ORIGINAL CONTRIBUTION

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CMC packing in functional endoscopic sinus surgery: does it affect patient comfort?*

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SUMMARY

Background: *Functional endoscopic sinus surgery (FESS) has become the treatment of choice for patients with medically resistant chronic rhinosinusitis (CRS and nasal polyposis). Nasal packing is usually placed after the surgery to minimize mucosal bleeding and support the wound healing process. Both the packing itself and its removal are often associated with pain and discomfort.*

Objective: *To evaluate the effect of carboxymethylcellulose (CMC) nasal packing on patient comfort following FESS.*

Methods: *Forty consecutive patients underwent bilateral FESS. One side of the nasal cavity was packed with CMC (mesh or gel) and the opposite side was not packed, the sides having been randomly selected. Postoperatively, patients were given visual analog scales to rate nasal airway obstruction and headache/pressure separately for the right and left sides. They also rated sleep disturbance and general well-being.*

Results: *No significant differences were found between the CMC-packed side and the unpacked side with regard to patient comfort. No significant differences were found between CMC mesh and CMC gel.*

Conclusion: *Based on the presented data concerning patient comfort, CMC appears to be an ideal packing material following FESS. However, there is no other study revealing an identical study design focusing on other resorbable packing material. As a consequence, other available resorbable packing material should be investigated to find the ideal packing material following FESS, if packing is required.*

Key words: Endoscopic sinus surgery, nasal packing, patient comfort, carboxymethylcellulose

INTRODUCTION

Functional endoscopic sinus surgery (FESS) has become the treatment of choice for nasal polyposis and chronic rhinosinusitis that cannot be adequately managed with medical therapy [(1)]. But while the surgical technique of FESS has become recognized as the gold standard, there is still disagreement with regard to postoperative care. The use of nasal packing is especially controversial. While some authors advocate the use of nasal packing [(2)], others state that it should be withheld in the majority of patients [(3,4)].

Nasal packing is a source of pain and discomfort for patients [(5,6)]. The packing may cause nasal airway obstruction, headache/pressure, and painful dryness of the mouth and pharynx due to prolonged oral breathing. Pack removal also causes discomfort, and some patients consider it the most objectionable part of the whole procedure [(7)]. The optimum solution in terms of patient comfort would be to withhold nasal packing altogether.

In recent years, absorbable biomaterials have become available for intranasal packing [(8)]. These materials eliminate the need for pack removal, resulting in improved patient comfort [(9)].

The goal of the present study was to evaluate the effect on patient comfort of using carboxymethylcellulose, a modern biomaterial, for intranasal packing after FESS. While carboxymethylcellulose (CMC) is not absorbable, it is flushed out of the nose by saline irrigation, eliminating the need for extraction. The study was designed to investigate two different forms of CMC in comparison with no packing: a CMC mesh (Rapid Rhino® Sinu-Knit, AthroCare UK Ltd., Glenfield, United

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Kingdom) and a CMC gel (Rapid Rhino® Sinus dressing, AthroCare).

MATERIAL AND METHODS

Study design

In an investigator-initiated, double-blind, randomized, controlled study, 40 patients with acute, chronic rhinosinusitis (CRS) or nasal polyps underwent bilateral FESS (Figure 1). The procedures done on each side were roughly identical according to the nomenclature of Stammberger et al. [10] (Figure 2). The surgery followed the technique of the Graz University Medical School [11]. All procedures were performed by the same surgeon.

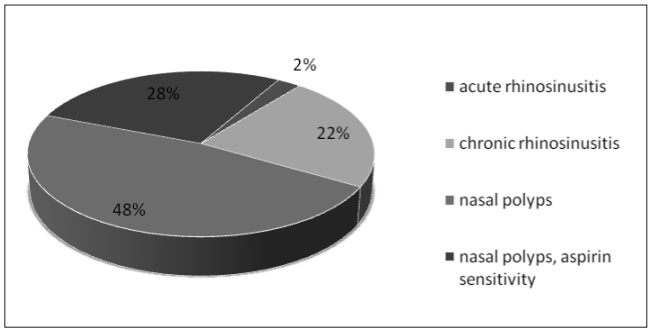

Figure 1. Diagnosis for surgery of the patients under study.

