

REMODEL Larger Cohort With Long-term Outcomes and Meta-Analysis of Standalone Balloon Dilation Studies

Rakesh K. Chandra, MD; Robert C. Kern, MD; Jeffrey L. Cutler, MD; Kevin C. Welch, MD;
Paul T. Russell, MD

Objectives/Hypothesis: To provide the final results from the REMODEL (randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up) full-study cohorts and perform meta-analyses of standalone balloon sinus dilation studies to explore long-term outcomes in a large patient sample.

Study Design: Randomized controlled trial and meta-analysis.

Methods: Final outcomes from the REMODEL randomized trial, including a larger cohort of 135 patients treated with functional endoscopic sinus surgery (FESS) or in-office balloon dilation, were evaluated. One hundred thirty patients had 12-month data, 66 had 18-month data, and 25 had 24-month data. In addition, a meta-analysis evaluated outcomes from six studies including 358 standalone balloon dilation patients with up to 24 months follow-up.

Results: Outcomes out to 2 years from the REMODEL full-study cohort are consistent with 6-month and 12-month outcomes. In the meta-analysis of standalone balloon dilation studies, technical success is 97.5%, and mean 20-item Sino-Nasal Outcomes Test scores are significantly and clinically improved at all time points ($P < .0001$). There are significant reductions ($P < .0001$) in work/school days missed, homebound days, physician/nurse visits, acute infections, and antibiotic prescriptions. Mean recovery time is 1.4 days. Comparison of 12-month symptom improvements and revision rates between the REMODEL FESS arm ($n = 59$), REMODEL balloon dilation arm ($n = 71$), and pooled single-arm standalone balloon dilation studies ($n = 243$) demonstrated no statistical difference.

Conclusions: All outcomes are comparable between FESS and balloon dilation at all time points from 6 months to 24 months. Balloon dilation produces faster recovery, less postoperative pain, and fewer debridements than FESS. There is significant, durable benefit in a large series of 358 patients undergoing standalone balloon dilation.

Key Words: Balloon sinus dilation, chronic rhinosinusitis, endoscopic sinus surgery, randomized controlled trial, meta-analysis, long-term outcomes.

Level of Evidence: 1b/2a.

Laryngoscope, 00:000-000, 2015

INTRODUCTION

Balloon dilation of sinus ostia has been studied in randomized controlled trials with comparison to standard functional endoscopic sinus surgery (FESS). Previous reports of the REMODEL (randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up) randomized trial of standalone balloon sinus dilation versus FESS provided results for the

first 92 treated patients, exceeding the 72 patients required to statistically evaluate the primary endpoints.^{1,2} Total enrollment in REMODEL included 135 patients who were treated with one of the two interventions. The first goal of the present report was to provide data on this larger final study cohort and 24-month follow-up data. In addition to REMODEL, Entellus Medical (Plymouth, MN) sponsored five multicenter, prospective, controlled, single-arm, standalone balloon dilation studies that are used in a meta-analysis.³⁻¹⁰ Three of the five studies have been previously published in peer-reviewed journals. The studies include: XprESS[®] Transnasal Maxillary Multi-Sinus (NCT01612780³), XprESS[®] Maxillary Pilot (NCT01525862⁴), RELIEF (healthcare utilization and outcomes of FinESS[®] (functional infundibular endoscopic sinus system) treatment in the office) (NCT00986830⁵), FinESS[®] Registry (NCT00849953 [unpublished data]), and BREATHE (balloon remodeling antrostomy therapy) (NCT00645762/NCT01319305⁶⁻¹⁰). The second goal of the present report was to perform a meta-analysis of these data to explore the long-term impact of this intervention on outcomes in a large patient sample and compare them with the outcomes from the REMODEL FESS cohort.

From the Department of Otolaryngology (R.K., P.R.), Vanderbilt University School of Medicine, Nashville, Tennessee; Department of Otolaryngology (R.K., K.W.), Northwestern University Feinberg School of Medicine, Chicago, Illinois; Associates of Otolaryngology (J.C., K.W.), Denver, Colorado, U.S.A.

Editor's Note: This Manuscript was accepted for publication June 5, 2015.

This work was funded by Entellus Medical. Dr. Cutler is a paid consultant and stockholder of Entellus Medical.

The authors have no other funding, financial relationships, or conflicts of interest to disclose.

