

## Comparing the microdebrider and standard instruments in endoscopic sinus surgery: a double-blind randomised study

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**Key-words.** Endoscopic sinus surgery; instrument; microdebrider; outcome; powered

**Abstract.** *Comparing the microdebrider and standard instruments in endoscopic sinus surgery: a double-blind randomised study.* **Objective:** It is frequently stated that microdebriders provide better mucosal preservation in endoscopic sinus surgery (ESS), and therefore better and faster healing, when compared to the standard Blakesley instruments. However, evidence from comparative prospective studies is lacking. In this study, we compared the results of microdebriders with traditional surgical instruments for ESS.

**Methods:** A prospective, randomised, comparative, double-blind study in 50 patients undergoing bilateral ESS. Each patient was operated on with both instruments: one side of the nose with the microdebrider only, and the other side with standard instruments. The outcome of surgery was measured by using a symptom score and an endoscopic score at five time points during the first six postoperative months.

**Results:** Both instruments resulted in symptom improvement and in endoscopically visible healing over time, but no significant difference was found between the two techniques. In endoscopic evaluation, only the total score at 3 weeks after surgery was significantly better in the microdebrider group. No significant difference was found at any other time point. Synechia formation, patency of middle meatal antrostomy, and open access to the ethmoid were the same in both groups.

**Conclusion:** In this study of endoscopic sinus surgery the use of the microdebrider does not offer major advantages compared to the standard instruments.

### Introduction

Polyposis nasi, recurrent acute sinusitis and chronic hyperplastic rhinosinusitis are common diseases, frequently needing surgery when conservative treatment fails. Endoscopic sinus surgery (ESS) is the technique of choice in the surgical approach to sinus disease. This minimal invasive operation technique under endoscopic guidance aims to restore ventilation and mucociliary drainage while preserving healthy mucosa as much as possible. As with all operative procedures, surgeons continue to adapt and modify their techniques in order to achieve improved outcomes with fewer complications. One modification

in ESS technique is the use of the microdebrider.<sup>1</sup> The microdebrider is an electrically powered instrument with a small, rotating blade for the sharp excision of polyps, mucosa, and bone. An outer sheath protecting the blade is blunt and smooth, further reducing the risk of inadvertent tissue trauma. The instrument was originally designed for small-joint arthroscopic surgery and later used in temporomandibular joint surgery.<sup>2</sup> In 1992 Setliff introduced this alternative instrument for the non-cutting instruments in ESS. The continuous suction feature of this instrument results in less frequent removal and reintroduction, minimising the additional potential for tissue injury.<sup>3</sup>

Numerous advantages of microdebriders over traditional techniques have been cited.

Setliff *et al.*<sup>4</sup> concluded that the precision of this powered instrument coupled with the delivery of real-time suction are the major advantages over other techniques. Gross<sup>5</sup> reported increased safety, improved results, decreased blood loss, and potential cost savings as a result of the use of the microdebrider. In a retrospective study by Krouse and Christmas,<sup>1</sup> the use of the microdebrider as a form of powered instrumentation in a group of 250 patients was compared with a group of 225 patients undergoing traditional procedures. This study indicated that the use of the microdebrider resulted in

faster healing with less crusting than with standard techniques, as well as decreased bleeding, synechia formation, lateralisation of the middle turbinate, and ostial reocclusion. The faster healing in the debrider group was explained by its non-traumatic handling of normal tissue.

Bernstein *et al.*<sup>3</sup> presented 40 cases of endoscopic sinus surgery performed with the microdebrider and reported rapid mucosal healing, minimal crust formation, and a low incidence of synechia formation. The description of a new technique raises the question of whether this technique represents a significant advance in methodology compared with the conventional procedure. The present study was designed to evaluate the use of the microdebrider compared with standard endoscopic techniques for sinus surgery.

## Materials and methods

### Study design

A prospective double-blind study was performed between November 2003 and March 2004. One side was operated on with the microdebrider, the other side using traditional Blakesley instruments. The decision about which instrument to use on the left or right side was subject to randomisation. The same surgeon operated on all patients (MJ). The surgeon always started with the left side. Each patient served as his/her own control. In other words, standard instruments were used on one side and the microdebrider was used on the other side. The local ethics committee approved the study and informed consent was obtained from all patients.

