II)</td>
</tr>
<tr>
<td>Intervention (number of patients)</td>
<td>Balloon sinus dilation (15-1036)</td>
<td>Balloon sinus dilation (n=50)</td>
<td>Balloon sinus dilation (n=12)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FESS (n=42)</td>
<td>FESS (n=12)</td>
</tr>
<tr>
<td>Followup</td>
<td>Up to 2 years</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Conflict of interest</td>
<td>No conflicts of interests declared</td>
<td>The first and third authors are paid consultants and stockholders of Entellus Medical, Inc.</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

FESS: functional endoscopic sinus surgery; NA: Not applicable.

BlueCross BlueShield 2013

The systematic review aimed to determine the safety and efficacy of balloon sinus dilation compared with FESS. A systematic search of MEDLINE was conducted, with the latest publication date set for December 2012. Additional limits included English-language articles and studies performed on humans. Studies were excluded if they did not report clinical outcomes, were of unusual or special patients, or were case series of fewer than 10 patients. A formal quality assessment of the included studies was not undertaken.

The literature search identified one RCT (level II Intervention evidence), three non-randomised controlled trials (level III Intervention evidence) and nine case series studies (level IV Intervention evidence) evaluating balloon sinus dilation for chronic rhinosinusitis (Table 2). Two balloon dilation technologies with differing indications...
were included in the review: the Relieva® Balloon Sinuplasty System (Acclarent, Inc., Menlo Park, CA, USA), for chronic rhinosinusitis in the frontal, maxillary and sphenoid sinuses, and FinESS (Entellus Medical, Inc., Plymouth, MN, USA) for chronic rhinosinusitis in the maxillary, anterior and ethmoid sinuses. In several studies, patients were treated with both balloon sinus dilation and the traditional FESS procedure.

The authors of the systematic review could not draw conclusions regarding the comparative efficacy of balloon sinus dilation and FESS. The single RCT was of poor quality, with no formal comparison between the two treatment arms. In addition, it was statistically underpowered to detect any clinically meaningful difference in

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**Table 2  Details of studies included in the BlueCross BlueShield report**

<table>
<thead>
<tr>
<th>Author, year Location</th>
<th>Study design (evidence level)</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaza et al (2011) (4) Spain</td>
<td>RCT (II)</td>
<td>Balloon sinus dilation + mandatory anterior ethmoidectomy n= 16  FESS + mandatory anterior ethmoidectomy n= 16</td>
</tr>
<tr>
<td>Ramadan &amp; Terrell (2010) (5) USA</td>
<td>Non-randomised comparative study (III-2)</td>
<td>Balloon sinus dilation + adenoidectomy n= 30  Adenoidectomy n= 19</td>
</tr>
<tr>
<td>Friedman et al (2008) (6) USA</td>
<td>Non-randomised comparative study (III-3)</td>
<td>Balloon sinus dilation n= 35  FESS + ethmoidectomy n= 35</td>
</tr>
<tr>
<td>Thottam et al (2012) (7) USA</td>
<td>Non-randomised comparative study (III-3)</td>
<td>Balloon sinus dilation + ethmoidectomy n= 15  FESS + ethmoidectomy n= 16</td>
</tr>
<tr>
<td>Levine et al (2008) (8) 27 practice sites USA</td>
<td>Case series (IV)</td>
<td>Registry of 1,036 patients with varying balloon sinus dilation + FESS procedures n= 203</td>
</tr>
<tr>
<td>Karanfilov et al (2012) (9) USA</td>
<td>Case series (IV)</td>
<td>Balloon sinus dilation n= 203</td>
</tr>
<tr>
<td>Bolger et al (2007) (10) USA</td>
<td>Case series (IV)</td>
<td>Balloon sinus dilation n= 109/115</td>
</tr>
<tr>
<td>Kuhn et al (2008) (Same patients as Bolger et al) (11) USA</td>
<td>Case series (IV)</td>
<td>Balloon sinus dilation n= 70 of the original 115</td>
</tr>
<tr>
<td>Weiss et al (2008) (12) (Same patients as Bolger et al) USA</td>
<td>Case series (IV)</td>
<td>Balloon sinus dilation n= 65 of the original 115</td>
</tr>
<tr>
<td>Cutler et al (2011) (13) USA</td>
<td>Case series (IV)</td>
<td>Balloon sinus dilation n= 71</td>
</tr>
<tr>
<td>Stankiewicz et al (2012) (14) USA</td>
<td>Case series (IV)</td>
<td>Transantral balloon dilation n= 59</td>
</tr>
<tr>
<td>Ramadan et al (2010) (15) USA</td>
<td>Case series (IV)</td>
<td>Balloon sinus dilation n= 32</td>
</tr>
<tr>
<td>Kutluhan et al (2009) (16) Turkey</td>
<td>Case series (IV)</td>
<td>Balloon sinus dilation n= 30</td>
</tr>
</tbody>
</table>

FESS: functional endoscopic sinus surgery.
outcomes between the two patient groups. However, it is worth noting that both balloon sinus dilation and FESS achieved similar reductions in disease severity as assessed by the Lund-Mackay scoring system.

