

A randomized trial of Rapid Rhino Riemann and Telfa nasal packs following endoscopic sinus surgery

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Objectives: To compare Telfa with the Rapid Rhino Riemann nasal pack for use following endoscopic sinus surgery.

Design: Prospective, randomized, double-blind, paired trial.

Setting: Tertiary otolaryngology hospital.

Participants: Forty-five adult patients undergoing bilateral endoscopic sinus surgery for either chronic rhinosinusitis or nasal polyps.

Main outcome measures: A visual analogue scale was used to assess discomfort caused by the presence of the packs in the nose and by their removal. The amount of bleeding was noted with the packs in place and following their removal. Crusting and adhesions were assessed 2 and 6 weeks following surgery.

Results: Both packs performed well giving good haemostasis and causing little bleeding on removal. Both packs

caused only mild discomfort while in the nose. On the visual analogue scale of 0–10 cm the mean visual analogue score for Rapid Rhino Riemann pack was 1.7 and for Telfa 2.0 ($P = 0.371$). The Rapid Rhino Riemann pack caused significantly less pain on removal compared with the Telfa pack with a mean visual analogue score of 2.0 in comparison with 3.7 for Telfa ($P = 0.001$). There were less adhesions with the Rapid Rhino Riemann than Telfa pack but this was not statistically significant ($P = 0.102$).

Conclusions: Both Telfa and Rapid Rhino Riemann packs can be recommended as packs that control postoperative haemorrhage, do not cause bleeding on removal and cause little discomfort while in the nose. The Rapid Rhino Riemann pack has the advantage of causing significantly less pain on removal.

Nasal packs have been used following a variety of nasal operations for many years to stop haemorrhage. Patients often complain that the removal of nasal packs after nasal surgery is the worst part of their surgical experience.¹ This has led to the search for a better nasal pack. An ideal nasal pack should fulfil its primary role to prevent bleeding while in place and not cause abrasion and recurrence of bleeding on removal. It should also be comfortable in place and cause little discomfort on removal. Some manufacturers also claim that the materials they use have additional beneficial effects on healing, reducing crusting and adhesions. Nasal packs are continually evolving with packs on the market now that will dissolve and so do not need removal. The next generation appears to be 'packs' that are injected as a foam and therefore dissolve and are gone within a few days. These all need investigation both

into their efficacy as haemostatic agents and effects on healing and adhesion formation.

As discomfort experienced on removal is such a significant factor for patients,¹ it has been suggested that when at all possible nasal packs should be avoided. The problem with this is that some bleeding will inevitably occur after surgery. If it is mild, it leaves the patient with a nose full of blood clots, which may promote adhesion formation. If heavier the patient is likely to swallow blood while in the immediate postoperative period resulting in nausea and vomiting. If the bleeding persists, it will necessitate the insertion of nasal packs on the ward, which will be painful in a nose that has been operated on recently.

We set out to compare two nasal packs both of which we believed to cause less discomfort than other packs in common use. Telfa is a non-adherent absorbent dressing that has been compared favourably with other packs in previous trials.^{2,3} The Rapid Rhino Riemann 4 cm pack is a relatively new pack with a gel coat that is claimed to

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promote haemostasis and also to ease removal. Our objective was to compare these two nasal packs both for control of bleeding and comfort and also for their effects on postoperative healing.

Materials and methods

Participants

All patients over 18 years, undergoing bilateral endoscopic sinus surgery, on admission, were given an information sheet about the study and later asked by one of the authors (A.S.C., A.K and I.S.) if they were willing to take part. Exclusion criteria were the patient being under 18 years of age, unilateral surgery, visual or motor impairments preventing use of a visual analogue scale and patients not consenting to take part in the trial. Indication for surgery included both chronic rhinosinusitis and nasal polyps. Patients were recruited between June 2003 and June 2004.

Setting and location

This was a single centre trial at a tertiary otolaryngology hospital in central London, UK.

Randomization

A random sequence for which pack was to be placed in the left and right nostrils of each patient was created using the generator provided by <http://www.randomisation.com>. The instructions for each patient were placed and sealed in numbered envelopes by the first author (A.S.C.). The assignment schedule was also sealed in an envelope that was not opened until all patients had been recruited and data had been collected and was ready for analysis.