### Patients

Fifty patients (100 sides) were enrolled in this study. All patients underwent maximum medical therapy before surgery. Inclusion and exclusion criteria can be found in Table 1. Patients were male in 54% (n = 27) and female in 46% (n = 23) of cases. The mean age was 44 years (range: 22 to 77 years). Preoperative evaluation included anterior rhinoscopy, nasal endoscopy, CT of the sinuses establishing a CT score,<sup>6</sup> and an evaluation of subjective symptoms. The symptom score included lateralised symptoms (nasal blockage, headache, maxillary pressure, secretions) with a maximum possible score of 12 points and non-lateralised symptoms (postnasal drip, sneezing, coughing, smell and overall condition)<sup>7</sup> (Table 2). The endoscopic score included synechia formation, recurrent polyps, purulent secre-

tions, crust formation, oedema, blood and secretions.<sup>7</sup> The maximum score was 21 (Table 2). Thirty-one (62%) patients had chronic sinusitis, 12 (24%) nasal polyps and 7 (14%) recurrent acute sinusitis. In 30 (60%) patients the surgery was performed under general anaesthesia, 20 (40%) interventions were performed under local anaesthesia. All patients underwent identical postoperative treatment including the use of oral betamethasone (Celestone®). The dosage was five days at 2 mg, five days at 1.5 mg, five days at 1.0 mg, five days at 0.5 mg and daily nasal washings. No other instruments were used during the surgical procedure on the microdebrider side. Straight and/or curved microdebrider serrated blades were used depending on the anatomy, the pathology and the extent of the surgery. The bony partitions between the different ethmoidal cells and sinuses were

Table 1  
Inclusion and exclusion criteria

<b>Inclusion criteria</b>
<i>Males and females, 12 years of age</i>
<i>Chronic sinusitis, recurrent acute sinusitis, polyposis nasi</i>
<i>Equal extent of disease on both sides of the nose. (according to scoring system of LUND and KENNEDY: difference between right and left side &lt;3)</i>
<i>Patients requiring ESS</i>
<i>Failure of medical treatment or contra-indications to medical treatment</i>
<b>Exclusion criteria</b>
<i>Previous history of sinus surgery</i>
<i>Cystic fibrosis and primary ciliary dysfunction</i>
<i>Immune-compromised patients</i>
<i>Paranasal sinus tumours</i>
<i>Females who are pregnant or breast feeding, or are likely to become pregnant during the study</i>
<i>Surgical contra-indications</i>
<i>Mental condition rendering the subject unable to understand the nature, scope, and possible consequences of the study</i>

Table 2  
Subjective symptom score and endoscopic score

Subjective evaluation: patient questionnaire at each visit			
<b>Lateralised symptoms</b>			
	right	left	difference
Headache	0-3	0-3	
Maxillary pressure	0-3	0-3	
Nasal blockage	0-3	0-3	
Secretions	0-3	0-3	
<hr/>			
Total symptom score	0-12	0-12	
<b>Non-lateralised symptoms</b>			
Postnasal drip, smell, coughing, sneezing, global condition,...			
0: no subjective burden		1: little subjective burden	
2: moderate subjective burden		3: severe subjective burden	
Endoscopic evaluation: investigator form at each visit			
	right	left	difference
Secretions	0-3	0-3	
Pus	0-3	0-3	
Blood	0-3	0-3	
Crusts	0-3	0-3	
Oedema	0-3	0-3	
Polyps	0-3	0-3	
Adhesions	-3	0-3	
<hr/>			
Total endoscopic score	0-21	0-21	yes/no
0: no endoscopic presence		1: little endoscopic presence	
2: moderate endoscopic presence		3: severe endoscopic presence	