Send correspondence to Rakesh Chandra, MD, Vanderbilt University Department of Otolaryngology, 1215 21st Ave. South, 7209 MCE South Tower, Nashville, TN 37232-8605. E-mail: rakesh.chandra@vanderbilt.edu

DOI: 10.1002/lary.25507

TABLE I.
Participant Flow for REMODEL and Five Other Entellus Standalone Balloon Dilation Studies.

| Study | No. of Participants | | | | |
|-----------------------------------------------------------------------|---------------------|----------------|----------------|-------------|--------------|
| | Treated | 6 Months | 12 Months | 18 Months | 24 Months |
| REMODEL FESS | 61 | 60 | 59 | 29 | 10 |
| REMODEL Balloon Dilation*† | 74 | 73 | 71 | 37 | 15 |
| XprESS Multi-Sinus* | 81 | 72 | 76 | | |
| XprESS Maxillary Pilot* | 21 | 21 | | | |
| RELIEF† | 69 | 62 | 65 | | |
| FinESS Registry†‡ | 42 | 32 | 35 | | |
| BREATHE† | 71 | 70 | 67 | | 59 |
| Total balloon dilation, followed/eligible (% follow-up compliance) | 358 | 330/358 (92.2) | 314/337 (93.2) | 37/37 (100) | 74/77 (96.1) |

Empty cells indicate follow-up visits that were not required for the particular study.

*The XprESS Multi-Sinus Dilation System is intended to dilate the maxillary ostia/ethmoid infundibula, frontal, and/or sphenoid sinuses by a transnasal approach.

†The FinESS Sinus Treatment is intended to dilate the maxillary ostia/ethmoid infundibula by a transantral approach.

‡Includes only standalone balloon dilation participants from the FinESS Registry.

FESS = functional endoscopic sinus surgery.

MATERIALS AND METHODS

Final REMODEL Data

The REMODEL trial was a multicenter, randomized controlled trial comparing the outcomes of standalone balloon sinus dilation performed in the office setting versus standard FESS done in an operating room. The trial was statistically powered, with a minimum of 36 patients per arm needed to provide 90% power to detect a change of 0.8 in mean 20-item Sino-Nasal Outcomes Test (SNOT-20) score.^{1,2} In total, 61 patients underwent treatment with FESS and 74 with balloon dilation. All patients met the definition of medically refractory chronic rhinosinusitis (CRS) according to the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) clinical practice guidelines.¹¹ Outcome measures included technical success, change in SNOT-20 score, number of debridements, ostial patency, acute exacerbation of rhinosinusitis episodes, recovery outcomes, rates of surgical revision, and complications through the last follow-up.

The 6-, 12-, 18-, and 24-month data for the outcome measures are summarized using standard statistics (e.g., mean, standard deviations, counts, percentages). Statistical comparisons between the randomized trial arms were made using two-sample *t* tests (two-sided) for continuous measures and Fisher exact tests for categorical measures. The statistical significance of within group changes from baseline were assessed using one-sample paired *t* tests (two-sided). *P* values <.05 are considered statistically significant. All analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC).

Meta-analysis

The meta-analysis includes data from six trials that investigated standalone balloon dilation using Entellus devices, including the balloon dilation arm of REMODEL.^{1–10} Standalone balloon procedures entailed dilation of the maxillary ostia/ethmoid infundibula, frontal, and/or sphenoid sinuses by transnasal or transantral approaches. In total, 358 patients from 38 distinct centers were treated with this modality. The REMODEL FESS arm was used as a comparator cohort in some meta-analyses. The number of patients with data at each milestone time point (6, 12, 18, and 24 months) is given in Table I. Note that follow-up varied by study protocol, as originally designed, from 6 to 24 months. Compliance with the

planned follow-up intervals across all studies was excellent, with 93.2% (314/337) of eligible patients followed to 12 months. All the studies used similar strict inclusion/exclusion criteria that matched the AAO-HNS criteria for medically necessary FESS. The studies also used similar combinations of multiple objective and patient-reported outcomes. Outcomes studied from this pooled dataset included technical success, change in SNOT-20 score at each of the respected time points out to 2 years, debridements, recovery outcomes, Work Limitation Questionnaire (WLQ), pain assessments, revision rates, and healthcare utilization outcomes.

Standard statistics were used to summarize meta-analysis outcome data across all studies. Statistically significant changes from baseline were assessed using one-sample paired *t* tests (two-sided). Statistical comparisons between the REMODEL FESS arm, REMODEL balloon dilation arm, and pooled single-arm standalone balloon dilation studies were made using analysis of variance *F* tests for continuous variables and χ^2 tests for categorical variables. Additional meta-analyses were conducted to estimate the population mean of continuous outcomes and their changes from baseline using random-effects modeling, where linear mixed models were estimated by the restricted maximum likelihood method. The random-effects meta-analysis models used take into account correlation of repeated measurements within-patient and between-study variation (i.e., study heterogeneity). *P* values less than .05 are considered statistically significant. All analyses were performed using SAS version 9.3 (SAS Institute).