The results from the three non-randomised comparative studies were inconclusive. The retrospective analysis in two studies introduced significant bias. In addition, the study selection by Friedman et al (6) induced a significant imbalance between the two groups, whereby the patients in the FESS group had more severe sinusitis. Despite this, there was no difference in mean postoperative disease severity scores between the two groups. Thottam et al demonstrated no improvement in symptoms after either balloon sinus dilation or FESS (7), while Ramadan and Terrell compared balloon sinus dilation with adenoidectomy instead of FESS (5).

The nine case series studies, three of which reported on the same patient population, demonstrated an overall improvement in sinusitis symptoms after balloon sinus dilation, with long-term results indicating relief for up to two years following the intervention. However, the lack of a comparator meant that the efficacy of balloon sinus dilation could not be conclusively determined. In addition, the findings were further complicated by the heterogeneity of the studies with respect to patient selection, disease severity and concurrent sinus procedures. Adverse events resulting from balloon sinus dilation were uncommon in the case series studies.

BlueCross BlueShield concluded that the current evidence base was insufficient to demonstrate that balloon sinus dilation improved health outcomes in the investigational setting. Despite the lack of clinical effectiveness and robust outcomes data, however, the technology appears to be widely diffused in the USA.

Cutler et al 2013

One hundred and five adults with either chronic or acute recurrent rhinosinusitis were recruited into an RCT (level II Intervention evidence) across 10 centres in the USA. (3) Patients with posterior ethmoid, sphenoid, or frontal rhinosinusitis requiring FESS, fungal sinusitis, a deviated septum resulting in obstruction, gross sinonasal polyposis, previous surgery within three months and anyone requiring concomitant sinonasal surgery were excluded from the trial. A physician blinded to treatment assignment performed scoring of the baseline computed tomography scans and debridement details. Patients were randomly assigned on a 1:1 basis to either balloon sinus dilation or FESS. However, 13 patients subsequently withdrew (2 from the balloon sinus dilation group and 11 from FESS). Consequently, 92 patients (50 balloon dilation and 42 FESS) were treated. Postoperative follow-up appointments were scheduled for one week, and one, three and six months following the intervention. One patient in the balloon dilation group was lost to follow-up after three months.
There was no difference in preoperative patient demographics between the two groups with respect to age, sex distribution, ethnicity, smoking history, allergies, SNOT-20 score, previous nasal surgery, Lund-Mackay score, chronicity of rhinosinusitis or other prognostic variables \((p>0.05\) for all variables). The balloon sinus dilation and FESS cohorts reported a mean age of 47 (16 men and 34 women) and 48 years (19 men and 23 women), respectively.

**Safety**

No deaths or complications occurred in either the balloon sinus dilation or FESS study arms.

**Efficacy**

Technical success was achieved in 97 of 98 balloon dilation procedures (99%) and 80 of 81 FESS procedures (99%).

The study’s primary outcomes are listed in Table 3. The mean changes in SNOT-20 scores were similar in both groups at one week and six months after treatment. Comparison of the mean change in SNOT-20 at 6 months determined that the mean symptom improvement for patients undergoing balloon sinus dilation was non-inferior to patients undergoing FESS. Patients who underwent balloon sinus dilation required significantly fewer postoperative debridement procedures compared with FESS \((p<0.0001)\).

