Clinical Consensus Statement: Balloon Dilation of the Sinuses

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objective. To develop a clinical consensus statement on the use of sinus ostial dilation (SOD) of the paranasal sinuses.

Methods. An expert panel of otolaryngologists was assembled to represent general otolaryngology and relevant subspecialty societies. The target population is adults 18 years or older with chronic or recurrent rhinosinusitis (with or without nasal polyps, with or without prior sinus surgery) for whom SOD is being recommended, defined as endoscopic use of a balloon device to enlarge or open the outflow tracts of the maxillary, frontal, or sphenoid sinuses, as a standalone procedure or with endoscopic surgery. A modified Delphi method was used to distill expert opinion into clinical statements that met a standardized definition of consensus.

Results. After 3 iterative Delphi method surveys, 13 statements met the standardized definition of consensus while 45 statements did not. The clinical statements were grouped into 3 categories for presentation and discussion: (1) patient criteria, (2) perioperative considerations, and (3) outcomes. Strong consensus was obtained for not performing SOD in patients without sinonasal symptoms or positive findings on computed tomography (CT) in patients with symptoms only of headache or sleep apnea without criteria for sinusitis. In addition, strong consensus was met that CT scan of the sinuses was necessary before performing SOD and that surgeons need to understand and abide by regulations set forth by the US Food and Drug Administration if they choose to reuse/reprocess devices.

Conclusion. Expert panel consensus may provide helpful information for the otolaryngologist considering the use of SOD for the management of patients with a diagnosis of rhinosinusitis. This panel reached consensus on a number of statements that defined the use of SOD as inappropriate in the management of a variety of symptoms or diseases in the absence of underlying sinusitis. When patients meet the definition of chronic sinusitis as confirmed by CT scan, SOD of the sinuses can be indicated and/or effective in certain scenarios. Additional consensus statements regarding proper setting and safeguards for performing the procedure are described.

Keywords

sinusitis, dilatation, balloon dilation, operative surgical procedure, paranasal sinuses, consensus

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Chronic rhinosinusitis (CRS) is a common illness that affects approximately 12% of the US adult population. The disease burden of CRS includes the morbidity from symptoms, the economic consequences of lost work and school time, and the costs and risks of medical and surgical interventions. Sinus surgery is often performed for CRS, resulting in approximately 257,000 ambulatory sinus operations in 2006. Medicare billing data for 2000 to 2014 demonstrated that the total number of sinus procedures per 10,000 beneficiaries (PP10K) nationwide increased by 3.7% annually.

In 2005, the US Food and Drug Administration (FDA) approved sinus ostial dilation (SOD) for diagnostic and therapeutic approaches to the paranasal sinuses. SOD uses a high-pressure balloon to compress the sinus mucosa and creates microfractures in the bone surrounding the sinus ostium or outflow tract in an effort to improve sinus drainage and ventilation. It can be performed alone or in conjunction with traditional endoscopic sinus surgery. The absence of formally agreed upon criteria for the appropriate use of SOD, however, has led to wide variation in national practice patterns. For example, anecdotal evidence suggests that some providers are using SOD for diseases that range from sinusitis with radiographic abnormalities, to headaches without radiographic abnormalities, to nasal obstruction, to even obstructive sleep apnea. A recent review of balloon use by physicians within the Department of Defense health care system also indicated that SOD is often used for indications for which there is currently no evidence of efficacy. Furthermore, between 2011 and 2014, the number of balloon SOD procedures increased in excess of the drop in nonballoon procedures. This rise in SOD procedures, without a commensurate reduction in traditional functional endoscopic sinus surgery, has caused increased scrutiny by payers and providers, which is further intensified by concern over potential inappropriate use of the procedure.

Given the knowledge gap that exists regarding the role of SOD in managing CRS and the increasing rates of utilization, the Physician Payment Policy Working Group (3P) of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) submitted SOD to the AAO-HNS Foundation (AAO-HNSF) Guideline Task Force as a potential topic for a clinical practice guideline. Due to limited evidence to support a guideline, the topic of SOD was selected for clinical consensus statement (CCS) development. The objectives of the CCS are to promote appropriate selection of patients and criteria for the use of sinus ostial dilation, define proper use of imaging in the treatment decision-making process, identify perioperative factors that are associated with a reduction in adverse events and better patient outcomes, and determine areas for future research.

Methods
This CCS was developed using an a priori protocol with the following steps: (1) evaluating the suitability of sinus ostial dilation as the subject of a clinical consensus statement, (2) recruiting the expert panel, (3) vetting potential conflict of interests among proposed panel members, (4) performing a systematic literature review, (5) determining the scope and population of interest for the consensus statement, (6) developing and implementing a modified Delphi survey, (7) revising the clinical statements in an iterative fashion based on survey results, and (8) aggregating the data for analysis and presentation. The pertinent details of each of these steps will be briefly described.