Table 3  
Subjective findings: percentage of patients with score 1, 2 or 3

<i>Maxillary pressure</i>			
	3 weeks	2 months	6 months
<b>Standard</b>	1010/49 = 20.4%	6/43 = 14%	5/46 = 10.6%
<b>Microdebrider</b>	6/49 = 12.2%	4/43 = 9.3%	4/46 = 8.7%
<i>Nasal blockage</i>			
	3 weeks	2 months	6 months
<b>Standard</b>	1421/49 = 42.8%	12/43 = 27.9%	8/46 = 17.4%
<b>Microdebrider</b>	19/49 = 38.8%	11/43 = 25.6%	9/46 = 18.4%
<i>Headache</i>			
	3 weeks	2 months	6 months
<b>Standard</b>	14 18/49 = 36.7%	5/43 = 11.6%	4/46 = 8.7%
<b>Microdebrider</b>	18/49 = 36.7%	4/43 = 9.3%	6/46 = 13%
<i>Secretions (subjective)</i>			
	3 weeks	2 months	6 months
<b>Standard</b>	14 22/49 = 44.9%	13/43 = 30.2%	18/46 = 39%
<b>Microdebrider</b>	25/49 = 51%	14/43 = 32.6%	14/46 = 30.4%

gently removed, as were the diseased mucosa. A standard surgical procedure was performed on the standard-instruments side. This consisted of sickle knife uncinectomy, anterior to posterior ethmoidectomy using non-cutting Blakesly forceps, middle meatal antrostomy using back biting forceps, conchal scissors and non-cutting Blakesly forceps and, when needed, sphenoid and frontal recess surgery.<sup>7,8</sup>

*Evaluation*

The duration of the operative procedures on the right and left sides was noted.

Follow-up visits were performed at 5 different time points: 1, 2 and 3 weeks, 2 and 6 months postoperatively. During every visit the subjective findings of the patient for the left and right side were noted and suction cleaning was performed.

A symptom score and an endoscopic score was used, as described previously.<sup>7,8</sup> The patients were asked to indicate whether there was a best side or no difference.

Other parameters investigated postoperatively were free access to the ethmoid complex and patency of the middle meatal antrostomy. We defined free access to the ethmoid complex as the possibility of looking directly into the ethmoid, and patency of the middle meatal antrostomy as open access to the maxillary sinus from the nasal cavity.

The adverse events were evaluated.

*Statistics*

The Student's t-test was used to look for statistically significant differences. The mean subjective

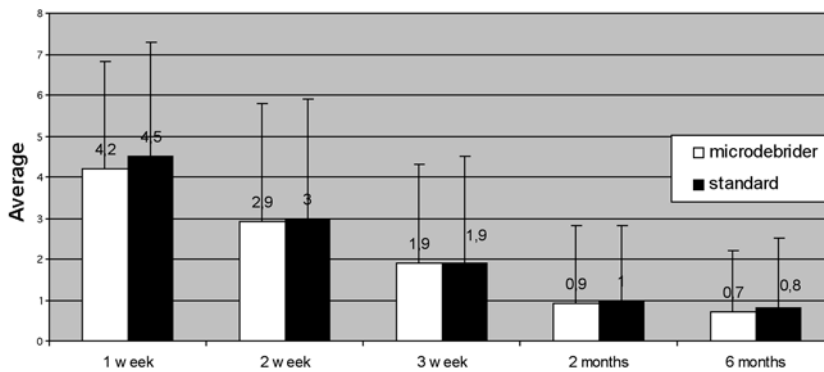


Figure 1  
Total symptom score

There is an improvement in the average total symptom score over time. At 1 week, the average scores are 4.5 and 4.2 respectively for the side of the nose operated on with standard instruments and the side of the nose operated on with the microdebrider at 1 week. The final average scores at 6 months are 0.8 and 0.7.

