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ORIGINAL RESEARCH

Long-term outcome analysis of balloon catheter sinusotomy: Two-year follow-up

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OBJECTIVE: Assess two-year postoperative clinical outcomes for patients receiving balloon catheter sinusotomy.

METHODS: Patients who had sinus ostia dilated with balloon catheters were prospectively evaluated two years after surgery by Sinonasal Outcome Test (SNOT-20) and computed tomographic (CT) scan.

RESULTS: Sixty-five patients (195 ballooned sinuses) were followed for two years after surgery, including 34 "balloon-only" patients and 31 "hybrid" patients. SNOT-20 symptom scores were significantly improved from baseline (0.87 vs 2.17 baseline, $P < 0.001$) and stable compared to six months and one year; this was the case for both balloon-only (1.09 vs 2.09, $P < 0.001$) and hybrid (0.64 vs 2.26, $P < 0.001$) patients. Lund-MacKay CT scores were significantly improved from baseline (2.69 vs 9.66, $P < 0.001$) and stable compared to one year, confirmed for both balloon-only (1.75 vs 5.67, $P < 0.015$) and hybrid (3.25 vs 12.05, $P < 0.001$) subsets of patients. A total of 85% of patients reported improvement of their sinus symptoms, with 15% same and 0% worsened. Revision treatment was required in seven of 195 sinuses (3.6%) in six of 65 patients (9.2%).

CONCLUSION: Patients who receive balloon catheter sinusotomy in endoscopic sinus surgery have significant improvement in symptoms two years after surgery. Radiographic evidence also confirms resolution of disease after two years. This demonstrates durability of clinical results previously reported at 24 weeks and one year after surgery.

Paranasal balloon catheter devices represent a recently developed suite of small, flexible tools that enable surgeons to endoscopically create an opening in a patient's blocked or significantly narrowed sinus ostia and transition spaces while maximizing tissue preservation and minimizing iatrogenic mucosal injury.[1,2]

Initial evidence of the safety and effectiveness of balloon catheter sinusotomy has been encouraging. The 24-week results of the prospective multicenter CLEAR (CLinical Evaluation to confirm sAfety and efficacy of sinuplasty in the paRanasal sinuses) study of 115 patients included a favorable safety profile with zero adverse events, durability of patency in 98% of observed ostia, and significant improvement in patient symptoms.[3] One year after surgery, the impressive ostial patency and symptom improvement results remained durable; in addition, there was significant resolution of disease by CT examination.[4]

In addition, safety and effectiveness have also been assessed in a large-scale, "real-world" registry of 1036 patients, in which there were no serious adverse events and 96% of patients reported symptom improvement with less frequency and severity of infections after an average follow-up of 40 weeks.[5] In a comparative study of endoscopic sinus surgeries with and without balloon catheters, patients receiving balloons experienced significantly greater improvement in sinus symptoms, quality of life, and patient satisfaction at an equivalent (primary cases) or lower cost (revision cases) relative to a comparable group of patients who had not received balloon catheter sinusotomy after a follow-up of 12 weeks.[6]

Longer-term outcome data for balloon catheter sinusotomy will provide meaningful insight into the durability of the clinical results previously reported. The purpose of this study is to evaluate the long-term subjective and objective clinical outcomes for patients receiving balloon catheter sinusotomy by extending the follow-up period of the original CLEAR study to two years postsurgery.

METHODS

This is a prospective multicenter two-year study of balloon catheter dilation devices in patients with chronic sinusitis (CRS) who have failed medical management. It extends analysis of the previously reported 24-week[3] and one-year[4] data collection periods from the CLEAR study.

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Patient selection, study inclusion criteria, description of the balloon catheter sinusotomy, and study designs have been previously described and reported.[3,4] At completion of the one-year study, patient follow-up was extended to two years at the six participating institutions with Institutional Review Board (IRB) approval. Regulations regarding human subject research and safeguarding of confidential patient data were followed. Each successfully contacted patient signed an IRB-approved informed consent for the two-year follow-up study.