RESULTS

Final REMODEL data

Among the 135 patients treated, 74 were randomized to balloon dilation and 61 to FESS. Follow-up data were available for 130/135 (96.3%) treated patients, 66/66 (100%) eligible patients, and 25/25 (100%) eligible patients at 12 months, 18 months, and 24 months, respectively.

Follow-up data at 1 year have been reported on a smaller cohort.² Within this larger cohort, there were no significant differences in baseline characteristics between groups, including baseline mean SNOT-20 and

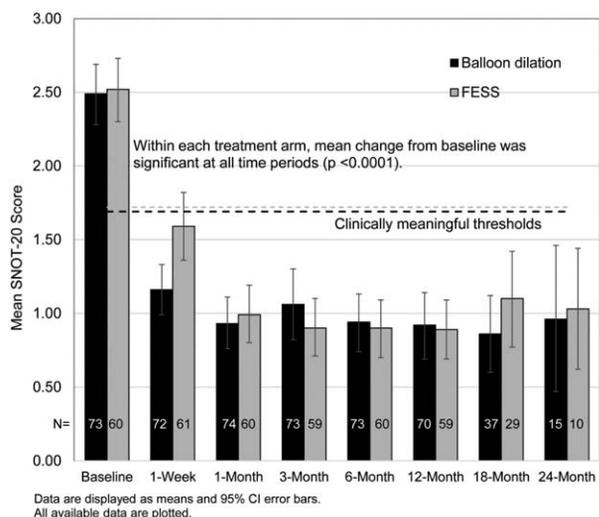


Fig. 1. REMODEL trial: SNOT-20 overall scores by treatment arm for all treated patients by follow-up period. FESS = functional endoscopic sinus surgery; SNOT-20 = 20-item Sino-Nasal Outcomes Test; REMODEL = randomized evaluation of maxillary antrotomy versus ostial dilation efficacy through long-term follow-up.

Lund-Mackay scores. Technical success in the balloon dilation arm was 99.3% (145 successes/146 attempted sinuses). Patients in the balloon dilation arm experienced significantly faster recovery time (1.7 vs. 5.0 days; $P < .0001$), less nasal bleeding after discharge (32% vs. 56%; $P = .009$), and shorter duration of prescription pain medication use (1.0 vs. 2.8 days; $P < .0001$); postoperative

nausea and duration of over-the-counter pain medication use were similar between groups. The primary outcome of number of debridements per patient demonstrated superiority of the balloon arm over FESS (0.2 vs. 1.0, $P < .0001$). Twelve-month ostial patency rate was $>90\%$ in both groups and not significantly different between them. Comparing the year after to the year before treatment, both arms demonstrated a marked reduction ($P < .0001$) in acute exacerbations from an average of 5.1 to 0.9 in the balloon arm and 4.5 to 0.8 in the FESS arm (between arms $P = .258$).

Regarding changes in symptoms over the long term (Fig. 1) as measured by mean SNOT-20 scores, significant ($P < .0001$) improvements from baseline were observed in both treatment groups. Standalone balloon dilation was noninferior to FESS (margin of 0.8; $P < .001$). When examining patients with long-term data, these findings were durably maintained to the 24-month time point. The mean changes from baseline in the balloon arm and FESS arm at 12 months were -1.59 ($P < .0001$) and -1.60 ($P < .0001$), respectively. Symptom reduction in both arms was approximately two times the level needed to demonstrate a clinically meaningful change from baseline (mean reduction of at least 0.8). The mean changes from baseline in the balloon arm and FESS arm at 24 months were -1.65 ($P < .0001$) and -1.45 ($P < .0001$), respectively.