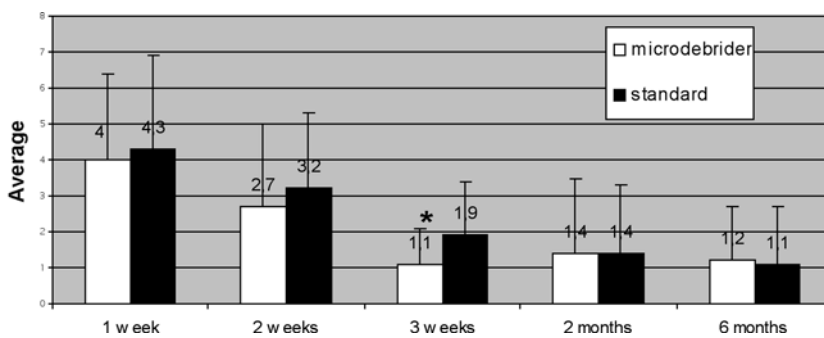


Figure 2  
Total endoscopic score (\* =  $p < 0.05$ )

There is an improvement in the average endoscopic score over time. The average score is 4.3 on the side of the nose operated with standard instruments and 4.0 on the side of the nose operated with the microdebrider at 1 week. These scores improve to a final average endoscopic score at 6 months of 1.1 and 1.2 respectively. At 3 weeks postoperatively there is a statistically significant difference between the total endoscopic scores: 1.9 for the standard instruments as compared with 1.1 for the microdebrider.

and endoscopic patient scores with standard deviations were calculated for each group and compared. We adopted 5% as the critical level of significance in our tests.

## Results

### A. Subjective symptoms

The use of both the standard instruments and the microdebrider resulted in an improvement in the

total symptom score over the 5 postoperative visits, from an average score of 4.5 and 4.2 respectively at 1 week to a final average score at 6 months of 0.8 and 0.7 (Figure 1). No significant difference between the two instruments was found at any of the time points.

The results for the individual, subjective, lateralised symptoms of nasal blockage, secretions, headache and maxillary pressure for the postoperative visits at

3 weeks, 2 and 6 months are shown in Table 3.

A statistical significance was found in favour of the microdebrider 6 months postoperatively (39% compared with 30.4%) ( $p < 0.05$ ) (Table 3).

### B. Endoscopic findings

The total endoscopic score (maximum score = 21), as experienced by the 50 patients, went down over the course of the 5 postoperative visits (Figure 2).

There was a clear improvement in the average endoscopic score over time: an average score of 4.3 on the standard-instrument side and 4.0 on the microdebrider side at week 1 went down to final average endoscopic scores at 6 months of 1.1 and 1.2 respectively. At 3 weeks postoperatively there was a statistically lower total endoscopic score for the side of the nose operated on with the microdebrider ( $p < 0.05$ ).

The endoscopist scored both sides similarly at most of the follow-up visits (Figure 3). At 3 weeks postoperatively, there was a statistically significant difference: the microdebrider was the best side in 56% of the patients ( $p < 0.05$ ). This correlates with the lower total endoscopic score at 3 weeks postoperatively.

The detailed endoscopic findings, such as opening of the middle meatal antrostomy, access to the ethmoid complex, synechia formation and purulent secretions for the follow-up visits at 3 weeks, 2 and 6 months, are shown in Table 4.

There is an insignificant tendency at 6 months towards more purulent secretions with the use of the microdebrider ( $p = 0.11$ ). Secretions found using endoscopy

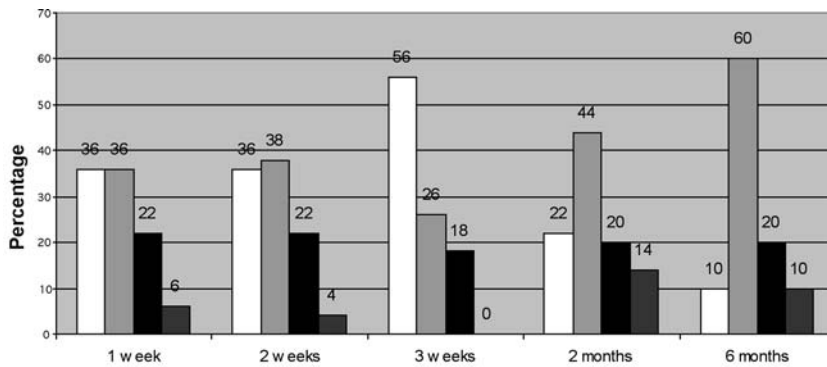


Figure 3 Percentages of endoscopic differences over time

The endoscopist generally scores both sides similarly during the follow-up visits. At 3 weeks postoperatively there is a statistically significant difference: the microdebrider is the best side in 56% of the patients ( $p < 0.05$ ).

