

Patient Quality of Life Improvements with and without Computer Assistance in Sinus Surgery: Outcomes Study

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ABSTRACT

Background: Chronic rhinosinusitis affects millions of North Americans and has been increasing annually since 1991. This study aimed to evaluate the effectiveness of functional endoscopic sinus surgery (FESS) done with the use of computer assistance (CASS) and without the use of computer assistance on patient quality of life. As of this writing, there is no published study that measures the difference in patient quality of life with and without image guidance in endoscopic sinus surgery.

Methods: A nonrandomized prospective study was performed on 95 patients. A 31-item quality of life (Rhinosinusitis Outcome Measures Form [RSOM-31]) questionnaire was administered to patients prior to surgery and 6 months following surgery during a 3-year enrollment period. Patients assessed both rhinologic and nonrhinologic symptoms using a statistically validated scoring system. Statistical analysis was performed using both equal and unequal variance sample *t*-tests when appropriate.

Results: Statistically significant improvement in mean score analysis between preoperative and postoperative results for all symptom subgroups was reported when the entire study population was included. When the improvement in quality of life was compared between the CASS and FESS surgical groups, the CASS group demonstrated an overall greater improvement in quality of life.

Conclusion: Quality of life restrictions in patients with chronic rhinosinusitis were greatest in the areas of nasal symptoms and sleep deprivation, which were significantly improved by endoscopic sinus surgery. Although the long-term effect of CASS as measured by patient quality of life remains relatively unknown, there appears to be a significant trend indicating greater quality of life improvement in the short term over non-computer-assisted FESS techniques.

SOMMAIRE

Introduction: La sinusite chronique affecte des millions de Nord Américains et son incidence augmente annuellement depuis 1991. Cette étude compare l'efficacité de la chirurgie endoscopique fonctionnelle utilisée avec et sans l'assistance par ordinateur (AO) sur la qualité de vie des patients. Au moment d'écrire ce papier, il n'y a aucune publication sur ce sujet.

Méthode: Nous avons évalué prospectivement 95 patients sans cependant les randomiser. Durant leur participation de trois ans à cette étude, nous avons utilisé le questionnaire RSOM-31 (rhinosinusitis outcome measures form) pour évaluer la qualité de vie des patients avant la chirurgie et 6 mois après l'intervention. Les patients ont évalué des symptômes rhinologiques et généraux en utilisant un système validé statistiquement. L'analyse statistique utilise le *t*-test.

Résultats: Nous avons noté une amélioration statistique dans les scores moyens de toutes les catégories quand nous avons analysé la population dans son entier. En comparant les résultats entre le groupe sans et avec AO, ce dernier montre une plus grande amélioration de la qualité de vie.

Conclusion: Les effets de la rhinosinusite chronique sur la qualité de vie des patients étaient plus grands dans les sphères des symptômes nasaux et du manque de sommeil et étaient beaucoup améliorés par la chirurgie endoscopique. Bien que les effets à plus long terme de l'AO sur la qualité de vie des patients demeurent inconnus, on note une tendance significative vers une plus grande amélioration à court terme par rapport à la chirurgie endoscopique simple.

Key words: chronic rhinosinusitis, computer-assisted sinus surgery (CASS), functional endoscopic sinus surgery (FESS), outcomes measure

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With more than 32 million cases of rhinosinusitis reported throughout the United States in 2002 and increasing annually since 1991, chronic rhinosinusitis is among the most common reasons patients seek physician care.^{1,2} Since being introduced in the late 1970s, functional endoscopic sinus surgery (FESS) has become a common otolaryngologic procedure to treat chronic rhinosinusitis.¹ The technique involves the use of a small telescopic endoscope linked to a monitor to aid in nasal visualization.³ Compared with previous techniques, FESS has significantly improved patient acceptance of sinus surgery.³ FESS, however, has its own set of complications, including but not limited to a lack of depth perception and the incapacity to visualize nearby extranasal anatomy.^{2,3} As an attempt to minimize FESS limitations and to improve the accuracy of sinus surgery, computer-assisted endoscopic sinus surgery (CASS) was introduced in the early 1990s.² Originally developed for neurosurgical and spinal procedures, CASS combines the use of computed tomography (CT) and endoscopic views with a three-dimensional navigation system.⁴ This surgical approach enables direct interaction with preoperative CT images, which theoretically decreases the operative risks traditionally associated with FESS while potentially improving the outcome of the procedure.³ It is felt that the use of an image-guided system during FESS allows for a more thorough operative procedure, thereby enhancing surgical success. Although studies are beginning to show that CASS increases surgical success, the effect of such treatment on general health and quality of life remains relatively unknown.