Determination of SOD as the Topic of a Consensus Statement, Panel Recruitment, and Vetting
SOD was first considered the subject of a clinical consensus statement based on a suggestion from an AAO-HNS member. After deliberation, the Guideline Task Force supported the suggestion, and consensus panel leadership was selected and administrative support was allocated. Panel membership was strategically developed to ensure appropriate representation of all relevant stakeholders within otolaryngology. The stakeholders were contacted about the consensus statement project with the requirements and desired qualifications for panel membership, and each then nominated their own representative content expert to participate.

Participating subgroups include the Triologic Society (J.M.D.), the American Rhinologic Society (P.S.B., D.D.R.), the American Academy of Otolaryngic Allergy (M.P.P.), and the American Academy of Allergy, Asthma & Immunology (F.M.B.) and the appropriate committees within the AAO-HNS, including the Board of Governors (D.R.E.); the Rhinology and Paranasal Sinus Committee (A.P.L.); the Physician Payment Policy Committee (R.P.M.); the Allergy, Asthma, and Immunology Committee (A.U.L.); the Imaging Committee (P.S.B.); and the Medical Devices and Drugs Committee (E.D.M.). The methodologist (R.M.R.) was a nonvoting member of the development group.

All the members are in active clinical practice. Once the panel was assembled, all members were asked to disclose potential conflicts of interest. Disclosures included balloon-related research funded by the medical device industry, non-balloon research funded by the medical device industry, and consulting or speaking fees paid by the medical device industry (list at end of article). Conflicts were vetted with the group, and a panel vote was used to determine whether a disclosed conflict of interest necessitated disqualification from panel participation. The panel chair (J.F.P.) and the panel assistant chair (S.C.P.) led the development of the clinical statements and the Delphi process with input from a senior consultant/methodologist from the Academy leadership in the Guidelines Task Force (R.M.R.) and administrative support from a Foundation staff liaison (M.D.C.).

Literature Review and Determination of the Scope of the Consensus Statement
A systematic literature review was performed by an information specialist to identify current evidence regarding the indications, perioperative considerations, and clinical outcomes for SOD in managing CRS.
The literature search was conducted in January 2017 and included all relevant publications in English from PubMed, National Guidelines Clearinghouse, CMA Infobase (Canada), NICE UK, and Health Technology Assessment Database (HTA) from 2006 using the following search terms:

The literature search yielded 248 articles. After screening for relevancy, 121 articles were retained. The 121 relevant articles were reviewed independently by the chair and assistant chair and classified based on the Oxford Centre for Evidence-Based Medicine (CEBM) 2011 Levels of Evidence.7

The panel made several decisions regarding the scope of this clinical consensus statement before formally beginning the Delphi process. It was decided that the target audience of the statement would specifically be otorhinolaryngologists. A working definition of SOD was determined to be “endoscopic use of a balloon device to enlarge or open the outflow tracts of the maxillary, frontal, or sphenoid sinuses performed either as a standalone procedure or in conjunction with endoscopic sinus surgery.” The use of serial dilations over time in the same patient was not considered. The target population was defined as adults 18 years or older with chronic or recurrent rhinosinusitis (with or without nasal polyps, with or without prior sinus surgery) for whom SOD was being recommended by an otorhinolaryngologist. The following exclusions were determined: cystic fibrosis, primary ciliary dyskinesia, and immune deficiency. These items were considered, and the panel thought these were important modifying factors, although the evidence base is not available to support consensus on the use of SOD in these populations. Once the target population and scope of practice were determined, the panel used the results of the literature review to identify and prioritize topics and questions for which knowledge gaps or uncertainty existed, which could most benefit from potential consensus from an expert panel. These areas were then used as the basis for the formulation of the initial statements that were then evaluated through the Delphi survey method.

**Delphi Survey Method Process and Administration**

A modified Delphi survey method was used to assess consensus for the proposed statements,6 with multiple anonymous surveys to minimize bias within the expert panel and facilitate consensus.8

Web-based software (www.surveymonkey.com) was used to administer confidential surveys to panel members. A potential topic list of 39 questions was developed by the panel during the first call and each panel member was invited to provide 1 draft statement for each of their top 5 ranked topic list choices. The survey period was broken down into 2 Delphi rounds. All answers were de-identified and remained confidential, but names were collected to ensure proper follow-up, if needed.