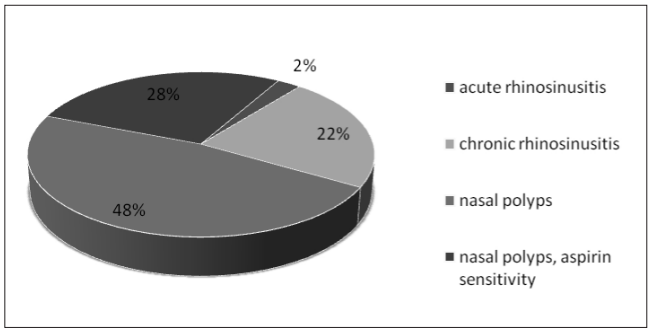

Figure 2. Surgical procedures of the patients under study.

Exclusion criteria included an indication for septoplasty, turbinate surgery, or use of other nasal packing, which would have hampered a valid comparison of the packed and unpacked sides. Other exclusion criteria were pregnancy or the possibility of pregnancy, nursing, poor language skills, or the presence of a severe medical or neuropsychiatric disorder. The research proposal was approved by the local ethics committee.

After giving signed informed consent and before the beginning of surgery, the patients were computer randomized to packing the right or left side of the nasal cavity with CMC, leaving the opposite side unpacked. The type of CMC packing (mesh or gel) was also randomized. In all cases the pack was placed in the middle meatus between the middle turbinate and lateral nasal wall at the end of the surgical procedure.

Questioning and visual analog scales

On the first postoperative day, a physician other than the operating surgeon questioned the patients with the aid of a visual analog scale. The patient and the observer were blinded to the packed side and the type of packing used. The patients self-rated the severity of nasal airway obstruction and headache separately for the right and left sides. The nonspecific parameters of general well-being and possible sleep disturbance were also rated so that our data could be compared with other studies. The questions were based on the formula devised by Weber and Hay [9] who investigated patient comfort in a different study design using finger-cot nasal packs.

Nasal airway obstruction was rated by agreement or disagreement with the following statement: “I can breathe very well through the right/left side of my nose.” The end points of the visual analog scale were labeled as “disagree completely” and “agree completely.” “Disagree completely” was at the zero end of the scale, and “agree completely” was at the 100 end of the scale.

Headache or pressure on the right or left side was rated on a scale from “no headache or pressure” (0) to “unbearable” (100). The scale for sleep disturbance ranged from “no sleep disturbance” (0) to “very severe sleep disturbance” (100). General well-being was rated from “very good” (0) to “very poor” (100). The visual analog scales were exactly 100 mm long and were presented to the patients without numerical markings. The rating was evaluated to an accuracy of 1 mm by measuring from the end of the scale with a ruler, yielding a value between 0 and 100.

Analysis and Statistics

All the data were stored in a Microsoft Access 2003 database, and all data were entered twice to minimize errors. Statistical analysis was performed with SPSS 16.0 for Windows software (SPSS Inc., Chicago, IL). We used the Wilcoxon test to compare the packed and unpacked side, and we used the nonparametric Mann-Whitney U test to compare the CMC gel group and CMC mesh group. The level of significance was defined as $p \leq 0.05$. A sample size calculation was performed with the expectation that the CMC packing would affect the nasal blockage in a similar way like the packing described by Weber et al. [9] and in comparison to the non packed side a difference of 10% was thought to be clinically significant, resulting in a sample size of 40 subjects.