In recent years, the use of patient-specific quality of life measures has been increasingly accepted as the technique of choice in evaluating surgical practices. The technique was first adopted by Lembcke in the early 1950s and has continued to be a vital factor in evaluating surgical success.⁵ In determining a patient's quality of life, an instrument that addresses both global health and disease-specific symptoms is ideal. Usually presented in the form of a self-reported questionnaire, the quality of life evaluation is directly determined by the patient.

The clinically validated 31-item Rhinosinusitis Outcome Measures Form (RSOM-31) has been widely used and tested as a general health assessment tool. The RSOM-31 contains 31 rhinosinusitis-specific questions grouped into seven classes: nasal symptoms, eye symptoms, sleep symptoms, ear symptoms, general symptoms, practical problems, and emotional consequences. Developed in conjunction with rhinosinusitis patients, this tool is reliable, valid, and easily administered.⁶ The data obtained with this tool were appropriate for statistical

evaluation, allowing a preoperative and a postoperative symptom profile. Collectively, the preoperative and postoperative RSOM-31 forms were statistically evaluated to compare quality of life changes in patients following sinus surgery. Directly related to the fact that so much of surgical success is based on improvement in patient symptoms and function, a quality of life determination is vital in evaluating surgical outcome.

The importance of outcome quality of life measurements in conjunction with other surgical evaluations is fundamental for ensuring that surgical procedures meet patient-specific needs.⁵ By using a self-administered format, patients are able to directly contribute to their surgical evaluation, and this can minimize errors associated with third-party interpretation.

The World Health Organization recognizes health as a large, multidimensional concept that includes all physical, mental, and social states of being.⁷ This study presents the unique opportunity to evaluate patient outcomes of endoscopic sinus surgery with and without the use of an image guidance system, as measured by the RSOM-31. Under the guidance of the senior author (A.R.J.), FESS was performed for patients with chronic sinusitis prior to the introduction of an image-guided system (InstaTrak, General Electric, Chicago, IL) to our institution in 2001. Following its introduction, CASS was carried out at two of three institutions, whereas non-computer assisted FESS was performed at the third hospital until this hospital closed in 2003. Using a common test sample, our objective was to determine if (1) FESS provided an improvement in global health and patient quality of life and (2) if the addition of image guidance in FESS provided further improvement and, if so, whether the difference was significant.

Methods

Over a 3-year period, a nonrandomized prospective study was carried out on patients who underwent sinus surgery at one of three health care facilities located in Vancouver, British Columbia (St. Paul's Hospital, St. Mary's Hospital, and False Creek Surgical Centre). A preoperative evaluation was conducted on each patient that involved CT, nasal endoscopy, and a complete head and neck examination prior to surgery. Patients in both study groups had access to similar medical care and received similar preoperative and postoperative surgical consultations. Chronic rhinosinusitis was defined according to the American Association of Otolaryngology's classification and evidence of sinus disease and abnormalities on CT and/or endoscopic examinations.^{5,8} Patients with allergic fungal

sinusitis, inverted papilloma, or nasal/sinus and skull base tumours were excluded from the chronic sinusitis study population.

The CT scans were used to stage sinus disease according to a statistically validated system.^{7,8} Stage 1 corresponded to unilateral disease and/or sinus anatomic abnormality, stage 2 to opacification confined to the ethmoid and/or maxillary sinuses, stage 3 to opacification of the sphenoid and/or frontal sinuses, and stage 4 to pansinus disease.

On completion of the preoperative evaluation and the preoperative RSOM-31 form, patients underwent either FESS or CASS by the same surgeon (A.R.J.) depending on the surgical location and the availability of CASS. All surgical procedures were performed under general anesthesia on an outpatient basis (ie, all patients were discharged home on the same day). Six months following surgery, patients were requested to complete a self-reported postoperative RSOM-31 form. The RSOM-31 form was either mailed to the patient or given to the patient at the clinic during the 6-month follow-up visit. At the time of completing the postoperative RSOM-31 form, patients were not given access to their preoperative test questionnaire or scores.