The patients had undergone an initial history and physical examination at the time of inclusion in the study. Standard endoscopic sinus surgery postoperative care was provided. Patients were assessed for any adverse event; symptom improvement, demonstrated by the Sinonasal Outcome Test (SNOT-20)[7] and standardized patient questionnaire regarding postoperative changes in symptoms; and radiographic evidence of disease by CT scan. The SNOT-20 rates the severity of 20 symptoms over the preceding two weeks, on a six-point scale (from 0 = "no problem" to 5 = "problem as bad as it can be"). If a patient neglected to rate more than five of the symptoms at a particular visit, that visit's test was not used. The standardized patient questionnaire rates sinusitis symptoms compared with those before treatment on a five-point scale: significantly improved = 2, improved = 1, same = 0, worse = −1, significantly worse = −2. The percentage of patients reporting improvement (scores of 1 or 2) was presented. CT scans were analyzed by the investigators using the Lund-MacKay radiographic staging system.[8]

The intrasubject changes from baseline were calculated based on the matched pairs (ie, patients with prebaseline and postbaseline values). No data were imputed for missing or nonreported data. The differences between patient subsets were analyzed using a one-factor analysis-of-variance test. Intrapatient changes from baseline were analyzed using a paired-difference t test. Probability values < 0.05 were considered significant. A Bonferroni adjustment was made for multiplicity for evaluating the differences in the individual SNOT-20 scores.

RESULTS

At the beginning of the 24-week CLEAR study, there were 109 patients (342 sinuses) who were successfully treated with balloon catheter sinusotomy at nine clinical sites. The study was extended to the one-year period at seven of the nine clinical sites, with two investigators not participating. Of the two sites not participating, one investigator moved and no longer had access to his patients and the other investigator could not reapply to his IRB in time for study inclusion. This left 86 possible candidates (258 sinuses) for inclusion, of which 70 patients (217 sinuses) participated at one year. In this current two-year analysis, 85 patients (256 sinuses) were available for enrollment at six study sites, as one study site with one patient (two sinuses) declined continued involvement in the longer follow-up period. Eighteen patients (58 sinuses) were lost to follow-up and two patients (three sinuses) were exited from the study due to unrelated deaths. This resulted in a cohort of 65 patients (195 sinuses) for which we report two-year longitudinal outcome data, corresponding to a participation rate of 77% (65 participants of 85 eligible). This is similar to the participation rate of 81% (70 of 86) in the preceding one-year study.

From this cohort of 65 patients, 34 were "balloon-only" (endoscopic sinus surgery in which balloon catheters were the only tools used for the sinusotomy portion of the surgery) and 31 were "hybrid" (endoscopic sinus surgery in which both balloon catheters and traditional rigid instruments were concurrently used as tools to treat different targeted sinuses) patients. For the balloon-only subset of patients, septoplasty was also performed in 21% of patients and turbinectomy in 0%. For the hybrid patients, the percentage of cases with adjunctive interventions rose to 41% with septoplasty and 52% with turbinectomy.

All 65 patients completed the SNOT-20 examination at two years postsurgery, but one patient had no preoperative baseline examination and three patients were excluded after revision surgery using non–balloon catheter instruments. As a result, 61 SNOT-20 examinations were available for analysis.

Thirty-five patients had CT scans at their two-year follow-up visit after surgery. Three of these scans were excluded after revision surgery using non–balloon catheter instruments, leaving 32 to evaluate.

Adverse Events

No serious adverse events were reported between one year and two years in the 65 study patients.

Symptom Assessment

Sixty-one patients completed the SNOT-20 preoperatively and two years postoperatively. The overall mean SNOT-20 score at two years postsurgery was 0.87, compared to a preoperative baseline score of 2.17 (Table 1). This symptom score decrease of −1.30 represents a clinically meaningful (>0.8) decrease[7] and a statistically significant change ($P <$ 0.001). The two-year SNOT-20 scores for this cohort of patients are consistent with their six-month (0.99, P = NS) and one-year (0.84, P = NS) scores, showing that the symptom improvement realized within the first six months postsurgery has been durable over time. To address potential follow-up bias, we analyzed the 24-week SNOT-20 results for the 60 patients who came back for two-year follow-up (improvement of −1.18 from baseline) vs the 24 patients who did not (improvement of −1.17 from baseline) and found no statistical difference.