**Table 3  Primary outcomes assessed by Cutler et al (3)**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Balloon dilation (n=50)</th>
<th>FESS (n=42)</th>
<th>(p) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) change in SNOT-20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 week</td>
<td>-1.5 (0.9)</td>
<td>-1.0 (1.1)</td>
<td>0.01</td>
</tr>
<tr>
<td>1 month</td>
<td>-1.7 (1.0)</td>
<td>-1.6 (1.0)</td>
<td>NR</td>
</tr>
<tr>
<td>6 months</td>
<td>-1.7 (1.1)</td>
<td>-1.6 (1.0)</td>
<td>(&lt;0.0001^*)</td>
</tr>
<tr>
<td>Mean (SD) number of postoperative debridement procedures per patient</td>
<td>0.1 (0.6) (7 procedures)</td>
<td>1.2 (0.9) (50 procedures)</td>
<td>(&lt;0.0001)</td>
</tr>
<tr>
<td>Number of patients not requiring debridement</td>
<td>46 (92%)</td>
<td>11 (26%)</td>
<td>(&lt;0.0001)</td>
</tr>
</tbody>
</table>

\(^*\)Statistically non-inferior to FESS

FESS: functional endoscopic sinus surgery; NR: not reported; SNOT: sinonasal outcome test; SD: standard deviation.

Secondary outcomes are listed in Table 4. Patients who received balloon dilation had fewer nasal bleeding discharges, recovered more quickly and required fewer days on prescription pain medication than those who underwent FESS. However, both groups reported similar rates of post-discharge nausea and use of over-the-counter pain medication.
Table 4  Secondary outcomes assessed by Cutler et al (3)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Balloon dilation (n=50)</th>
<th>FESS (n=42)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-discharge nausea (n)</td>
<td>3 (6%)</td>
<td>7 (17%)</td>
<td>0.18</td>
</tr>
<tr>
<td>Discharged with nasal bleeding (n)</td>
<td>14 (28%)</td>
<td>23 (55%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Mean (SD) recovery time (days)</td>
<td>1.6 (1.1)</td>
<td>4.8 (6.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>Mean (SD) duration of prescription pain medication (days)</td>
<td>0.9 (1.4)</td>
<td>2.8 (2.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean (SD) duration of over-the-counter pain medications (days)</td>
<td>1.6 (2.0)</td>
<td>2.7 (4.0)</td>
<td>0.13</td>
</tr>
</tbody>
</table>

FESS: functional endoscopic sinus surgery; SD: standard deviation.

Achar et al 2012

Twenty-four patients with chronic rhinosinusitis who were referred for surgery after medical treatment for their symptoms had failed, were recruited into this RCT. (2) Patients were excluded: if they were younger than 18 years of age; were unwilling to undergo endoscopic sinus surgery; had extensive sinonasal polyps; had undergone previous surgery or trauma to the sinonasal complex; had an aspirin sensitivity; had asthma, sinonasal tumours or obstructive lesions, ciliary dysfunction or cystic fibrosis; or were pregnant. Patients were assigned to either balloon sinus dilation (n=12) or FESS (n=12) using a block randomisation list. Follow-up appointments were conducted at 6, 12 and 24 weeks post-surgery. No patients were lost during follow up.

The preoperative patient demographics reported were limited to sex and age. The balloon sinus dilation and FESS cohorts reported a mean age of 38.9 and 44.1 years, respectively. Both groups reported similar numbers of men (3 of 12 undergoing balloon sinus dilation and 2 of 12 in the FESS group).

Limitations of this RCT included a lack of blinding, small patient numbers, exclusion of patients with severe polyposis and the performance of FESS in several patients in the balloon sinus dilation treatment group to reduce the polyposis.

Safety

No deaths or adverse events were reported.

Efficacy

The procedural success rate was not reported.

Patients undergoing balloon sinus dilation reported shorter postoperative recovery times, although the statistical significance of this result was not reported. The balloon sinus dilation group experienced a greater change in mean SNOT-20 and SCT scores, compared with FESS (p=0.03) (Table 5).
Table 5  Effectiveness outcomes assessed by Achar et al (2)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Balloon sinus dilation (n=12)</th>
<th>FESS (n=12)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative recovery time (days)</td>
<td>2.2</td>
<td>5.0</td>
<td>NR</td>
</tr>
<tr>
<td>Mean (SD) change in SNOT-20 score</td>
<td>43.8 ± 15.2</td>
<td>30.0 ± 12.3</td>
<td>0.03</td>
</tr>
<tr>
<td>Mean (SD) change in SCT time (minutes)</td>
<td>7.5 ± 5.1</td>
<td>3.5 ± 4.3</td>
<td>0.03</td>
</tr>
</tbody>
</table>

NR: not reported; SD: standard deviation; SNOT: sinonasal outcome test; SCT: saccharine clearance time.

2014 Economic evaluation

No cost effectiveness studies of balloon sinoplasting were identified in the literature.