Notably, one revision surgery in each arm had been reported previously during the first year.² Long-term data review revealed one additional revision in the FESS arm (bilateral frontal and left sphenoid sinuses) that occurred 476 days after the initial procedure. This patient likely manifested disease progression, as frontal

TABLE II.
Number of Treated Patients Contributing to Each Meta-analysis Outcome Measure for Each Standalone Balloon Dilation Study and Total.

| Outcome | REMODEL Balloon Dilation | XprESS Multi-Sinus | XprESS Maxillary Pilot | RELIEF | FinESS Registry | BREATHE | Total |
|-------------------------------------------------|--------------------------|--------------------|------------------------|--------|-----------------|---------|---------|
| Technical success (sinuses) | 146 | 313 | 42 | 135 | 79 | 131 | 846 |
| SNOT-20, baseline | 73 | 80 | 21 | 68 | 42 | 71 | 355 |
| SNOT-20, baseline and 6 months | 72 | 71 | 21 | 61 | 32 | 70 | 327 |
| SNOT-20, baseline and 12 months | 69 | 75 | | 64 | 35 | 67 | 310 |
| SNOT-20, baseline and 24 months | 15 | | | | | 59 | 74 |
| Debridements | 74 | | | | | 71 | 145 |
| Revision rate, 12 months | 71 | 76 | | 65 | 42 | 67 | 321 |
| Revision rate, 24 months | 16 | | | | | 59 | 75 |
| Postdischarge nausea | 74 | | 21 | | | 71 | 166 |
| Nasal bleeding at discharge | 74 | | 21 | 66 | | 71 | 232 |
| Recovery time | 73 | | 21 | | | | 94 |
| Duration of Rx pain medications | 73 | | 21 | | | | 94 |
| Duration of OTC pain medications | 73 | | 21 | | | | 94 |
| Procedural pain assessment | | 81 | 21 | 69 | | 70 | 241 |
| Baseline and 12-month RSI domains, range* | | 72–74 | | 59–64 | 30–34 | | 161–172 |
| 12-month Work Limitation Questionnaire, range*† | 46–50 | | | | | 46–50 | 92–100 |

*The questionnaires include multiple items, and not all patients responded to all items. The ranges reflect the minimum and maximum number of patients responding to the questionnaire items.

†The Work Limitation Questionnaire is intended for employed patients only.

OTC = over the counter; RSI = Rhinosinusitis Symptom Inventory; Rx = prescription; SNOT-20 = 20-item Sino-Nasal Outcomes Test.

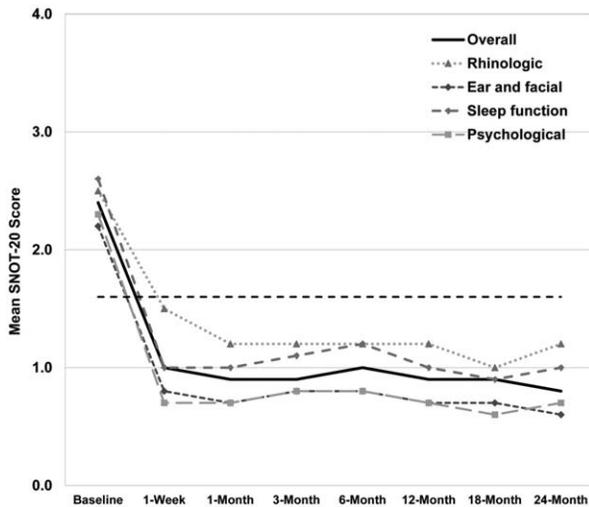


Fig. 2. Meta-analysis of standalone balloon dilation studies: random effects model for mean SNOT-20 overall score and subscale scores over time. SNOT-20 = 20-item Sino-Nasal Outcomes Test.

and sphenoid disease were exclusion criteria in the REMODEL trial. Overall revision rates at 18 months were 2.7% (1/37) and 6.9% (2/29) in the balloon and FESS arms, respectively, and not significantly different. The complication rate remained at 0% for both treatment arms up to 24 months.

Meta-analysis of Standalone Balloon Dilation Studies

The number of treated patients available for the various outcome measures included in the meta-analysis are summarized by study in Table II. Demographic and baseline characteristics were compared across the standalone balloon dilation studies and demonstrated no significant differences between the study populations with respect to age, sex, asthma status, smoking history, or allergies. The pooled technical success rate for the six studies was 97.5% (825/846 sinuses). In the random-effects model, both the overall mean SNOT-20 change and mean subscale changes from baseline were significantly improved and clinically meaningful at all follow-up time points (Fig. 2).

When examining the pooled standalone balloon dilation data with regard to recovery outcomes; 12.7% (21/166) complained of nausea and 13.8% (32/232) reported nasal bleeding. Prescription pain medications were taken for a mean (standard deviation) of 0.8 (1.3) days and over-the-counter pain medication for 1.5 (2.7) days. The mean recovery time was 1.4 (1.3) days, and mean procedural pain score was 2.6 (2.3) on a scale from 0 to 10, where 0 reflected no pain and 10 the worst conceivable pain. The number of postoperative debridements per patient averaged 0.16 (0.55).