Similar SNOT-20 results were obtained for the "balloon-only" and "hybrid" subsets of patients. For the balloon-only patients, the decrease in SNOT-20 from preoperative to two years postoperative was −1.00 ($P < 0.001$) and stable from

Table 1
SNOT-20 symptom scores

Time	N	Pre-op mean	95% CI	Post-op mean	95% CI	Δ from baseline	95% CI	*P* value
All patients								
Postoperative 24 weeks*	60	2.17	(1.86, 2.48)	0.99	(0.73, 1.26)	−1.18	(−1.54, −0.82)	<0.001
Postoperative 1 year†	55	2.13	(1.80, 2.48)	0.84	(0.61, 1.07)	−1.29	(−1.63, −0.96)	<0.001
Postoperative 2 years*†	61	2.17	(1.86, 2.48)	0.87	(0.64, 1.11)	−1.30	(−1.64, −0.95)	<0.001
Balloon-only patients								
Postoperative 24 weeks‡	31	2.09	(1.72, 2.46)	1.07	(0.71, 1.42)	−1.02	(−1.41, −0.65)	<0.001
Postoperative 1 year§	28	2.07	(1.66, 2.47)	0.99	(0.62, 1.36)	−1.08	(−1.45, −0.70)	<0.001
Postoperative 2 years‡§	32	2.09	(1.71, 2.46)	1.09	(0.73, 1.44)	−1.00	(−1.37, −0.63)	<0.001
Hybrid patients								
Postoperative 24 weeks‖	29	2.27	(1.73, 2.80)	0.92	(0.51, 1.32)	−1.35	(−1.99, −0.71)	<0.001
Postoperative 1 year**	27	2.26	(1.64, 2.75)	0.68	(0.39, 0.98)	−1.58	(−2.10, −0.93)	<0.001
Postoperative 2 years‖**	29	2.26	(1.73, 2.80)	0.64	(0.33, 0.96)	−1.62	(−2.23, −1.01)	<0.001

*Matched-pairs difference between 24-week and two-year scores not statistically significant ($P = 0.496$).
†Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.841$).
‡Matched-pairs difference between 24-week and two-year scores not statistically significant ($P = 0.942$).
§Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.712$).
‖Matched-pairs difference between 24-week and two-year scores not statistically significant ($P = 0.274$).
**Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.843$).

24 weeks to two years after surgery (Table 1). The hybrid patients had a greater decrease in SNOT-20 from preoperative to two years postoperative (−1.62, $P < 0.001$) and were consistent between 24 weeks and two years postoperative (Table 1).

Of the 61 respondents, there were 52 (85%) primary cases and nine (15%) revision cases (patients who previously had endoscopic sinus surgery with traditional rigid instrumentation). Both primary (2.08 preoperative to 0.83 at two years) and revision (2.67 preoperative to 1.13 at two years) cases showed significant improvement in symptoms, with no statistical difference between the two patient groups (Table 2). The improvement in symptoms is evident for both balloon-only and hybrid subsets of primary patients (Table 2). Even greater improvement by mean scores is observed for revision patients, though statistical significance was not reached with limited sample sizes.

To address the fact that only a subset of patients received a CT scan at two years, there was no statistical difference between SNOT-20 scores for patients who received a CT scan (n = 32, 2.13 preoperative to 0.80 at two years postoperative) and those who did not (n = 29, 2.22 preoperative to 0.96 at two years postoperative) (Table 3). This was confirmed for both balloon-only and hybrid subsets of patients (Table 3).