Based on the outcomes of the top-ranked topic list choices and resulting discussion, the panel chair developed the first Delphi survey, which consisted of 48 statements. Prior to dissemination to the panel, the Delphi surveys were reviewed by the methodologist for content and clarity. Questions in the survey were answered using a 9-point Likert scale wherein specific values were labeled (1 = strongly disagree, 3 = disagree, 5 = neutral, 7 = agree, and 9 = strongly agree) and the intervening integers were also allowed to be selected. The surveys were distributed, and responses were aggregated, distributed back to the panel, discussed via teleconference, and revised, if warranted. The purpose of the teleconference was to provide an opportunity to clarify any ambiguity, propose revisions, or drop any statements recommended by the panel.

The criterion for consensus was established a priori and followed the criteria below6:

- **Consensus:** statements achieving a mean score of 7.00 or higher and having no more than 1 outlier, defined as any rating 2 or more Likert points from the mean in either direction
- **Near consensus:** statements achieving a mean score of 6.50 or higher and having no more than 2 outliers
- **No consensus:** statements that did not meet the criteria of consensus or near consensus

In addition, for the purposes of emphasis within the discussion, strong consensus was subsequently defined as a mean Likert score of 8.00 or higher with no outliers.
Three iterations of the Delphi survey were performed. The panel extensively discussed (via teleconference) the results of each item after the first Delphi survey. Items that reached consensus were accepted, and items that did not meet consensus were discussed to determine if wording or specific language was pivotal in the item not reaching consensus. The second and third iterations of the survey were used to reassess items for which there was near consensus or for items for which there was suggestion of significant alterations in wording that could have affected survey results. The entire panel also extensively discussed the results of the second Delphi survey. All items reaching consensus were accepted. The factors leading to the remaining items not reaching consensus were not attributed to wording or other modifiable factors but rather a true lack of consensus.

The final version of the clinical consensus statements was grouped into 3 specific areas: (1) patient criteria, (2) perioperative considerations, and (3) outcomes. The final manuscript was drafted with participation and final review from each panel member.

Results

When revisions of the original 48 statements presented at the first Delphi round are included, a total of 58 clinical statements were developed for assessment through the Delphi survey method. All panelists completed all survey items. After 2 iterations of the Delphi survey, 13 statements (22%) met the standardized definition for consensus (Tables 1-3) and 45 (78%) did not (Tables 4-6). The clinical statements were organized into the 3 specific subject areas, and the results of each will be individually considered below.

Table 1. Statements That Reached Consensus: Patient Criteria.

<table>
<thead>
<tr>
<th>No.</th>
<th>Statement</th>
<th>Mean</th>
<th>Outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT.</td>
<td>9.00</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>Balloon dilation is not appropriate for the management of headache in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.</td>
<td>8.77</td>
<td>0</td>
</tr>
<tr>
<td>18</td>
<td>Balloon dilation is not appropriate for the management of sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.</td>
<td>8.77</td>
<td>0</td>
</tr>
<tr>
<td>17</td>
<td>CT scanning of the sinuses is a requirement before balloon dilation can be performed.</td>
<td>8.46</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>Balloon dilation is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.</td>
<td>8.08</td>
<td>1</td>
</tr>
<tr>
<td>11a</td>
<td>Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps.</td>
<td>7.62</td>
<td>0</td>
</tr>
<tr>
<td>13a</td>
<td>There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinuse surgery.</td>
<td>7.62</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>There is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and the CT evidence of ostial occlusion and mucosal thickening.</td>
<td>7.00</td>
<td>1</td>
</tr>
</tbody>
</table>

Abbreviations: AAO-HNSF, Academy of Otolaryngology—Head and Neck Surgery; CT, computed tomography; FESS, functional endoscopic sinus surgery.

Patient Criteria

A total of 8 statements reached consensus, while 12 did not achieve consensus in this subcategory (Tables 1 and 4). Consensus was reached that SOD is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease (Statement 2) or for patients who are without both sinonasal symptoms and positive findings on CT (Statement 4). Consensus was also reached that there is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis (RAS) as defined in the AAO-HNSF adult sinusitis guideline based on symptoms and CT evidence of ostial occlusion and mucosal thickening (Statement 6). The panel reached consensus that SOD is not appropriate for the management of headache (Statement 7) or sleep apnea (Statement 18) in patients who do not otherwise meet the criteria for CRS or RAS. The panel agreed that SOD can be appropriate as an adjunct procedure to functional endoscopic sinus surgery (FESS) in patients with chronic sinusitis without nasal polyps (Statement 11a) and that there can be a role for SOD in patients with persistent sinus disease who have had previous sinus surgery (Statement 13a). Finally, consensus was reached that CT scanning of the sinuses is a requirement before SOD can be performed (Statement 17).