Data from the WLQ were collected for employed patients for two of the studies and analyzed using a random-effects model (Fig. 3). Statistically significant improvements from baseline were observed in 4 of the 5

domains (time management, mental/interpersonal, output, and productivity loss) at all time points through 24 months.

The Rhinosinusitis Symptom Inventory was used to determine the impact of standalone balloon dilation on various work and social metrics (work/school days missed, homebound days, physician/nurse visits, acute infections) (Table III). Data included results from over 160 patients. The mean reduction in each of these measures from baseline to 12 months was highly significant ($P < .0001$). This analysis also assessed the mean number of antibiotic courses in the 12 months before intervention compared to the 12 months after, and this difference was also markedly significant (4.5 vs. 1.6, $P < .0001$).

Subgroup meta-analyses were performed to compare balloon dilation patients with CRS versus recurrent acute rhinosinusitis (RARS) and to compare patients with versus without anterior ethmoid disease. All studies with a 12-month follow-up were included in the subgroup analyses, with the exception that the BREATHE study was not included in the CRS/RARS analysis because patients were not differentiated by disease type for that study. At 12 months follow-up, both patients with CRS ($N = 191$) and RARS ($N = 52$) experienced statistically significant ($P < .0001$) and clinically meaningful improvements in mean SNOT-20 scores, with no significant difference between groups. Likewise, at 12 months follow-up, patients with ethmoid disease ($N = 97$) as well as those without ($N = 211$) had statistically significant ($P < .0001$) and clinically meaningful improvements over baseline but no significant difference between groups.

Meta-analysis of Standalone Balloon Dilation Versus FESS

As shown in Figure 4, the mean SNOT-20 scores were highly consistent across the five single-arm standalone balloon dilation studies, the REMODEL balloon arm, and the REMODEL FESS arm. The mean change in SNOT-20 scores from baseline was significantly

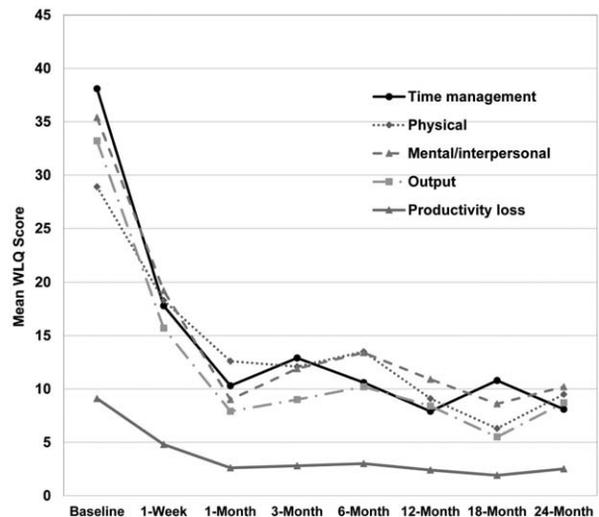


Fig. 3. Meta-analysis of standalone balloon dilation studies: random effects model for Work Limitations Questionnaire (WLQ) over time.

TABLE III.
Meta-analysis of Standalone Balloon Dilatation Studies: Changes in Rhinosinusitis Symptom Inventory Healthcare Use and Work Status From Baseline to 12 Months.

| Rhinosinusitis Symptom Inventory Parameter | No. | Baseline [†] | 12 Months [†] | Change [†] | P Value [†] |
|--------------------------------------------------|-----|-----------------------|------------------------|---------------------|----------------------|
| Work/school missed due to nasal problems, d | 161 | 8.5 ± 11.0 | 3.6 ± 5.9 | -5.0 ± 9.5 | <.0001 |
| Homebound due to nasal problems, d | 167 | 8.3 ± 14.4 | 2.0 ± 6.5 | -6.3 ± 11.3 | <.0001 |
| No. of physician/nurse visits for nasal problems | 172 | 6.8 ± 10.6 | 2.3 ± 7.0 | -4.5 ± 11.5 | <.0001 |
| No. of acute infections of the nose/sinuses | 167 | 5.4 ± 4.8 | 1.5 ± 2.4 | -3.9 ± 4.5 | <.0001 |
| No. of antibiotic courses | 165 | 4.5 ± 2.9 | 1.6 ± 2.1 | -2.9 ± 3.1 | <.0001 |

*Data are displayed as mean ± standard deviation.