Examining each of the 20 individual symptoms of the SNOT-20 individually (Table 4), the greatest improvement in symptoms is a reduction in the most common sinus

Table 2
SNOT-20 scores by surgery history

Week	N	Pre-op mean	95% CI	Post-op 2-year mean	95% CI	Δ from baseline	95% CI	*P* value
All patients								
Primary surgery	52	2.08*	(1.76, 2.41)	0.83†	(0.59, 1.07)	−1.26	(−1.62, −0.89)	<0.001
Revision surgery	9	2.67*	(1.54, 3.79)	1.13†	(0.16, 2.11)	−1.54	(−2.83, −0.23)	0.026
Balloon-only patients								
Primary surgery	28	2.03	(1.65, 2.41)	1.05	(0.69, 1.41)	−0.98	(−1.38, −0.58)	<0.001
Revision surgery	4	2.60	(0.34, 4.67)	1.35	(0.94, 3.64)	−1.16	(−3.07, −0.76)	0.150
Hybrid patients								
Primary surgery	24	2.15	(1.58, 2.72)	0.58	(0.27, 0.88)	−1.58	(−2.22, −0.93)	<0.001
Revision surgery	5	2.80	(0.70, 4.90)	0.96	(0.60, 2.51)	−1.84	(−4.43, −0.75)	0.120

*Preoperative SNOT-20: matched-pairs difference between primary and revision surgeries not statistically significant ($P = 0.185$).
†Postoperative two-year SNOT-20: matched-pairs difference between primary and revision surgeries not statistically significant ($P = 0.330$ for mean, $P = 0.572$ for delta).

Table 3
SNOT-20 scores by CT scan

Week	N	Pre-op mean	95% CI	Post-op 2-year mean	95% CI	Δ from baseline	95% CI	*P* value
All patients								
Patients with CT scan	32	2.13*	(1.72, 2.54)	0.80†	(0.46, 1.14)	−1.33	(−1.80, −0.86)	<0.001
Patients without CT scan	29	2.22*	(1.72, 2.71)	0.96†	(0.60, 1.31)	−1.26	(−1.81, −0.72)	<0.001
Balloon-only patients								
Patients with CT scan	11	2.15	(1.50, 2.81)	1.10	(0.38, 1.81)	−1.06	(−1.65, −0.46)	0.003
Patients without CT scan	21	2.05	(1.57, 2.54)	1.08	(0.64, 1.52)	−0.97	(−1.48, −0.46)	<0.001
Hybrid patients								
Patients with CT scan	21	2.11	(1.55, 2.68)	0.64	(0.26, 1.03)	−1.47	(−2.15, −0.80)	<0.001
Patients without CT scan	8	2.66	(1.15, 4.16)	0.64	(0.06, 1.33)	−2.02	(−3.63, −0.41)	0.021

*Preoperative SNOT-20: matched-pairs difference between those who received and did not receive CT not statistically significant ($P = 0.774$).
†Postoperative SNOT-20: matched-pairs difference between those who received and those who did not receive CT not statistically significant ($P = 0.607$ for mean, $P = 0.844$ for delta).

symptoms (facial pain and pressure), followed by five metrics relating to fatigue and lack of productivity (wake up tired, lack of a good night's sleep, fatigue, frustrated, and reduced productivity).

The standardized patient questionnaire regarding change in sinusitis symptoms compared with those before balloon catheter sinusotomy revealed improvement that was durable across time (Table 5). The percentage of study patients who reported that their symptoms improved (score of 1 or 2) was 85% (51 of 60) at two years, with 15% (nine of 60) the same and 0% (zero of 60) worsened. Among patients treated with balloon catheter devices alone, symptoms were improved in 77% (24 of 31); for hybrid patients, symptoms were improved in 93% (27 of 29).

CT Scan Results

The mean Lund-MacKay CT scores decreased significantly, from 9.66 preoperatively to 2.69 postoperatively at two years ($P < 0.001$) (Table 6). There was no significant difference between CT scores at one year and two years. There was also no significant difference between one-year