Perioperative Considerations

A total of 3 statements reached consensus, while 4 did not achieve consensus in this subcategory (Tables 2 and 5). Consensus was reached that SOD can be performed under local anesthesia with or without sedation (Statement 19). The panel also reached consensus that SOD can be performed...
under any setting as long as proper precautions are taken and appropriate monitoring is performed (Statement 21). In addition, consensus was reached that if surgeons were to consider the reuse of balloon dilation devices on multiple patients, they should understand the regulations set forth by the FDA for reprocessing such devices and ensure that they are followed (Statement 25).

Outcomes

In the area of outcomes related to SOD of the sinuses, 2 statements met consensus (Table 3) and 28 did not (Table 6). Consensus was reached that SOD can improve short-term quality-of-life outcomes in patients with limited chronic rhinosinusitis without nasal polyps (CRSsNP) (Statement 32a) and that SOD can be effective in frontal sinusitis (Statement 42a). The panel could not reach consensus on the efficacy of SOD with respect to the maxillary or sphenoid sinuses (Table 6, Statements 43a and 45a). As the published literature suggests the potential for SOD of the peripheral sinuses to address ethmoid disease,10,11 the panel also sought to meet consensus regarding this. The panel did not reach consensus on either of 2 statements regarding whether SOD of the peripheral sinuses was or was not effective in managing ethmoid sinusitis.

Discussion

Patient Criteria

There was consensus that objective evidence of inflammation on CT imaging was necessary in addition to sinonasal symptoms for a patient to be deemed appropriate to undergo a SOD procedure. Also, the panel reached consensus that CT scanning of the sinuses is a requirement before SOD can be performed. This central criterion is also evident in several of the consensus statements in which SOD was considered inappropriate for patients with CT scans showing no evidence of sinus mucosal inflammation and/or ostial occlusion, despite the presence of sinonasal symptoms.

The requirement of objective evidence of inflammation in addition to sinonasal symptoms suggestive of rhinosinusitis is consistent with AAO-HNSF diagnostic criteria for rhinosinusitis.9 However, evidence of inflammation or other findings on a CT scan was not deemed sufficient alone to make a patient a candidate for balloon dilation. The consensus that both symptoms and objective evidence of sinonasal disease are needed to deem a patient appropriate for a SOD procedure is also reflected in many of the randomized clinical trials involving balloon dilation. The inclusion criteria for many of these trials require that the patient be deemed appropriate for conventional sinus surgery, which includes a trial of medical therapy and the presence of sinonasal symptoms in addition to objective evidence of sinus mucosal inflammation.12-14 On the surface, this statement may seem incompatible with the guidelines9 that mandate the presence of objective findings but do not specify which objective findings those are (ie, polyps, purulence, or CT findings) for the diagnosis of CRS. However, the panel felt that the transition from diagnosis to management requires additional information. In that vein, a CT scan is necessary before proceeding with surgical management, and the findings of that CT scan would direct which sinuses were to be addressed. It was also agreed that an improved taxonomy for the

Table 2. Statements That Reach Consensus: Perioperative Consideration.

<table>
<thead>
<tr>
<th>Number</th>
<th>Perioperative Statement</th>
<th>Mean</th>
<th>Outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Surgeons who consider reusing devices intended for dilation of the sinuses should understand the regulations set forth by the FDA for reprocessing such devices and ensure that they are followed.</td>
<td>8.92</td>
<td>0</td>
</tr>
<tr>
<td>21</td>
<td>Balloon dilation can be performed under any setting as long as proper precautions are taken and appropriate monitoring is performed.</td>
<td>7.92</td>
<td>0</td>
</tr>
<tr>
<td>19</td>
<td>Balloon dilation can be performed under local anesthesia with or without sedation.</td>
<td>7.58</td>
<td>1</td>
</tr>
</tbody>
</table>

Abbreviation: FDA, Food and Drug Administration.

*Statements are ordered according to mean value for the 9-point Likert scale of agreement, with the statement obtaining the highest amount of agreement listed first.

Table 3. Statements That Reached Consensus: Outcome.

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>Mean</th>
<th>Outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>32a</td>
<td>Balloon dilation can improve short-term quality-of-life outcomes in patients with limited CRS without polyposis.</td>
<td>7.23</td>
<td>1</td>
</tr>
<tr>
<td>42a</td>
<td>Balloon dilation can be effective in frontal sinusitis.</td>
<td>7.08</td>
<td>1</td>
</tr>
</tbody>
</table>

Abbreviation: CRS, chronic rhinosinusitis.

*Statements are ordered according to mean value for the 9-point Likert scale of agreement, with the statement obtaining the highest amount of agreement listed first.
classification of sinusitis would be helpful to improve the quality of clinical research.