[†]Comparison of mean change from baseline to follow-up; P value from paired t test.

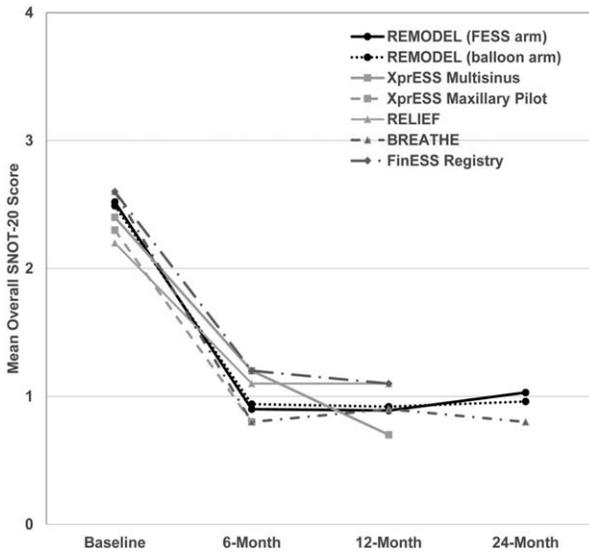


Fig. 4. Mean SNOT-20 overall scores for standalone balloon dilatation studies included in meta-analysis and REMODEL FESS arm. FESS = functional endoscopic sinus surgery; SNOT-20 = 20-item Sino-Nasal Outcomes Test.

improved in every study at all time points. Statistical analysis of the mean changes in SNOT-20 scores from baseline between the REMODEL FESS arm, REMODEL balloon dilatation arm, and the pooled single-arm standalone balloon dilatation studies showed no statistical difference at any time point (Table IV). Likewise, there was

no significant difference in 1-year revision rates between the REMODEL FESS arm (1.7%), REMODEL balloon arm (1.4%), and the pooled single-arm standalone balloon dilatation studies (3.2%; $P = .628$). Furthermore, there was no significant difference in the mean change in SNOT-20 scores ($P = .856$) or revision rates ($P = 1.000$) between the REMODEL FESS arm and the six pooled standalone balloon dilatation studies at 1 year.

DISCUSSION

Significant data of standalone balloon sinus dilatation have been accumulated from multiple case series and from randomized controlled trials with comparisons to standard FESS. In principle, the three cardinal questions are 1) whether balloon dilatation improves patients with respect to baseline status, 2) whether particular subsets of balloon dilatation patients have consistently better or worse outcomes, and 3) whether this intervention is comparable in efficacy to FESS. The mounting evidence examining outcomes with the use of devices from one manufacturer (Entellus Medical in the present article) allows for reliable consolidation of these patient-level data in pursuit of answers to these questions. Furthermore, improvement can be assessed from multiple perspectives, which may be disease specific or general, and also may be either subjective or objective.

Results of the final study cohort of 135 patients in the REMODEL trial, with follow-up from 1 to 2 years postprocedure, are consistent with the earlier reports

TABLE IV.
Meta-analysis: Comparison of Mean SNOT-20 Score Change From Baseline by Follow-up Between REMODEL FESS Arm, REMODEL Balloon Dilatation Arm, and the Pooled Single-Arm Standalone Balloon Dilatation Studies.

| Time Period | REMODEL FESS | | | REMODEL Balloon Dilatation | | | Pooled Single-Arm Balloon Dilatation Studies | | | P Value [†] |
|-------------|--------------|-------------|----------|----------------------------|-------------|----------|----------------------------------------------|-------------|----------|----------------------|
| | No. | Mean Change | P Value* | No. | Mean Change | P Value* | No. | Mean Change | P Value* | |
| 6 months | 59 | -1.60 | <.0001 | 72 | -1.56 | <.0001 | 255 | -1.36 | <.0001 | .199 |
| 12 months | 58 | -1.60 | <.0001 | 69 | -1.59 | <.0001 | 241 | -1.49 | <.0001 | .682 |
| 24 month | 10 | -1.45 | <.0001 | 15 | -1.65 | <.0001 | 59 | -1.86 | <.0001 | .482 |

*Comparison of mean change from baseline to follow-up; P value from paired t test.

[†]Comparison of mean change between studies; P value from analysis of variance F test.

FESS = functional endoscopic sinus surgery; SNOT-20 = 20-item Sino-Nasal Outcomes Test.

from a smaller cohort of patients.^{1,2} Improvements in sinus symptoms after balloon dilation are maintained over a 2-year time period and are similar to the improvements observed with FESS.