Table 4
Individual SNOT-20 scores, ranked by magnitude of change: All patients

Question	Symptom	N	Preoperative mean	Postoperative 2-year mean	Δ from baseline	*P* value
10	Facial pain/pressure	61	3.0	1.0	−2.0	S
14	Wake up tired	61	2.8	1.1	−1.8	S
13	Lack of a good night's sleep	61	2.6	1.0	−1.7	S
15	Fatigue	61	2.7	1.0	−1.6	S
18	Frustrated/restless/irritable	61	2.4	0.8	−1.6	S
16	Reduced productivity	61	2.4	0.8	−1.6	S
12	Wake up at night	61	2.4	0.9	−1.5	S
5	Postnasal discharge	59	3.0	1.5	−1.5	S
17	Reduced concentration	61	2.2	0.8	−1.4	S
11	Difficulty falling asleep	61	2.2	1.0	−1.2	S
6	Thick nasal discharge	61	2.2	1.0	−1.2	S
4	Cough	60	2.0	0.9	−1.2	S
7	Ear fullness	61	2.1	1.0	−1.1	S
8	Dizziness	61	1.5	0.5	−1.0	S
9	Ear pain	61	1.6	0.6	−1.0	S
3	Runny nose	61	1.9	0.9	−1.0	S
1	Need to blow nose	59	2.1	1.1	−1.0	S
20	Embarrassed	61	1.3	0.4	−1.0	S
2	Sneezing	60	1.9	0.9	−0.9	S
19	Sad	61	1.2	0.5	−0.7	S

S, significant change from baseline (alpha = 0.05/20).

Table 5
Patients reporting improved sinusitis symptoms after sinusotomy using balloon catheter devices

	All patients		Balloon-only patients		Hybrid patients	
Post-op time	N*	% improved	N*	% improved	N*	% improved
1 week	48/60	80%	24/31	77%	24/29	83%
24 weeks	51/58	88%	26/30	87%	25/28	89%
1 year	52/55	95%	27/28	96%	25/27	93%
2 years	51/60	85%	24/31	77%	27/29	93%

*N = number of patients reporting improvement over the number of patients responding to the structured questionnaire.

CT scores for those who were subsequently followed at two years vs those lost to follow-up.

Lund-MacKay CT scores are also presented for balloon-only and hybrid patient subsets. The preoperative CT patient scores in the balloon-only patients reflect fewer sinuses involved than in the hybrid patients, due to the ethmoid sinuses not being involved in the balloon-only patients. CT scores decreased in the balloon-only group from 5.67 preoperative to 1.75 at two years postoperative ($P = 0.015$) (Table 6). The corresponding decline in the hybrid group was from 12.05 preoperative to 3.25 at two years postoperative ($P < 0.001$) (Table 6).

Revision Results

For this cohort of 65 patients followed longitudinally across two years, revision treatment was required in seven sinuses (seven of 195 sinuses, 3.6%) in six patients (six of 65 patients, 9.2%): two sinuses in two patients in the first 24 weeks, 0 sinuses in 0 patients between 24 weeks and one year, and five sinuses in four patients between one year and two years. Of the seven sinuses revised, two were frontal and five were maxillary sinuses; three of the revisions were performed using balloon catheters compared to four using traditional rigid instruments. An additional two sinuses in two patients (one reported in the 24-week study and one reported in the one-year study) had previously required revision but were lost to follow-up in this study; both of these were frontal sinuses that were revised with balloon catheters.

DISCUSSION

"Failure" rates for endoscopic sinus surgery have been reported to be up to 25% for primary cases and as high as 37% for revision cases.[9] While there is variability in how different studies have defined success and failure rates, most have appropriately defined "success" as the resolution or improvement of symptoms, as chronic sinusitis is primarily a symptom-based disease.[9] However, symptoms often do not correlate well with radiographic resolution of disease,[10,11] emphasizing the importance of evaluating patient clinical outcomes as a combination of objective and subjective results. As a result, the authors of the initial CLEAR study chose to measure clinical effectiveness of balloon catheter sinustomy as a clinical triad of 1) improvement of patient symptoms by SNOT-20 symptom scores and structured patient questionnaires, 2) resolution of radiographic evidence of disease by Lund-MacKay CT scores, and 3) pa-