There was strong consensus that SOD is not appropriate for managing sleep apnea or headaches in patients who did not otherwise meet criteria for rhinosinusitis based on symptoms and objective evidence of sinonasal inflammation. No prospective studies have been performed to determine the efficacy of SOD in managing primary headache disorders. Some studies have looked at headaches as an outcome after balloon dilation, but all included patients who had symptoms and objective evidence of rhinosinusitis.15,16 Moreover, there are no studies showing any direct effect of SOD on sleep apnea.

Recurrent acute rhinosinusitis (RARS) is defined by AAO-HNSF guidelines as having 4 or more episodes of acute bacterial rhinosinusitis per year, which are described as symptoms and signs of acute sinusitis that fail to improve after 10 days or initially improve but then worsen.
within 10 days.\textsuperscript{9} Between episodes, there are no signs or symptoms of rhinosinusitis. Several prospectively collected database studies for SOD have included patients diagnosed with RARS.\textsuperscript{17,18} Overall, these longitudinal studies report improved sinonasal symptoms with balloon dilation, but these studies are limited by possible selection bias.

Consensus was reached by the panel that there is a role for SOD for management of RARS. The panel specified that patients with RARS should be defined not only by history of symptoms but also by presence of CT findings suggestive of inflammation or evidence of ostial blockage. While it would not be appropriate to recommend CT scanning during acute episodes of uncomplicated sinusitis, the transition from meeting a formal diagnosis of RARS to surgical intervention oftentimes requires more objective evidence than history alone. It was the consensus of the panel that treatment should be directed at the sinuses involved during these episodes as opposed to those that may be adjacent to the primary focus of the disease, and it was that concept that formed the foundation of this specific statement.

In terms of the role of SOD relative to conventional endoscopic sinus surgery, the panel came to a consensus that SOD can be appropriate as an adjunctive procedure to sinus surgery in patients with chronic sinusitis without nasal polyps. The panel also reached consensus that there can be a role for SOD in patients with persistent sinus disease despite prior sinus surgery. Consensus was met only after the statement was modified to present SOD as only a possible option rather than a requisite step within a surgical algorithm for the treatment of chronic rhinosinusitis. Several studies are supportive of the role of SOD as an adjunctive procedure to conventional sinus surgery, including a recent randomized controlled trial (RCT) in which patients with CRS undergoing a medically indicated FESS were randomized to a hybrid approach to the frontal or conventional

### Table 6. Statements That Did Not Reach Consensus: Outcomes.\textsuperscript{a}

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>Mean</th>
<th>Outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>Balloon dilation is effective for mild to moderate sinusitis based on CT scoring.</td>
<td>6.58</td>
<td>3</td>
</tr>
<tr>
<td>37</td>
<td>Balloon dilation is effective for severe sinusitis based on CT scoring.</td>
<td>3.58</td>
<td>3</td>
</tr>
<tr>
<td>38</td>
<td>Balloon dilation is effective for any severity of sinusitis based on CT scoring.</td>
<td>3.58</td>
<td>3</td>
</tr>
<tr>
<td>29</td>
<td>Balloon dilation can improve symptoms of CRS in patients with CRS with polyposis.</td>
<td>3.92</td>
<td>5</td>
</tr>
<tr>
<td>28</td>
<td>Balloon dilation can improve symptoms of CRS in patients with CRS without polyposis.</td>
<td>6.92</td>
<td>4</td>
</tr>
<tr>
<td>26</td>
<td>Balloon dilation can improve quality-of-life outcomes in patients with chronic sinusitis without polyposis.</td>
<td>6.75</td>
<td>4</td>
</tr>
<tr>
<td>40</td>
<td>Balloon dilation is not effective for severe sinusitis based on CT scoring.</td>
<td>6.08</td>
<td>4</td>
</tr>
<tr>
<td>44</td>
<td>Balloon dilation of the peripheral sinuses can be effective in managing ethmoid sinusitis.</td>
<td>3.83</td>
<td>4</td>
</tr>
<tr>
<td>27</td>
<td>Balloon dilation can improve quality-of-life outcomes in patients with CRS with polyposis.</td>
<td>3.58</td>
<td>4</td>
</tr>
<tr>
<td>45a</td>
<td>Balloon dilation can be effective in sphenoid sinusitis.</td>
<td>3.92</td>
<td>3</td>
</tr>
<tr>
<td>31</td>
<td>Balloon sinuplasty can reduce the use of antibiotics in patients with RABS.</td>
<td>6.33</td>
<td>3</td>
</tr>
<tr>
<td>32</td>
<td>Balloon dilation is effective in improving short-term outcomes for sinus disease.</td>
<td>6.67</td>
<td>2</td>
</tr>
<tr>
<td>33</td>
<td>Balloon dilation is effective for mild to moderate sinusitis based on CT scoring.</td>
<td>3.17</td>
<td>2</td>
</tr>
<tr>
<td>34</td>
<td>Balloon sinuplasty can reduce the frequency of infection in patients with RABS.</td>
<td>6.25</td>
<td>2</td>
</tr>
<tr>
<td>35</td>
<td>Balloon dilation is not effective in improving long-term outcomes for sinus disease.</td>
<td>4.25</td>
<td>2</td>
</tr>
<tr>
<td>49</td>
<td>Balloon dilation is not effective in sphenoid sinusitis.</td>
<td>3.33</td>
<td>2</td>
</tr>
<tr>
<td>46</td>
<td>Balloon dilation is not effective in frontal sinusitis.</td>
<td>3.08</td>
<td>2</td>
</tr>
<tr>
<td>47</td>
<td>Balloon dilation is effective in maxillary sinusitis.</td>
<td>6.83</td>
<td>1</td>
</tr>
<tr>
<td>43a</td>
<td>Balloon dilation can be effective in maxillary sinusitis.</td>
<td>6.69</td>
<td>1</td>
</tr>
<tr>
<td>48</td>
<td>Balloon dilation of the peripheral sinuses is not effective for managing ethmoid sinusitis.</td>
<td>6.50</td>
<td>1</td>
</tr>
<tr>
<td>36a</td>
<td>Balloon dilation can be effective for limited sinusitis based on CT scoring.</td>
<td>6.38</td>
<td>1</td>
</tr>
<tr>
<td>36b</td>
<td>Balloon dilation can be effective for mild to moderate sinusitis based on CT scoring.</td>
<td>6.00</td>
<td>1</td>
</tr>
<tr>
<td>47a</td>
<td>Balloon dilation is not effective in maxillary sinusitis.</td>
<td>3.33</td>
<td>1</td>
</tr>
<tr>
<td>39</td>
<td>Balloon dilation is not effective for mild to moderate sinusitis based on CT scoring.</td>
<td>3.17</td>
<td>0</td>
</tr>
<tr>
<td>33</td>
<td>Balloon dilation is not effective in improving short-term outcomes for sinus disease.</td>
<td>3.00</td>
<td>0</td>
</tr>
</tbody>
</table>