2014 Ongoing research

Five clinical trials were identified, from searches of the ClinicalTrials.gov website and the Australian and New Zealand Clinical Trials Register, that are investigating balloon sinus dilation for treatment of chronic rhinosinusitis in either adult or paediatric patients (Table 6). Three studies are utilising technology by Acclarent, Inc., (RELIEVA Spin® or ULTIRRA®) and two studies are using the Entellus Medical, Inc. (XprESS™) system.

Table 6  Current clinical trials evaluating balloon sinus dilation

<table>
<thead>
<tr>
<th>Trial Identifier/ Location</th>
<th>Trial status</th>
<th>N</th>
<th>Details</th>
<th>Diagnosis</th>
<th>Interventions</th>
<th>Estimated completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01525849/ USA</td>
<td>Ongoing, but not recruiting</td>
<td>120</td>
<td>RCT Single centre</td>
<td>Chronic sinusitis</td>
<td>Balloon sinus dilation (Entellus Medical, Inc.) vs. Functional endoscopic sinus surgery</td>
<td>December 2014</td>
</tr>
<tr>
<td>NCT01714687/ USA</td>
<td>Recruiting</td>
<td>400</td>
<td>RCT Single centre</td>
<td>Recurrent acute rhinosinusitis</td>
<td>Balloon sinus dilation (Acclarent, Inc.) vs. Medical management</td>
<td>October 2014</td>
</tr>
<tr>
<td>NCT01990820/ USA</td>
<td>Recruiting</td>
<td>48</td>
<td>RCT Single centre</td>
<td>Chronic rhinosinusitis in children</td>
<td>Balloon sinus dilation (Acclarent, Inc.) + irrigation vs. Adenoidectomy + maxillary sinus irrigation</td>
<td>March 2016</td>
</tr>
<tr>
<td>NCT01685229/ USA</td>
<td>Recruiting</td>
<td>250</td>
<td>Non-randomised comparative study</td>
<td>Chronic rhinosinusitis</td>
<td>Balloon sinus dilation (Acclarent, Inc.) vs. Medical management</td>
<td>March 2014</td>
</tr>
<tr>
<td>NCT01612780/ USA</td>
<td>Ongoing, but not recruiting</td>
<td>120</td>
<td>Case series Single centre</td>
<td>Not mentioned</td>
<td>Balloon sinus dilation (Entellus Medical, Inc.)</td>
<td>April 2014</td>
</tr>
</tbody>
</table>

NCT01525849: primary outcome is improvement in chronic sinusitis symptoms during the first 12 months following treatment; secondary outcomes were not mentioned.
NCT01714687: primary outcome is change in quality of life 24 weeks after the intervention; secondary outcomes include disease specific medication usage, number of school/work days missed due to sinusitis, number of sinus infections, number of revisions required, number of patients electing to cross over to balloon dilation and time to return to normal activity.

NCT01990820: primary outcome is quality of life during the first 12 to 18 months following the intervention; secondary outcomes were not mentioned.

NCT01685229: primary outcome is change in quality of life 24 weeks after the intervention; secondary outcomes include disease-specific medication usage, number of school/work days missed due to sinusitis, number of sinus infections, number of revisions required, number of patients electing to cross over to balloon dilation and time to return to normal activity.

NCT01612780: primary outcome is change in quality of life and rate of revision or additional sinus surgery during the first 12 months following treatment; secondary outcomes were not mentioned.

2014 Other issues

Although not apparent in the included studies, high procedural failure rates with balloon sinus dilation have been reported in the literature (>65%) (17). This may be attributable to the significant learning curve associated with the procedure.

2014 Summary of findings

Balloon sinus dilation is a novel therapy for chronic rhinosinusitis. The highest level of evidence, the BlueCross BlueShield systematic review, determined there was insufficient evidence that balloon sinus dilation improved health outcomes in the investigational setting when compared with FESS. Furthermore, the BlueCross BlueShield noted that the studies of higher intervention evidence (levels II and III) were often of poor quality and contained significant biases. One RCT published after the systematic review showed greater improvements in SNOT-20 scores in patients undergoing balloon sinus dilation, compared with FESS. A second RCT showed equivocal results. Both studies reported that patients undergoing balloon sinus dilation had a quick recovery and less pain as compared to patients undergoing FESS. Both procedures were associated with a minimal number of adverse events. However, the short-term follow up, conflicts of interest and small patient numbers limited the conclusions of these two studies.