Table 6
Lund-MacKay CT scores

Week	N	Pre-op mean	95% CI	Post-op mean	95% CI	Δ from baseline	95% CI	*P* value
All patients								
Postoperative 1 year*	26	10.15	(7.90, 12.40)	2.19	(0.83, 3.55)	−7.96	(−10.62, −5.30)	<0.001
Postoperative 2 years*	32	9.66	(7.70, 11.61)	2.69	(1.45, 3.92)	−6.97	(−9.27, −4.67)	<0.001
Balloon-only patients								
Postoperative 1 year†	8	5.63	(1.18, 10.07)	1.13	(0.83, 3.55)	−4.50	(−10.62, −5.30)	0.071
Postoperative 2 years†	12	5.67	(2.76, 8.58)	1.75	(0.60, 2.90)	−3.92	(−6.89, −0.94)	0.015
Hybrid patients								
Postoperative 1 year‡	18	10.63	(9.94, 14.39)	1.13	(0.83, 3.55)	−9.50	(−10.62, −5.30)	<0.001
Postoperative 2 years‡	20	12.05	(9.97, 14.13)	3.25	(1.36, 5.14)	−8.80	(−11.91, −5.69)	<0.001

*Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.583$).
†Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.481$).
‡Matched-pairs difference between one-year and two-year scores not statistically significant ($P = 0.649$).