RESULTS

All recruited patients were able to participate in the study, and none had to be excluded. A complete data set was obtained for all participants. An identical surgical procedure was performed on both sides in 88% of cases based on our nomenclature. Twenty patients were packed with CMC gel (Figures 3a and 3b) and 20 with CMC mesh (Figures 4a and 4b). Twenty-one

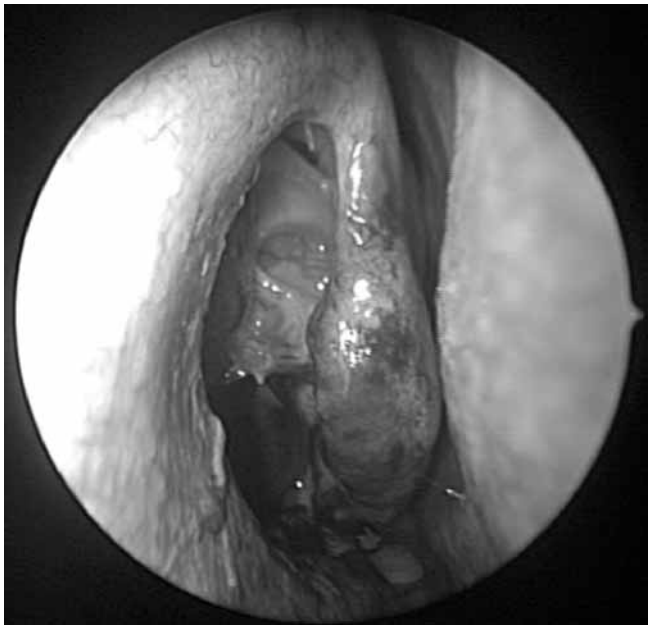

Figure 3a. Endoscopic view (0° Karl Storz endoscope, Tuttlingen, Germany) at the end of surgery before packing with CMC gel.

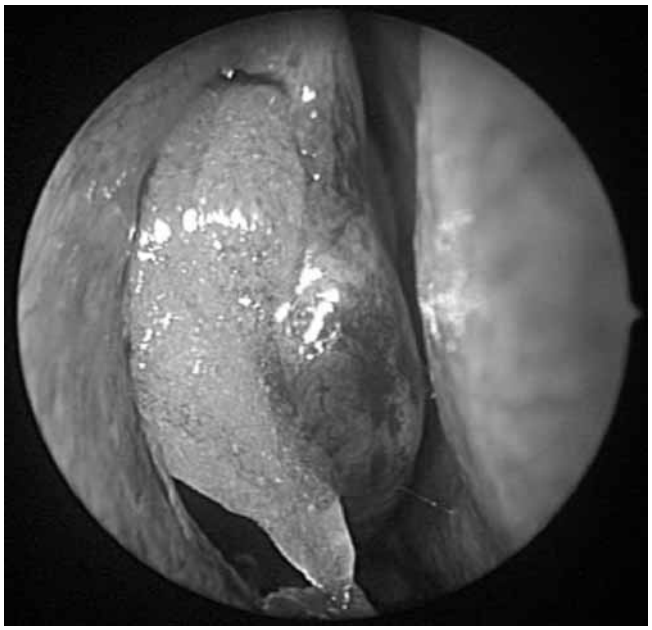

Figure 3b. Endoscopic view (0° Karl Storz endoscope, Tuttlingen, Germany) in the same patient after packing with CMC gel.