Abbreviations: CRS, chronic rhinosinusitis; CT, computed tomography; RABS, recurrent acute bacterial sinusitis.

*Items in boldface text reached “near consensus”; all other items reached “no consensus.” Statements are ordered according to the number of outliers, with the statement obtaining the highest number of outliers listed first. When more than 1 statement had the same number of outliers, the statements were then ordered according to the mean value for the 9-point Likert scale of agreement, with the statement obtaining the highest amount of agreement listed first.
frontal sinusotomy. Hathorn et al\textsuperscript{12} reported similar patency of the frontal sinus ostium at 1-year follow-up between the hybrid and conventional frontal sinusotomy approach.

Original Statements 11 (Balloon dilation is appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps) and 13 (There is a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery) were near consensus and not consensus because the phrases “is appropriate” and “There is” were felt to be too broad and possibly construed as meaning “always appropriate.” The consensus change to “can be” (Statements 11a and 13a) conveyed that SOD is only appropriate under certain circumstances, to be clarified in other consensus statements.

Statement 12 (For patients with CRS with limited sinus disease who meet criteria for surgery, balloon dilation is an appropriate standalone procedure before considering more extensive sinus) had 2 major points of disagreement preventing consensus. First, agreement could not be reached on the meaning of “limited sinus disease.” The panel made attempts to define the extent of the sinusitis as “mild, moderate, and severe” or to quantify by Lund-Mackay staging, but these discussions did not resolve the issue. While the term limited suggested a milder form of the disease—presumably excluding pan-sinus involvement or significant generalized inflammation—some committee members felt that SOD may have a role even in those cases and should not be expressly discounted. Many SOD studies have restricted patient populations that are stated to have mild or isolated sinus disease, but these terms are not consistently defined.\textsuperscript{19-25} Other panel members felt that SOD was not uniformly appropriate even in mild disease and objected to the use of the word is for the reasons previously mentioned.

The second topic of disagreement with Statement 12 was with regard to the possible perceived role of SOD as a requisite intermediate step before considering traditional sinus surgery. Although there is evidence supporting efficacy of SOD as a standalone procedure, some committee members felt that this statement might be construed as recommending a stepwise approach in which SOD must be attempted before FESS is indicated. There is no direct support for such a role in the literature. Once again, the word is may have been problematic, and perhaps this concern would have been overcome by a change to can be, but in this case, the statement was not amended and reconsidered.