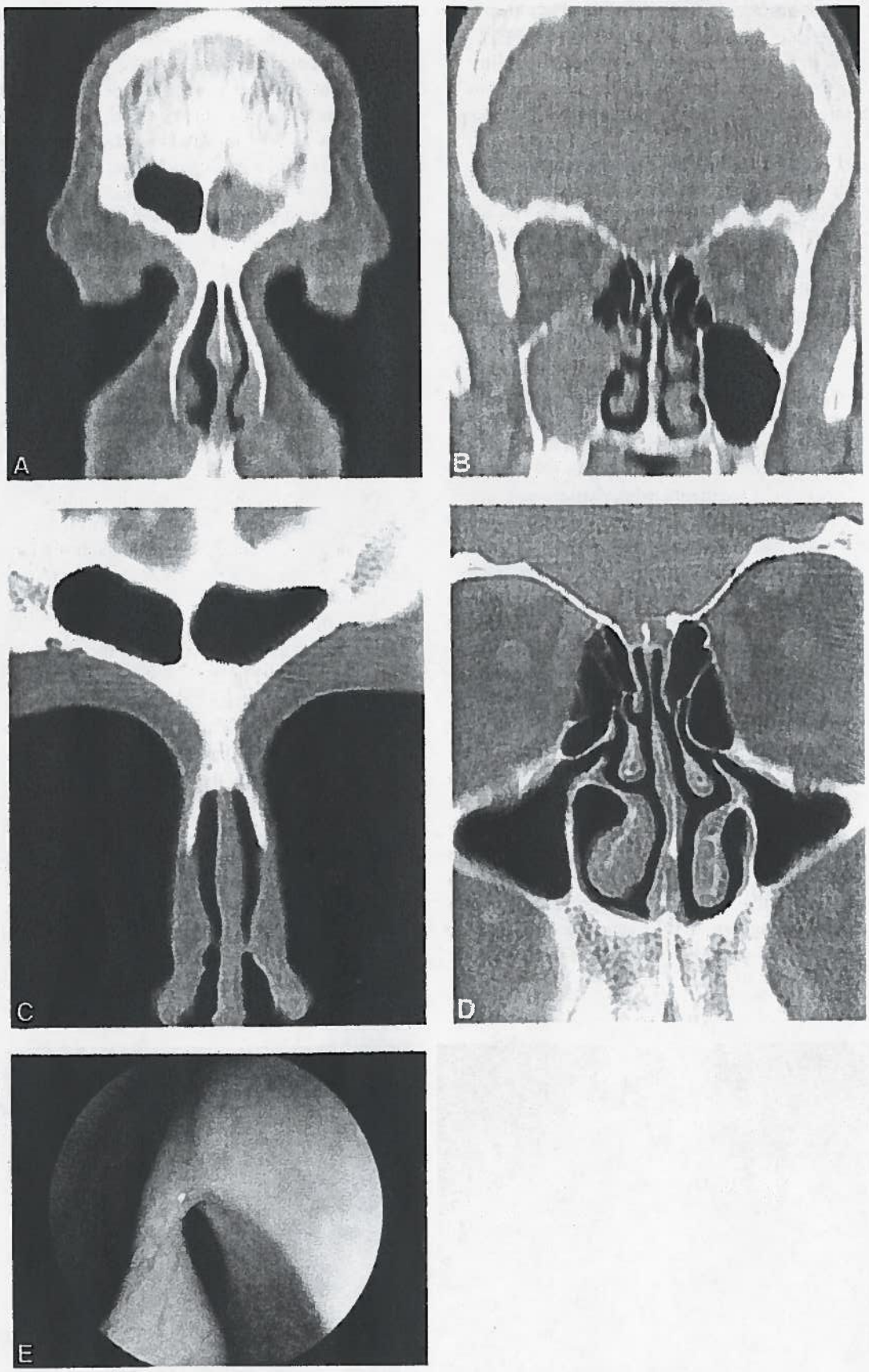

Figure 1 Case example of 38 year old female with chronically opacified frontal and maxillary sinuses, which have remained ventilated two years after balloon dilation. **(A)** Preoperative CT of opacified left frontal sinus. **(B)** Preoperative CT of opacified right maxillary sinus. **(C)** Two-year-postoperative CT of left frontal sinus after balloon dilation, comparable to (A). **(D)** Two-year-postoperative CT of right maxillary sinus after balloon dilation, comparable to (B). **(E)** Left frontal drainage pathway, two years after balloon dilation.

tency rates by endoscopic examination. This two-year study, as an extension of the 24-week and one-year CLEAR studies, offers the opportunity to assess the durability of clinical effectiveness results longitudinally across multiple time points using CT scan scoring and patient assessment.

The three CLEAR studies have systematically demonstrated a statistically significant ($P < 0.001$) and clinically significant (>0.8) improvement in SNOT-20 symptom scores at every time point (postoperative one week, 12 weeks, 24 weeks, one year, and now two years). This long-term durability of symptom improvement indicates that initial symptom improvement can be maintained long term. It is also encouraging that previously reported functional endoscopic sinus surgery (FESS) symptom improvement results at 1.5 years were subsequently stable from 1.5 years to 7.8 years after surgery.[12] One concern is not knowing the corresponding results for patients lost to follow-up. However, we re-examined the 24-weeks-postoperative SNOT-20 scores for all patients who participated in the initial CLEAR 24-week study, and there was no statistical difference between patients who ended up dropping out of the study and those who ended up participating through two years. In complement to the significant improvement in SNOT-20 symptom scores, 85% of patients also reported sinus symptom improvement across the two-years-postsurgery period, suggesting a high "success" rate for balloon sinusotomy patients.

While longitudinal postoperative CT scans are not typically obtained for patients doing well symptomatically, we felt it was important to complement the subjective symptom improvement results with objective CT staging data to more comprehensively assess effectiveness of balloon catheter sinusotomy. As a result, IRB approval was granted in the two-year CLEAR study to obtain CT scans for patients who voluntarily agreed to the additional radiographic examinations. The resulting longitudinal CT analysis is informative, with evidence of disease resolution that is consistent at one-year and two-year time points (Fig 1). As not all patients who completed the SNOT-20 examination had a CT scan, given the voluntary nature of the CT exam at two years, we also compared the SNOT-20 scores between those who had and those who had not received CT scans and found no statistical difference between the patient groups. There was also no statistical difference between baseline Lund-MacKay CT scores for the original CLEAR cohort (n = 115, mean 8.33) and those who received scans at two years postsurgery in this study (n = 32, mean 9.66).

Patency rates for balloon catheter sinusotomy have been already studied extensively in the 24-week and one-year CLEAR studies and are not recapitulated in this study. As the typical wound-healing process occurs over the initial three to four months after tissue injury, by which time collagen remodeling has leveled off, we believe evidence of ostial restenosis would be definitive at the 24-week, and certainly one-year, time point.[13,14] Furthermore, in a recent study of frontal ostial restenosis using traditional endoscopic sinus surgical tools, in which 29% of patients (22 of 77) had significant restenosis by endoscopic examination, all cases of restenosis occurred within the first 12 months postsurgery.[15] While these patients may have had a different extent of disease, this study still speaks to the time period of 12 months as to when much of frontal sinus stenosis will occur. In view of this, it is reasonable to assume that the sinus has healed and the scar is mostly stable and matured after one year (Fig 2).