The postoperative RSOM-31 form was identical to the preoperative RSOM-31 form with the exception of a single postsurgical quality of life question. The additional question asked patients to indicate on a 7-point scale whether their surgery resulted in hardly any or little change, moderate change, or extreme change to their quality of life. The preoperative and postoperative forms were scored according to the sum of patient responses to individual magnitudes and the importance scales for specific questions. The individual questions were further analyzed by grouping them into seven symptom subgroups: nasal symptoms, eye symptoms, sleep, ear symptoms, general symptoms, practical problems, and emotional consequences. Using patient responses to both magnitude and importance scales, a symptom-impact score was created that was unique and patient specific.⁶

The postoperative RSOM-31 forms were mailed to 130 patients (45% from St. Paul's Hospital, 10% from St. Mary's Hospital, and 45% from the False Creek Surgical Centre). Of the 130 post-RSOM-31 forms administered, 95 were returned completed and accounted for the test population. A demographically similar control population consisting of 16 subjects with no history of sinusitis was obtained by having them complete a self-administered RSOM-31 form.

Statistical analysis was performed using a statistical package provided by the University of British Columbia's

Department of Statistics (SPSS, version 11.5, SPSS Inc, Chicago, IL). Mean scores were calculated for individual questions and subgroups for CASS, FESS, and both groups combined. Change in patient quality of life (patient quality of life pretreatment versus patient quality of life post treatment) was compared between the CASS and FESS groups in an effort to control for differences in patient pretreatment quality of life. To account for the unequal sample size distribution, an equal variance or an unequal variance two-sample *t*-test was performed for each symptom subgroup based on the results of an *F*-test. A power test analysis was also performed to address the validity of the unequal sample size.

Results

Ninety-five patients were enrolled in the study and administered the RSOM-31 form prior to surgery and 6 months following surgery. Among the population ($n = 95$), 45% were male and 55% were female, with a mean age of 52.9 ± 12.9 years, ranging in age from 22 to 82 years. CT scans as reported by the four-level staging system were distributed as follows: stage 1, 0%; stage 2, 20%; stage 3, 12%; and stage 4, 68%. Nasal septal deviation was reported in 20% of patients. The CASS study group ($n = 80$) was composed of 40% males and 60% females, with a mean age of 48 years. Fifteen percent of CASS patients had CT scans of stage 2, 9% of stage 3, and 76% of stage 4. The FESS study group ($n = 15$) was composed of 67% male and 33% female participants, with a mean age of 52 years. Forty-one percent of patients had CT scans of stage 2, 29% of stage 3, and 30% of stage 4. Forty-six percent of FESS surgeries were performed the year prior to the introduction of CASS surgery. All other surgeries were performed over the subsequent 2 years.

Statistically significant ($p < .001$) improvement in mean score analysis of preoperative and postoperative results for all seven symptom subgroups was reported when the entire study population was included in the paired *t*-test analysis (Table 1). When surgical techniques were analyzed independently, CASS demonstrated a statistically significant improvement in all 31 questions and seven subgroups, whereas FESS demonstrated statistically significant improvement in 13 of the 31 questions and in all subgroups except sleep and eye symptoms (see Table 1).

The change in quality of life was compared between the CASS and FESS patient groups (Table 2). A significant improvement in quality of life was observed, following CASS compared with FESS, in the subgroups nasal

Table 1. Comparison of Mean RSOM-31 Scores with Standard Deviation prior to Surgery and 6 Months Following Surgery for the CASS and FESS Groups

Subgroup	CASS Surgery (n = 80)			FESS Surgery (n = 15)		
	Preoperative	6 mo	p Value	Preoperative	6 mo	p Value
Nasal symptoms	2.90 ± 1.12	1.41 ± 1.02	< .001	1.96 ± 1.12	1.04 ± 0.66	.006
Eye symptoms	1.88 ± 1.54	0.91 ± 1.27	< .001	1.13 ± 1.45	0.77 ± 0.92	NS
Sleep	2.62 ± 1.50	1.35 ± 1.36	< .001	2.30 ± 1.43	1.60 ± 1.36	NS
Ear symptoms	1.48 ± 1.16	0.73 ± 0.94	< .001	0.91 ± 0.97	0.33 ± 0.50	.014
General symptoms	2.56 ± 1.22	1.18 ± 1.08	< .001	1.84 ± 1.64	1.04 ± 1.00	.015
Practical problems	2.57 ± 1.23	1.00 ± 1.00	< .001	1.50 ± 1.46	0.75 ± 0.57	.028
Emotional consequences	2.54 ± 1.47	0.98 ± 1.27	< .001	2.02 ± 1.57	1.00 ± 1.17	.024