The meta-analysis included 846 treated ostia in 358 patients, among whom 314 patients were followed for at least 1 year and 74 patients for 2 years. In this analysis, SNOT-20 was used as the primary outcome measure and exhibited significant improvement from baseline at all time points. Moreover, the mean degree of improvement was greater than the threshold for clinically meaningful change, overall and for each subscale (rhinologic, ear/facial, sleep, psychological). Together, these observations imply impact not only on symptoms of sinonasal disease specifically, but also upon other factors that affect overall quality of life. DeConde et al.¹² recently demonstrated that surgical outcomes can be analyzed by SNOT-22 when the latter is subdivided according to symptom category. Their sample included 339 patients followed to 6 months, and the authors concluded that FESS had a positive impact on rhinologic outcomes, as well as those in the ear/facial, psychological, and sleep subcategories. The present series (n = 358) demonstrates similar findings in those who underwent standalone balloon dilation, and confirms that this effect can be maintained for 2 years postintervention. The impact of improving sleep quality and psychological functioning could potentially enhance productivity in the workplace, which was also durably improved up to the 2 years in the 74 patients followed to this time point. This has obvious health economic implications given the impact of CRS on variables such as absenteeism and presenteeism, and healthcare resource utilization. In fact, one recent report estimated that the productivity cost of refractory CRS was greater than \$10,000 per year per patient affected.¹³ Thus, it is significant that the present meta-analysis also revealed long-term benefits with regard to days missed, homebound days, physician/nurse visits, acute infections, and antibiotic use for acute exacerbations.

Subgroup meta-analysis demonstrated that patients with RARS benefit similarly to patients with persistent CRS after balloon dilation. Also, patients with anterior ethmoid disease demonstrated similar outcomes to patients without ethmoid disease, despite the fact that balloon dilation is not used directly on the ethmoid sinuses. This indicates that standalone balloon dilation is efficacious when used as a first-line therapy even in patients with anterior ethmoid disease.

The benefit of FESS compared to continuing medical therapy alone has been evaluated in prospective controlled trials. In one notable study, the advantage of surgery was established with statistical significance ($P < .05$) for subjects followed for at least 1 year postoperatively using both the Rhinosinusitis Disability Index and Chronic Sinusitis Survey.¹⁴

Standalone balloon sinus dilation has now been compared to standard FESS in the REMODEL trial and two other randomized trials. A series of 24 patients was reported by Achar et al., where patients were randomized to either balloon dilation or FESS.¹⁵ Mean

SNOT-20 scores improved from baseline in both groups, with a greater change observed in the balloon dilation arm. The latter cohort also experienced a faster return to routine activities (2.2 vs. 5 days). This trial differed from the present series in that both arms were treated under general anesthesia. Similar findings were also reported by another group who employed SNOT-22 scoring to examine outcomes at 3 months in 30 patients randomized to either balloon sinus dilation or FESS.¹⁶ Although these smaller randomized trials did not achieve the enrollment necessary to provide statistical power (0.8), it is noteworthy that their observations are indeed consistent with those of the REMODEL trial, which demonstrates persistent benefit up to 2 years after treatment across an array of both rhinologic and nonrhinologic symptoms.

This report also used meta-analyses to statistically evaluate and determine that there were no significant differences in mean SNOT-20 symptom improvements and revision rates between the following three groups with follow-up at 1 year: REMODEL FESS arm (n = 59), REMODEL balloon dilation arm (n = 71), and five single-arm standalone balloon dilation studies (n = 243). This was also true for comparison between the REMODEL FESS arm (n = 59) and the 6 balloon dilation studies (n = 314). The number of studies and number of patients included in each study are significant, and the design and inclusion criteria of each study provide a high level of homogeneity within the meta-analysis. These results are very powerful in that, unlike many meta-analyses that compare summary outcomes between studies, these meta-analyses included assessment of individual patient-level data.

CONCLUSION

Final outcomes from the REMODEL randomized trial, including a larger cohort of 135 patients treated with standalone balloon dilation or FESS, demonstrate the two treatment strategies are comparable at all time points: 6, 12, 18, and 24 months. Meta-analysis of standalone balloon dilation studies demonstrates significant and durable benefit from baseline in a large series of patients (n = 358), among whom 74 were followed to 2 years. Meta-analysis also demonstrates no significant difference in symptom improvement and revision rates between the REMODEL FESS arm (n = 59) and a large standalone balloon dilation patient sample (n = 314). These findings are remarkable in that standalone balloon sinus dilation can be performed as an in-office procedure, with faster recovery, decreased postprocedural pain, and less requirement for debridement. These findings suggest that for patients with uncomplicated sinusitis, standalone balloon sinus dilation is an efficient and effective management option.