While not all cases of restenosis result in revision surgery, typically 10% to 15%[15-20] and as many as 18% to 25%[12,21] of FESS patients do receive revisions after their initial surgery. It is therefore reassuring that the incorporation of minimally invasive balloon catheter instruments does not increase, and may decrease, the revision rates for endoscopic sinus surgery after two years of follow-up.

While the number of patients and sinuses is small, this paper still represents a longitudinal follow-up for the majority of patients who were entered in CLEAR. It provides insight into their symptoms and CT scans from their surgery using balloon catheter technology. While these numbers are

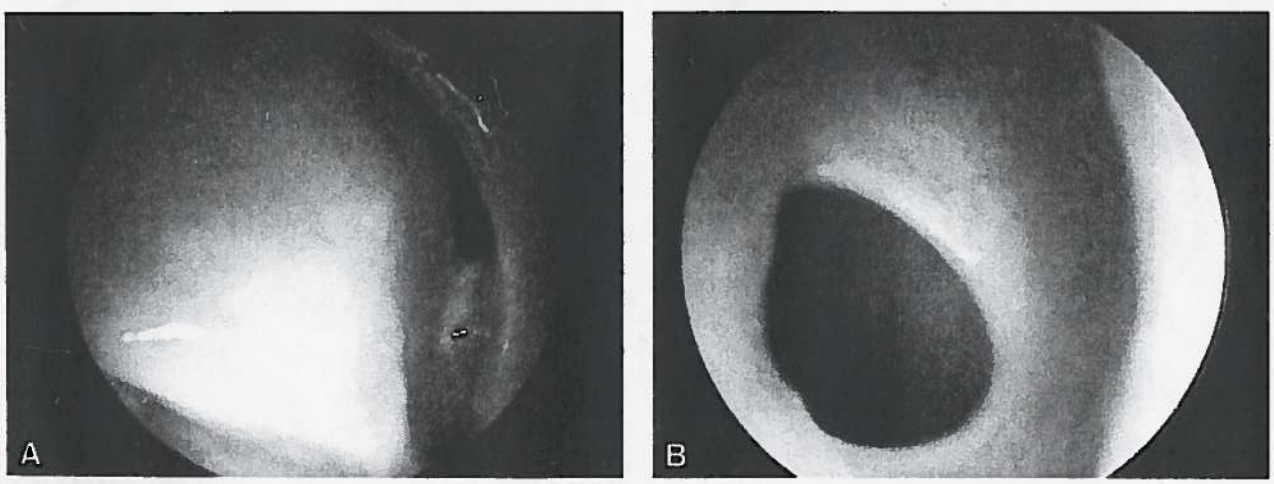

Figure 2 Endoscopic evidence of maxillary and sphenoid ostia patency two years after balloon dilation. **(A)** Left maxillary ostium; **(B)** Left sphenoid ostium.

modest, these complement the PatiENT Registry study[5] in which there were larger numbers of patients and balloon catheter dilation used by a broader group of otolaryngologists. Clinical investigations for medical devices, like our CLEAR studies, most commonly are case series (single arm/no control group) that evaluate safety, device performance, and effectiveness at performing the intended task. As with any study there are compromises and limitations, which are extensively discussed in the initial CLEAR 24-week study.[3] Where there is no randomized control group, there are possible other contributors to outcomes, including the "halo" effect, placebo effect, natural history, and regression to a mean symptom state on outcomes. It can be assumed that the "halo" and placebo effects are lessened by time and would reflect in the patient symptom questions. The strength and consistency of positive responses indicate that there is little of the "halo" and placebo effects occurring.

CONCLUSION

The results from this two-year study indicate long-term durability of clinical outcomes of balloon catheter sinusotomy used in endoscopic sinus surgery. The impressive improvement in patient symptoms previously reported at 24 weeks and one year is sustained through two years postsurgery. The resolution of disease on CT scan previously observed at one year is also sustained in this two-year analysis.

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Raymond L. Weiss, MD, investigator, author of paper; **Christopher A. Church, MD**, investigator; **Frederick A. Kuhn, MD**, investigator; **Howard L. Levine, MD**, investigator; **Michael J. Sillers, MD**, investigator; **Winston C. Vaughan, MD**, investigator.

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