CASS = computer-assisted sinus surgery; FESS = functional endoscopic sinus surgery; NS = not significant at .05 level.

symptoms, sleep, general symptoms, and practical problems. No significant difference was observed in the subgroups eye symptoms, ear symptoms, and emotional consequences. When all subgroups were analyzed together, it was observed that there was a significantly greater overall improvement in patient quality of life following CASS compared with improvement of patient quality of life following FESS.

A power test comparing the power of the unequal sample size with that of a balanced sample size was also carried out (Table 3). Among the three subgroups that showed no significant difference in quality of life improvements between CASS and FESS (eye symptoms, ear symptoms, and emotional consequences), eye symptoms and emotional consequences had relatively small powers. These small powers suggest that the conclusion of an insignificant difference between CASS and FESS improvements in quality of life obtained from paired *t*-test analysis in the subgroups eye symptoms and emotional consequences is not reliable. As a result of its relatively

large power, the conclusion that there is no significant difference in ear symptoms between the CASS and FESS improvements in quality of life is reliable. All other subgroups showed a significant increase in quality of life improvement following CASS compared with FESS, thereby not being subject to Type II statistical error.

Preoperative scores showed a statistically significant difference between the test and control population in all subgroups. When FESS and CASS patients were compared preoperatively, the RSOM-31 scores showed that the CASS patients demonstrated greater quality of life restrictions in the subgroups nasal symptoms ($p = .03$), practical problems ($p = .03$), and general symptoms ($p = .037$). All other subgroups showed no statistically significant differences between CASS and FESS preoperative scores.

Restriction of quality of life in patients with chronic rhinosinusitis (FESS and CASS patients) was greatest in the subgroups nasal symptoms and sleep symptoms prior to surgery. The greatest health impact of both CASS and FESS surgery as measured by *p* value sensitivity was

Table 2. Comparison of Quality of Life Improvements of CASS and FESS Patients Following Surgery

Subgroup	Mean Improvement in CASS Patients	Mean Improvement in FESS Patients	p Value
Nasal symptoms	1.49	0.91	.003
Eye symptoms	0.97	0.37	NS
Sleep	1.26	0.68	.032
Ear symptoms	0.76	0.57	NS
General symptoms	1.38	0.80	.002
Practical problems	1.57	0.75	< .001
Emotional consequences	1.56	1.02	NS
Overall	1.30	0.75	< .001

CASS = computer-assisted sinus surgery; FESS = functional endoscopic sinus surgery; NS = not significant.

Table 3. Power Analysis between the Unbalanced Sample Design and the Balanced Sample Design

	<i>Nasal Symptoms</i>	<i>Eye Symptoms</i>	<i>Sleep</i>	<i>Ear Symptoms</i>	<i>General Symptoms</i>	<i>Practical Problems</i>	<i>Emotional Consequences</i>	<i>Overall</i>
Power percentage with unbalanced allocation	91	59	70	98	97	86	63	100
Power percentage with balanced allocation	73	40	43	93	84	68	40	99

observed in descending order as follows: nasal symptoms, ear symptoms, general symptoms, emotional consequences, practical problems, sleep symptoms, and eye symptoms.

It is interesting to note that results from patient-determined symptom importance demonstrated a statistically significant difference between the relative symptom importance as measured by the study group and that of the control group in the categories nasal symptoms and general symptoms. The results show that chronic sinus patients rank the importance of the above symptom subgroups significantly higher than the control population. All other subgroups showed no statistically significant difference between relative importance as measured by the study population and relative importance as measured by the control population.