Table 4

Endoscopic findings: percentage of patients with score 1,2 or 3 (purulent secretions and synechia formation), percentage of patients with score 0 (middle meatal antrostomy open and access to ethmoid open)

Purulent secretions			
	3 weeks	2 months	6 months
Standard	14 14/49 = 28.6%	5/43 = 11.6%	2/46 = 4.4%
Microdebrider	11/49 = 22.4%	5/43 = 11.6%	5/46 = 10.9%
Access to ethmoid open			
	3 weeks	2 months	6 months
Standard	38 39/49 = 79.6%	32/43 = 74.4%	42/46 = 91%
Microdebrider	39/49 = 79.6%	35/43 = 81.4%	39/46 = 85%
Middle meatal antrostomy open			
	3 weeks	2 months	6 months
Standard	34 34/49 = 69.4%	33/43 = 76.7%	40/46 = 87%
Microdebrider	41/49 = 83.7%	32/43 = 74.4%	38/46 = 82.6%
Synechia formation			
	3 weeks	2 months	6 months
Standard	34 12/49 = 24.5%	8/43 = 18.6%	5/46 = 10.2%
Microdebrider	9/49 = 18.4%	5/43 = 11.6%	4/46 = 8.7%

were statistically fewer with the microdebrider for the postoperative visits at 1, 2 and 3 weeks ( $p < 0.05$ ) (Figure 4).

At 2 months, there was an insignificant tendency towards less synechia formation with the microdebrider (18.6% compared to 11.6%) ( $p = 0.11$ ) (Table 4).

Endoscopic examination indicated a statistically higher recurrence of polyps at 6 months on the microdebrider side ( $p = 0.010$ ) (Figure 5).

The group of patients was subsequently divided into subgroups depending on the indication and anaesthesia in order to exclude a

possible confounding effect of these variables on our findings if randomisation had not created comparable groups. The results of the subgroups were similar to the results of the complete patient group.

There was a significant difference in the average time needed for the microdebrider side (9.13 minutes) compared with the standard instrument side (7.38 minutes) ( $p < 0.05$ ). A learning curve was not seen.

### Discussion

The ESS concept of limited resection, while maximally preserving normal mucosa, to create adequate ventilation combined with optimal mucociliary clearance, remains a major determining factor in the search for improvement of endoscopic techniques. Several authors consider the instruments used to be a crucial element in the implementation of these principles and as a determining factor of better healing and postoperative outcome. It is important to consider the role of the surgeon and the technique used by the surgeon.

During the surgical procedure, it is especially important to reduce mucosal damage. Minimising tissue trauma and preserving normal mucosa are paramount in avoiding excessive scarring, synechia formation, and resultant complications.<sup>3</sup>

Numerous advantages of microdebriders over traditional techniques have been cited, including reduced operative time, decreased intra-operative and postoperative bleeding, improved visualisation and precision for tissue removal, decreased traumatization to tissue with mucosal preservation, decreased crusting

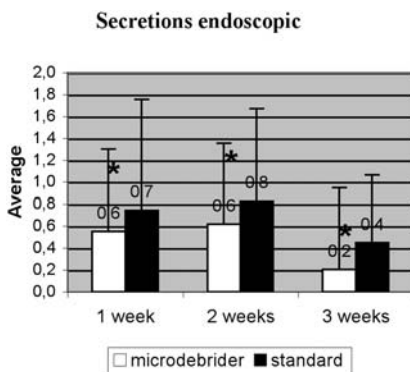


Figure 4  
Endoscopic findings for secretions  
(\* =  $p < 0.05$ )

Endoscopy found statistically fewer secretions after surgery with the microdebrider at the visits 1, 2 and 3 weeks postoperatively ( $p < 0.05$ ).