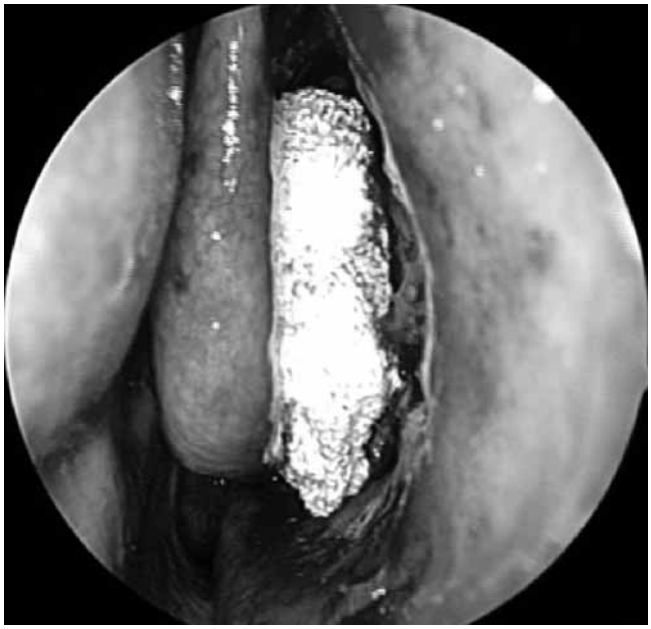

Figure 4a. Endoscopic view (0° Karl Storz endoscope, Tuttlingen, Germany) in a patient packed with CMC mesh at the end of surgery.

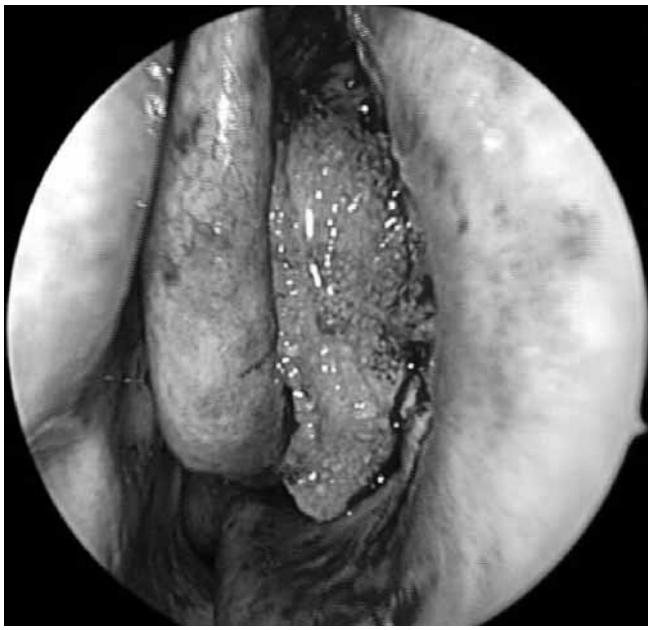

Figure 4b. Endoscopic view (0° Karl Storz endoscope, Tuttlingen, Germany) of hydrolyzed intranasal CMC mesh.

patients were packed on the right side and 19 on the left side. The average age was 49.9 years (SD 14.2); in the CMC gel group 50.7 (SD 10.9), in the CMC mash group 49.5 (SD 16.7) The male: female ratio was 2:1 in the CMC mesh and CMC gel group.

The visual analog scale (VAS) results for nasal airway obstruction are shown in Table 1. No significant differences were found between the CMC-packed and unpacked sides or between the CMC gel and CMC mesh.

The VAS results for headache/pressure are shown in Table 2. The assessment of sleep disturbance yielded a VAS rating of 13.5 (SD 27.2) in the subgroup packed with CMC gelatin and a rating of 30.9 (SD 34.9) in the subgroup packed with CMC mesh. The overall rating for sleep disturbance was 22.2 (SD 32.4).

The results for general well-being were as follows: a VAS rating of 21.3 (SD 20.4) in the subgroup packed with CMC gel and a rating of 24.4 (SD 19.4) in the subgroup packed with CMC mesh. The overall self-rating for general well-being was 22.9 (SD 20.0).

Table 1. Results of VAS self-ratings for nasal airway obstruction.

Airway obstruction	Packing	No packing	p value
CMC mesh	39.6	35.8	p = 0.526
CMC gel	32.4	32.4	p = 0.975
Overall	36.0	34.1	p = 0.716

Table 2. Results of VAS self-ratings for lateralized headache or pressure.

AHeadache/pressure	Packing	No packing	p value
CMC mesh	12.5	17.3	p = 0.180
CMC gel	5.7	4.2	p = 0.845
Overall	9.8	12.1	p = 0.206

DISCUSSION

Postoperative nasal packing is often very painful and uncomfortable for the patient. In a double-blind study design, we investigated the effect of nasal packing with CMC gel or CMC mesh on patient comfort based on a self-rated visual analogue scale. No statistically significant differences were found between the CMC-packed side and unpacked side or between the use of CMC gel or mesh.