**Perioperative Considerations**

SOD of the paranasal sinus ostia was initially performed exclusively under general anesthesia.\textsuperscript{26} This was necessary not only because of the novelty of the technique but also the need for fluoroscopic guidance of the guidewire in the early devices. Accrued experience and subsequent modifications to the dilation devices eliminated the need for fluoroscopy and facilitated the application of the technique to the office environment. Multiple studies have now evaluated SOD of the sinuses under local anesthetic alone.\textsuperscript{1,12,21,27-33} In these studies, sizable cohorts were reported to have successfully completed SOD in the office setting with local anesthesia. The panel considered the technical aspects of SOD and concluded that there was no intrinsic barrier to performing the procedure in the properly anesthetized awake patient. Moreover, the panel reached consensus that SOD could be performed in either the operating room or the office setting, provided that appropriate precautions are taken. This includes monitoring of the patient’s vital signs by a qualified individual in cases where sedation is used.\textsuperscript{34}

The risks of balloon SOD were also discussed in comparison to the risks of standard FESS. Consideration was given to the reported frequency of major adverse events such as orbital injury and cerebrospinal fluid leak, which are typically reported for standard FESS but less frequently reported with balloon SOD.\textsuperscript{35-37} A total of 114 adverse events, including orbital injuries and cerebrospinal fluid leaks during balloon SOD, were reported to the FDA over a 9-year period.\textsuperscript{35} Minor adverse events were also considered, including pain, postoperative infection, nonsevere bleeding, and congestion.\textsuperscript{38} These events have been reported in studies of SOD, although because of the relatively few head-to-head comparative studies of SOD with standard FESS,\textsuperscript{13,14,21,22} the relatively small sample sizes, and unknown overall incidence of complications from SOD, the panel could not reach consensus that these adverse events are less frequent with SOD. Similarly, consensus could not be reached that the risks of SOD are the same as the risks of standard FESS. The mean survey responses among the panel were in the neutral range for each of the statements about risks of sinus dilation, with multiple outliers occurring for the statements about overall risk and major adverse events.

The special situation of device reuse was considered by the panel. Most of the currently available SOD devices are marketed as single-use products. However, economic considerations may prompt a patient or practitioner to consider processing a device for reuse. Although there has been little study of the specific reuse of balloon devices, the panel noted that this has a precedent with other single-use devices and therefore could be feasible in this scenario as well. Members of the panel stressed that it is incumbent upon the practitioner to abide by regulations set forth by the FDA for reprocessing of such devices.

**Outcomes**

The highest level of evidence for efficacy of SOD is derived from studies where patients with sinusitis are randomized to different procedures (usually 2), one of which is balloon dilation. Outcomes usually include quality of life (mainly measured by the Sinonasal Outcome Test [SNOT])\textsuperscript{39,40} instruments, symptoms, patency, and CT evaluation. Multiple, less rigorous, observational studies usually include prospective or retrospective follow-up of patients undergoing SOD for various periods of time with aforementioned outcome measures.

Three studies compared the efficacy of FESS vs SOD in improving maxillary (± ethmoid) or frontal disease and showed equivalent improvement in the 20-item SNOT
(SNOT-20) scores for both techniques at 1 and 2 years. 30 All other randomized trials showed similar improvements comparing FESS to SOD at the 3- and 6-month marks. 13,21,25,41 All of these studies were conducted in patients without polyposis.

As similarly noted in the section regarding patient criteria, the panel found it difficult to define the exact role of SOD in terms of the duration of outcomes. Multiple prospective, nonrandomized, or retrospective trials have compared symptoms and quality-of-life outcomes before and at various lengths of time after surgery ranging from 1 to 6 years. 10,18,20,42-48 While data for FESS indicate durability of outcomes between the 6- and 20-month time points, 49 and despite the findings by Chandra et al, 20 the panel could not reach consensus that this information could be extrapolated to balloon SOD. Most studies that evaluate SOD in managing CRS out to 6 months and beyond, however, do show favorable improvement and, as such, the panel reached consensus on Statement 32a—namely, that SOD can improve short-term quality-of-life outcomes in patients with limited CRS without polyposis.

The panel also struggled to evaluate the evidence on managing the individual sinuses. Multiple statements were generated regarding the use of SOD to address frontal, maxillary, ethmoid, and sphenoid sinusitis. Most of the published evidence comes from observational studies that do not separate the individual sinuses and often include SOD as an adjunct procedure in addition to ethmoidectomy, septoplasty, or turbinate reduction. Therefore, while the panel members met consensus on the short-term effectiveness of SOD in the management of chronic sinusitis, it became difficult to ascribe this effect to individual sinuses. Randomized trials 12,14 and observational studies 15,31,50,51 and expert opinion 2,53 suggest a benefit in certain circumstances from SOD of the frontal sinus when applied as either a stand-alone or hybrid procedure. The combination of the literature and the experience of some panel members were cited by the group as explanation for reaching consensus on the possible ("can be" vs "is") use of SOD in the management of frontal sinusitis (Statement 42a). In terms of the sphenoid sinus, however, other than large registry data, 54 no other studies have focused solely on the role of SOD in this region. The panel agreed that not enough evidence existed to support a statement regarding the efficacy of SOD with respect to the sphenoid sinus (Table 6, Statement 45 or 49). The panel’s findings with respect to the maxillary sinus were less straightforward. One randomized trial (REMODEL) reported on the use of SOD of the maxillary sinus over various postprocedure time points. 2,12,22,30 This study indicated durable results out to 24 months with comparable improvements in the SNOT-20 between the SOD and maxillary antrostomy groups. In addition to these studies, a randomized controlled study by Bizaki and colleagues 24 and a number of observational studies 18,20,33,55,56 suggest effectiveness of the SOD for the maxillary sinus.