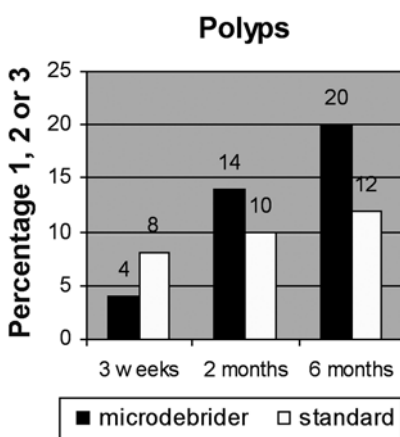


Figure 5  
Endoscopic findings for nasal polyps  
(\* =  $p < 0.05$ )

Endoscopy found statistically more polyps after surgery with the microdebrider at the visit 6 months postoperatively ( $p < 0.05$ ).

and synechia formation, reduced ostial reocclusion, and overall faster wound healing.<sup>1-5,9-11</sup>

As in many other revolutionary innovations in ESS instruments, others have adopted this concept, even though it has never been proven to have a better outcome in a comparison with standard instruments.

In our study, we compared the total symptom score and the endoscopic score in patients operated on using either standard instruments or a microdebrider.

The findings of our study demonstrate that use of the microdebrider is a safe, effective technique in the practice of endoscopic sinus surgery but that operative outcome is similar to that using standard instruments. Our study did not confirm the claimed theoretical advantages of the microdebrider. Analysis of the results of follow-up examinations of all subjective and objective criteria in this study revealed an improvement for all criteria independent of the type of surgical instruments.

When the individual parameters were examined, we found that the use of the microdebrider provides a short-term endoscopic advantage and a long-term subjective advantage. The most important statistically significant short-term results of the microdebrider are: the total endoscopic score at 3 weeks follow-up is statistically lower and there are fewer secretions at 1, 2 and 3 weeks postoperatively.

The most important long-term results are: a statistically significant subjective finding of fewer secretions at the side operated on with the microdebrider at 6 months.

In 2003, Selivanova *et al.*<sup>12</sup> described 24 patients with bilateral chronic rhinosinusitis. Surgery was performed with the shaver or conventional instruments. One side was operated on with conventional instruments and the opposite side was operated on with the microdebrider. In this study, they were unable to find a statistically significant difference in outcome

for patients between surgery using conventional instruments or mechanical debriders. A limitation of that study was the smaller patient group included in the study (24 patients). Another feature was the use of only one instrument per patient.

It is claimed that the microdebrider facilitates accurate removal of polyps with preservation of normal anatomy. In our study there was a statistically higher recurrence of polyps at 6 months.

In the study of Selivanova *et al.*<sup>12</sup> there was an insignificant tendency for the recurrence of polyps 6 months postoperatively in the group of patients operated on with conventional instruments.

Synechia formation is the most frequent complication after ESS. The minimisation of tissue trauma and the preservation of normal mucosa are paramount in avoiding excessive scarring, synechia formation and resultant complications. In 1998 Bernstein *et al.*<sup>3</sup> reported that the microdebrider may be advantageous in surgery for chronic sinusitis.

Our study found an insignificant tendency towards synechia formation at 2 months postoperatively in the group of patients operated on with the microdebrider.

Compared with the microdebrider, standard instruments involve a 30% shorter operating time.

The imitations of the current study include the following. First of all, we looked at the lateralised symptoms only. It is not possible to make conclusions about non-lateralised symptoms such as postnasal drip, smell, coughing, sneezing and general condition. Secondly, the instruments were only investigated for postoperative

outcome. Perioperative parameters such as blood loss were not investigated.

The postoperative use of corticosteroids may explain why no difference was found. Although this systemic medication influences both sides equally, the masking effect could conceal a small potential difference.

In addition, our study did not look at the cost-effectiveness of either approach.

### Conclusion

We can conclude that our study did not confirm the theoretical advantages of the microdebrider. The evaluation of symptom relief and the postoperative endoscopic impression of improvement did not establish a statistically significant difference between the two instruments. The microdebrider and the standard instruments result in identical postoperative outcome at 6 months. At the visit 3 weeks postoperatively, endoscopic outcome was better on the

microdebrider side, but the long-term results are similar.

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