Two large randomised clinical trials are anticipated to be completed within 2014. However, only one of these compares balloon sinus dilation with FESS, the most appropriate comparator. Therefore, balloon sinus dilation should be used utilised in the
context of research and clinical trials. Despite the lack of supporting evidence, balloon sinus dilation appears to be widely diffused in the USA and, potentially, Australia.

**2014 HealthPACT assessment**

Based on the level of evidence and the wide diffusion of balloon sinus dilation it is recommended that the technology be archived.

**2014 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 HealthPACT web site.

Total number of studies: 3

Total number of systematic reviews: 1 (level II to IV evidence)

Total number of Level II studies: 2

**2014 References**


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.

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).

2012 CLINICAL NEED AND BURDEN OF DISEASE

About 1.8 million Australians (9.2%) reported having CRS in 2004/05, 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).

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

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1 Similar data for New Zealand were not located.
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.

2012 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

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

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.
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).

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):
  - Based on currently available scientific medical evidence, endoscopic balloon dilation technology is acceptable and safe for use in the management of sinus disease.
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.

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.

In a group of selected patients, the use of balloon catheter dilation technology alone may eliminate the need for other surgical techniques.

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).

**2012 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). Two studies involved
comparisons between study arms where patients were given a choice between procedures, and blinding was not employed (Freidman et al and Ramadan et al, level III-2 intervention evidence). The two other studies were case series of patients receiving BSP (level IV intervention evidence).

Table 1: Overview of included studies

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

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 (year)</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>Freidman 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</td>
<td>Relief System Rx under local anaesthesia alone (9%), local with sedation (23%) or general anaesthesia (69%) or FESS Rx under general anaesthesia (10%)</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</td>
<td>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: Consecutive adults with CRS posterior ethmoid, frontal or sphenoid / evidence of fungal sinusitis</td>
<td>1-3 weeks of antibiotic Rx pre-surgery</td>
</tr>
<tr>
<td></td>
<td></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</td>
<td>FInESS Rx of sinuses under local (73%) or general (27%) anaesthesia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Excluded: CRS posterior ethmoid, frontal or sphenoid / evidence of fungal sinusitis</td>
<td>All surgery was performed by one surgeon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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:</td>
</tr>
<tr>
<td></td>
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<td>o 17 (35%) had BSP + adenoidectomy</td>
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<td></td>
<td></td>
<td></td>
<td>o 10 (21%) had only BSP (previous adenoidectomy or little tissue present)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>o 19 (39%) had only adenoidectomy</td>
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<td></td>
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<td>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 Freidman et al 2008) (Table 3). Where the rate of AEs following BSP and FESS were compared, no significant differences were observed.

### Table 3  Adverse events reported in included studies

<table>
<thead>
<tr>
<th>Authors (year)</th>
<th>Adverse Events reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolger et al (2007) &amp; Weiss et al (2008)</td>
<td>No serious AEs; Bolger et al reported that 9 patients had sinus infections in first 6 months</td>
</tr>
<tr>
<td>Freidman et al (2008)</td>
<td>Turinate lateralisation or scarring: BSP 8 versus FESS 3, p=0.19</td>
</tr>
<tr>
<td></td>
<td>Sinus infections (1-4) in follow-up period: BSP 6 versus FESS 9, p=0.65</td>
</tr>
<tr>
<td>Stankiewicz et al (2009)</td>
<td>Post-op bleeding: None=83%, resolved w/in 6 hours=13%, up to 48 hours=4%</td>
</tr>
<tr>
<td></td>
<td>Device-related AEs: Severe=0, mild=3 (tooth numbness, 2 facial numbness, 1)</td>
</tr>
<tr>
<td>Ramadan &amp; Terrell (2010)</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

BSP: balloon sinuplasty; FESS: functional endoscopic sinus surgery; w/in: within
Efficacy
The key efficacy outcomes reported in the four included studies are summarised in Table 4.

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 Ear and Eye 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.

- 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.

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4 Information from www.clinicaltrials.gov
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 website.

<table>
<thead>
<tr>
<th>Total number of studies</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of Level III-2 studies</td>
<td>2</td>
</tr>
<tr>
<td>Total number of Level IV studies</td>
<td>2</td>
</tr>
</tbody>
</table>

REFERENCES


United States Food & Drug Administration (US FDA) (2008a). Acclarent Inc. 501(k) summary for the Relieva Sinus Balloon Catheter (K043527) and Relieva Acella Sinus Balloon Catheter (K061903)
Balloon sinuplasty for chronic rhinosinusitis: update February 2012


**SEARCH CRITERIA TO BE USED**

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