CMC in its hydrolyzed form is a creamy, viscous material. Ultimately it does not matter whether the compound is hydrolyzed intranasally (mesh) or extranasally (gel), and we did not expect to find a significant difference between these two groups. Hereafter, therefore, we will refer only to CMC without distinguishing between the mesh and gel forms.

The unpacked side in this study represents the "gold standard" for patient comfort, since the absence of packing cannot adversely affect comfort.

We found no significant difference between the CMC side and the opposite side in terms of nasal airway obstruction. Because the opposite side was left unpacked, we may conclude that carboxymethylcellulose in situ does not cause clinically significant obstruction of nasal breathing. This represents a major advantage of CMC, firstly because some authors believe that airway obstruction by nasal packing is chiefly responsible for patient discomfort [4,7,12-14] and secondly because airway obstruction is associated with other risks and complications such as secondary eustachian tube dysfunction, greater proneness to sleeping problems, and decreased nocturnal oxygen saturation, which may be sufficient to cause obstructive sleep apnea syndrome [15-19]. These problems can be avoided by the use of carboxymethylcellulose nasal packing.

Similarly, the results for headache/pressure showed no clinically significant difference between the presence and absence of CMC packing. In reviewing the studies discussed below, it should be noted that the VAS rating values were scaled 10 times higher than in our own study. This means that comparable values would be 1.0 on the CMC side and 1.2 on the opposite side.

Arya et al. investigated the comfort of nasal packing with Merocel versus Rapid Rhino, again using visual analog scales [20]. In interpreting their results, it should be noted that the questions were formulated somewhat differently and that socioeconomic differences in pain perception may have affected the outcome. The VAS ratings were documented for both materials: 2.0 for Merocel and 2.4 for Rapid Rhino. Using a question format identical to that in our study, Weber and Hay also used a VAS to evaluate patient response to finger cot nasal packing [12]. The average rating was 3.5 although a direct statistically comparison is not correct. Buchanan et al. investigated the effect of unilateral topical anesthesia (bupivacaine) immediately following bilateral Merocel packing after bilateral nasal surgery, again using a VAS for self-assessment of postoperative pain [5]. The authors found an average VAS value of 2.1 without bupivacaine and 1.4 with bupivacaine, documenting a significant advantage for topical anesthesia use. We must note that different subjects and a different study design were involved; this fact limits a direct comparison. Nevertheless, perhaps the positive effect of the topical anesthetic could be combined with CMC packing. In this way the CMC could provide a vehicle for gradual anesthetic release, resulting in a prolonged duration of local anesthesia and a significant benefit in terms of patient comfort.

Besides making a direct side-to-side comparison, it is also useful to look at outcome measures that affect the overall postoperative condition of the patient. The current study yielded mean VAS ratings (divided by 10 for comparability) of 2.2 for sleep disturbance and 2.3 for general well-being. By contrast, Weber and Hay obtained ratings of 5.0 for sleep disturbance and 4.3 for general well-being elicited by identical questions in patients who received finger cot nasal packing [12]. However, a direct data comparison of our results with the results of other studies is difficult, because the patients in other studies may have had different severity or disease, different analgesia and post-operative regimes. In addition, the raw data from other studies was not available for formal statistical analysis and comparison with our data.

In summary, the present study revealed no differences between the CMC-packed side and unpacked side with respect to the evaluated outcome measures. The patients could not distinguish between the packed and unpacked sides. On the whole, good patient comfort is achieved when the nose is packed with CMC following FESS.

CONCLUSION

According to the results of the presented study, the use of CMC nasal packing after FESS in either the gel or mesh form does not adversely affect postoperative patient comfort. Based on the presented data possible indications for nasal packing at all following surgery on the ethmoid without "flanking measures" like septal correction or inferior turbinoplasty are on

one hand uncontrolled general bleeding, which cannot be managed with coagulation devices and on the other hand destabilisation of the middle turbinate.

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