Some evidence indicated that SOD of peripheral sinuses could have a role in the management of limited ethmoid disease, 10 and so statements regarding this were considered. In addition to Kuhn et al, 19 the ORIOS2 investigators also reported on this outcome. 11 In both instances, ethmoid improvement was noted in the absence of it being directly addressed. The panel agreed, though, that larger prospective studies with appropriate controls, specifically powered to look at this effect, would be required before consensus could be reached.

As noted in the section on patient criteria, RARS when diagnosed per AAO-HNS guidelines was considered an appropriate indication for SOD (Statement 6). However, after review of the available literature, no consensus could be reached that SOD is effective in reducing the frequency of episodes or the number of antibiotic courses (Statements 30 and 31). The findings in the literature show a reduction in the number of episodes of acute rhinosinusitis as well as the number of courses of antibiotics in the year following SOD in 2 observational studies without controls, 17,18 but the strength of the evidence was deemed inadequate for a strong supportive statement.

The panel attempted to qualify the effectiveness of SOD with respect to the extent of disease as determined by computed tomography (CT), with severity graded as mild, moderate, or severe based on the CT score (Statements 36-41). Given that most of the published studies use CT scoring as an enrollment criterion to document the presence of CRS, it was thought that some guidance could be provided in this area. The Lund-Mackay scoring system is used to report severity and, in studies that compare 2 techniques, the baseline CT scores are shown to be similar between groups. 12,14,21,23,25,30 However, most studies have not evaluated outcomes in the context of CT-graded severity of disease with the exception of 2 trials. Payne and colleagues 27 evaluated medical therapy vs SOD in patients with CRS and described worse outcomes among patients with worse CT scores, regardless of the treatment modality received. In another study, Friedman and colleagues 19 included patients with mild disease based on a Lund-Mackay CT score less than 12 and retrospectively evaluated the benefit of either routine endoscopic sinus surgery or functional endoscopic dilation of the sinuses. They found that both techniques resulted in equivalent improvement of SNOT-20 scores and patient satisfaction. This finding was not sufficient to reach consensus in relation to the outcomes of SOD in different severity levels as graded by CT. Prospective studies with appropriate controls; comprehensive preoperative assessments, including CT scan severity; and sufficient sample size and outcome events are needed to allow for robust multivariable analyses.

Conclusions

This clinical consensus statement was developed by and for otolaryngologists and is intended to promote appropriate and, when possible, evidence-based care for patients considering SOD of the sinuses. A series of clinical statements were developed by an expert panel using an objective survey method. As defined by the panel, and based on the
consensus reached on several statements, SOD is appropriate for certain indications, and the evidence supports its effectiveness in limited and well-defined circumstances. The consensus panel members anticipate that the application of these statements will result in decreased variations in the care of patients with sinusitis and an increase in the quality of care provided.

**Disclaimers**

Clinical consensus statements are based on the opinions of carefully chosen expert panels and provided for informational and educational purposes only. The purpose of the expert panel is to synthesize information, along with possible conflicting interpretations of the data, into clear and accurate answers to the question of interest. Clinical consensus statements may reflect uncertainties, gaps in knowledge, opinions, or minority view points, but through a consensus development process, many of the uncertainties are overcome, a consensual opinion is reached, and statements are formed. Clinical consensus statements are not clinical practice guidelines and do not follow the same procedures as clinical practice guidelines. Clinical consensus statements do not purport to be a legal standard of care. The responsible physician, in light of all the circumstances presented by the individual patient, must determine the appropriate treatment, diagnosis, and management. Consideration of clinical consensus statements will not ensure successful patient outcomes in every situation. The AAO-HNSF emphasizes that these clinical consensus statements should not be deemed to include all proper diagnosis/management/treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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The following organizations have endorsed this clinical consensus statement: American Academy of Allergy, Asthma & Immunology; American Academy of Otolaryngic Allergy; American Rhinologic Society; and Triological Society.

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