When both surgical techniques were analyzed together, 91% of patients reported "very important to extreme" or "moderate to important" change in their quality of life. Only 9% of the patients reported "little to no change" in quality of life (Figure 1). When analyzed independently, 58% of CASS patients reported "very important to extreme" change in quality of life improvements, whereas 35% experienced "moderate to important" change, for a total of 93%. Seven percent of CASS patients experienced "little to no change" in quality of life 6 months postsurgery. Fifty percent of FESS patients reported "very important to extreme" change, whereas 37% experienced "moderate to important" change, for a total of 87%. Thirteen percent of FESS patients experienced "little to no change" in quality of life 6 months after sinus surgery (see Figure 1).

Discussion

The social costs and patient quality of life burden associated with chronic sinusitis are substantial.⁹ In this prospective study, patient quality of life showed statistically significant improvement in overall quality of life and in all subgroups of the RSOM-31 following sinus surgery.

The quality of life subgroups general symptoms, nasal symptoms, and ear symptoms demonstrated the highest degree of improvement following sinus surgery when both CASS and FESS were analyzed together. Independently, FESS demonstrated an 87% postsurgical improvement rate (see Figure 1), similar to the results of Gliklich and Metson, who demonstrated an 82% improvement in patients following FESS.¹⁰ The patient's quality of life further improved in our study to 93% when computer assistance was used. These results suggest that sinus surgery, particularly with the addition of computer assistance, is an effective treatment of choice for chronic sinusitis as measured by patient quality of life.

In an attempt to compare the additional improvement that CASS provides to patient quality of life, a study design was chosen that compared the improvement in quality of life following CASS directly with the improvement in quality of life following FESS. This design, which holds pretreatment quality of life as an independent predictor, was chosen to eliminate patient variability. In addition, the ability to evaluate CASS versus FESS patients operated on by the same surgeon in a 3-year time window provided this study with the unique opportunity to eliminate the inconsistency of surgeon-specific variables, such as experience and technique. Comparing the quality of life improvements of CASS and FESS resulted in significantly

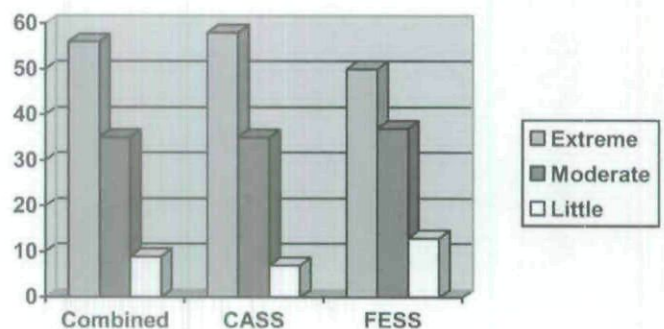


Figure 1. Percentage improvement in overall quality of life following sinus surgery.

greater improvement following CASS in the quality of life subgroups nasal symptoms, sleep, general symptoms, and practical problems. When the subgroups were analyzed together, the overall improvement in quality of life was increased following CASS compared with FESS, indicating that the addition of CASS further enhances quality of life improvements. In earlier studies, Fried and colleagues suggested that CASS permits surgeons increased accuracy and visualization, allowing for a more thorough and precise operation.³ Our study presents an interesting correlation between Fried and colleagues' findings of CASS enhancing surgical detail and CASS enhancing patient quality of life when compared with FESS.

A power analysis was performed to test the probability of making a Type II statistical error in this study's unbalanced design (95 patients: 80 CASS, 15 FESS) (see Table 3). Relatively small powers were observed in the subgroups eye symptoms and emotional consequences compared with the power obtained from a balanced study design. These findings suggest that the conclusion of no significant difference between the improvement in quality of life following CASS compared with FESS in the subgroups eye symptoms and emotional consequences may not be reliable and should not be considered statistically sound. All other conclusions determined from the unbalanced design were shown to be statistically valid as established by power analysis (see Table 3).

Patients were selected for either CASS or FESS depending on the availability of CASS and the time they were enrolled in the study (CASS was not available prior to 2001). As patients were not randomized, it was important to observe the severity of sinus disease between the two groups to ensure that patients in both groups exhibited similar preoperative sinus symptoms, thereby requiring similar sinus procedures. As noted earlier, no individuals

had sinus disease of stage 1, indicating that all patients had either bilateral or pansinus disease, with 85% of the CASS patients and 59% of the FESS patients having sinus disease of stage 3 or 4.