Acknowledgments

The authors thank Lisa M. Thackeray and Tyson Rogers of NAMSA for the biostatistical analysis. The authors also thank the participants and investigators of the REMODEL, XprESS[®] Transnasal Maxillary Multi-Sinus, XprESS[®] Maxillary Pilot, RELIEF, FinESS[®] Registry, and BREATHE studies.

BIBLIOGRAPHY

1. Cutler J, Bikhazi N, Light J, Truitt T, Schwartz M; REMODEL Study Investigators. Standalone, balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multi-center, randomized, controlled trial. *Am J Rhinol Allergy* 2013;27:416–422.
2. Bikhazi N, Light J, Schwartz M, Truitt T, Cutler J; REMODEL Study Investigators. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial with 1-year follow-up. *Am J Rhinol Allergy* 2014;28:323–329.
3. Gould J, Alexander I, Tomkin E, Brodner D. In-office, multisinus balloon dilation: 1-year outcomes from a prospective, multicenter, open label trial. *Am J Rhinol Allergy* 2014;28:156–163.
4. Gould JD. In-office balloon dilation: procedure techniques and outcomes using a malleable multi-sinus dilation tool. White paper. *Ear Nose Throat J*. New York, NY: Vendome Healthcare Media; 19 December 2012. Available at: <http://www.entjournal.com/whitepaper/office-balloon-dilation-procedure-techniques-and-outcomes-using-malleable-multi-sinus-dil>. Accessed 9 March 2015.
5. Levine SB, Truitt T, Schwartz M, Atkins J. In-office stand-alone balloon dilation of maxillary sinus ostia and ethmoid infundibula in adults with chronic or recurrent acute rhinosinusitis: a prospective, multi-institutional study with 1-year follow-up. *Ann Otol Rhinol Laryngol* 2013;122:665–671.
6. Stankiewicz J, Truitt T, Atkins J, et al. Two-year results: transantral balloon dilation of the ethmoid infundibulum. *Int Forum Allergy Rhinol* 2012;2:199–206.
7. Stankiewicz J, Tami T, Truitt T, et al. Impact of chronic rhinosinusitis on work productivity through one-year follow-up after balloon dilation of the ethmoid infundibulum. *Int Forum of Allergy Rhinol* 2011;1:38–45.
8. Cutler J, Truitt T, Atkins J, et al. First clinic experience: patient selection and outcomes for ostial dilation for chronic rhinosinusitis. *Int Forum Allergy Rhinol* 2011;1:460–465.
9. Stankiewicz J, Truitt T, Atkins J Jr. One-year results: transantral balloon dilation of the ethmoid infundibulum. *Ear Nose Throat J* 2010; 89:72–77.
10. Stankiewicz J, Tami T, Truitt T, Atkins J, Liepert D, Winegar B. Transantral, endoscopically guided balloon dilation of the ostiomeatal complex for chronic rhinosinusitis under local anesthesia. *Am J Rhinol Allergy* 2009;23:321–327.
11. Rosenfeld RM, Andes D, Bhattacharyya N, et al. Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg* 2007;137:S1–S31.
12. DeConde AS, Bodner TE, Mace JC, Smith TL. Response shift in quality of life after endoscopic sinus surgery for chronic rhinosinusitis. *JAMA Otolaryngol Head Neck Surg* 2014;140:712–719.
13. Rudmik L, Smith TL, Schlosser RJ, Hwang PH, Mace JC, Soler ZM. Productivity costs in patients with refractory chronic rhinosinusitis. *Laryngoscope* 2014;124:2007–2012.
14. Smith TL, Kern R, Palmer JN, et al. Medical therapy vs surgery for chronic rhinosinusitis: a prospective, multi-institutional study with 1-year follow-up. *Int Forum Allergy Rhinol* 2013;3:4–9.
15. Achar P, Duvvi S, Kumar BN. Endoscopic dilatation sinus surgery (FEDS) versus functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis: a pilot study. *Acta Otorhinolaryngol Ital* 2012;32:314–319.
16. Bizaki AJ, Taulu R, Numminen J, Rautiainen M. Quality of life after endoscopic sinus surgery or balloon sinuplasty: a randomized clinical study. *Rhinology* 2014;52:300–305.