We realize that patients undergoing CASS had an overall greater amount of disease and reported an overall lower preoperative quality of life than FESS patients, which could allow for a greater improvement in quality of life postoperatively. For this reason, this study held pretreatment quality of life as an independent predictor when directly comparing the preoperative and postoperative patient quality of life improvements (Figure 2).

Even though every attempt has been made to statistically validate the findings despite the presence of an unequal sample size between the two groups and recognizing that the CASS group had a greater amount of radiologic disease preoperatively, we realize that the trend showing an overall greater improvement in quality of life post-CASS when compared with post-FESS may be questionable to some readers. The difficulty in designing a study with an identical preoperative level of disease has continued for most institutions because CASS, when available, is being used universally for most of the difficult and revision cases.

According to Winstead and Barnett, chronic sinusitis not only affects sinus-specific symptoms but also impairs social and psychological functioning.⁹ It is therefore crucial to use an assessment tool that measures nonrhinologic symptoms in addition to identifying sinus-specific symptoms. The RSOM-31 quality of life assessment tool proved to be reliable, valid, and easy to complete by the patients. A magnitude and importance score created a unique opportunity to determine not only the severity of symptoms but also the symptoms' relative importance to patients. Comparing the symptom importance of sinus patients with

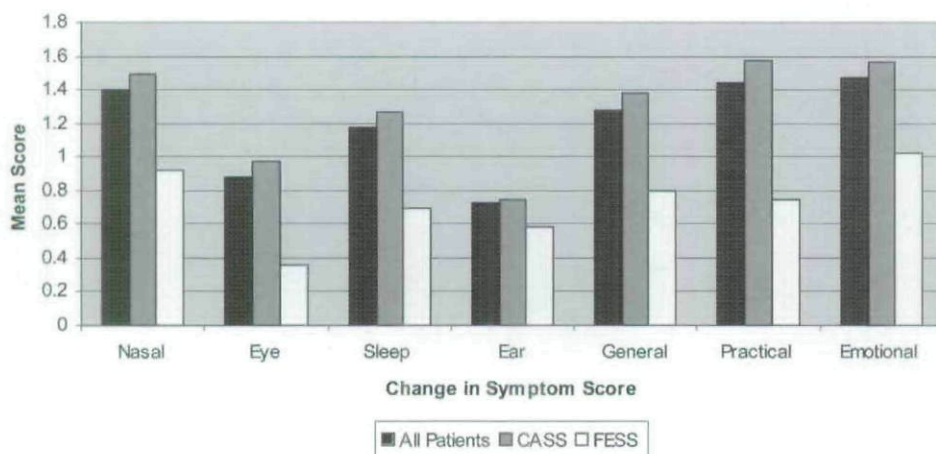


Figure 2. Change in quality of life symptom scores following sinus surgery.

the symptom importance of the control population, we established that patients with chronic rhinosinusitis acknowledge both sinus symptoms and global health symptoms as being greater determinants of overall quality of life. When analyzed in conjunction with the independent magnitude scale, the symptom importance score provided a better quality of life assessment than the magnitude scale alone.⁶ This format enables physicians to recognize symptom impact on patient quality of life. In addition to having sinus-specific questions, the RSOM-31 also addresses areas of patient concern, such as practical problems and emotional consequences. As noted by Piccirillo and colleagues, our study found the combination of rhinologic and nonrhinologic questions to be important in evaluating patient overall quality of life.⁶ In particular, areas of general health related to sleep deprivation and nasal symptoms proved to be affected severely by rhinosinusitis.^{9,11}

Quality of life questionnaires, including the RSOM-31, prove to be reliable tools for patient quality of life determinants; however, a unified assessment tool would enable more accurate cross-study comparisons and enhance overall outcome assessment. In addition, further postoperative follow-up is needed to monitor recurrent symptoms to determine the long-term surgical outcome.

Conclusion

Our study found that endoscopic sinus surgery resulted in significant improvement in patient quality of life as measured by the RSOM-31. Statistically significant improvement in both sinus-specific symptoms and nonrhinologic symptoms was reported 6 months after surgery, demonstrating an overall improvement in patient quality of life. Despite unequal sample sizes and preopera-

tive radiologic stage, which were statistically corrected, the improvement in overall quality of life 6 months post-FESS appeared to be further enhanced when computer assistance was added to endoscopic sinus surgery. To the best of our knowledge, this is the first study to show such a trend.

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