Operative details

The operations were performed by the senior authors (L.B. and V.J.L) under general anaesthetic. At the end of surgery, an envelope was opened that contained instructions to place a Rapid Rhino Riemann 4 cm pack into a specified nostril and to insert a roll of Telfa dressing into the other nostril. The instruction also stated that the Rapid Rhino Riemann pack should be soaked in sterile water before insertion and that no mention of which side each pack was inserted should be made in the operation note and that the instruction sheet should be destroyed. The extent of disease on each side of the nose was compared both from a clinical assessment as recorded in the

operative note and also CT scores according to Lund–MacKay grading system.⁵

Outcome measures

Primary. (1) The pain caused by the presence of packs within the nose.

The patient was asked to make a mark on a visual analogue scale to demonstrate the pain they were experiencing from each side of the nose as a result of the nasal pack being present. A visual analogue scale was chosen as a measure of pain both for its simplicity and as it has been validated in a wide variety of settings and has been found to be a sensitive and reproducible assessment of pain.^{6,7}

(2) The pain caused by removal of the nasal packs.

The packs were then removed by one of the ward nurses and again the patient was asked to make a mark on a visual analogue scale to represent the pain each pack caused on removal.

Secondary. (1) Control of haemorrhage.

Postoperatively a standard dressing bolster was placed in front of the nose and the ends of the bolster labelled 'left' and 'right'. After the patient returned to the ward, if the bolster needed replacing, removed bolsters were kept and the new bolster was labelled as before. The morning after surgery, a different doctor assessed the collected bolsters and compared the amount of blood that had come from each packed nostril onto each end of the bolster. He recorded on the data sheet whether there appeared to have been more bleeding from the left or right nostril or no difference. The doctor making the assessment varied but was never the doctor who had carried out the operation and they were not aware of which type of pack was in each nostril.

(2) The amount of bleeding after removal.

After removal the nursing staff made a note of how long each nostril continued to bleed and ticked a box to say if there was 'no bleeding', 'bleeding stopped within 3 min', 'bleeding stopped with ice' or the 'nose required repacking'. The nurse carrying out both removal and assessment of bleeding varied from patient to patient.

(3) The degree of nasal crusting and adhesions 2 and 6 weeks postoperatively.

The patients received a 2- and 6-week follow-up appointment. At each of the appointments the doctor seeing the patient made a rigid endoscopic assessment of crusting and adhesions in each nostril and scored this by the Kennedy–Lund grading system.⁸ The doctor was unaware of which pack had been used in which nostril. The assessing doctors were authors J.K and N.N.P.

Power calculations

Garth *et al.*² and Von Schoenberg *et al.*³ reported that on a 10 cm visual analogue scale the mean pain scores on removal of Telfa from the nose were 4.3 and 4.33 cm, respectively; the mean pain scores with Telfa packs within the nose postoperatively were 3.4 and 4.5 cm, respectively. We considered that a difference in pain of 1.5 cm in a 10 cm visual analogue scale would be clinically relevant. To calculate the number of patients required to detect this difference, we used standard deviations (SD) based on the nasal pack study by Shinkwin *et al.*⁴ (SD were not given in the former studies). The result was that to have a 90% chance of detecting a 1.5 cm difference, if it truly existed, in pain on removal of packs at a 5% level of significance would require 35 patients in a two-sided test (Shinkwin *et al.* mean difference was 17.52 mm, SD 27.64). Similarly, 24 patients would be needed in order to detect a 1.5 cm difference in pain while packs were *in situ* (Shinkwin *et al.*'s mean difference was 4.66 mm, SD 22.4). Taking into account, non-usable data and loss to follow up, we decided to recruit 45 patients.

Ethical considerations

Approval for the trial was gained from the Royal Free Hospital and Medical School Ethics Committee.

Results

Of the 45 patients, we retrieved 40 data sheets. Patient 28 was withdrawn from the trial as the nasal packs were removed on the evening of surgery as she had developed some right-sided facial pain and swelling and there was concern that this was because of a reaction to the Rapid Rhino Riemann pack. This possible reaction settled within 48 h without intervention. See Fig. 1 for flow of participants.

Patient demographics

The mean age of the patients was 47.8 years (range 22–70). Twenty-seven of the patients were male and 13 were female. None of the patients were taking regular aspirin or anti-coagulants. From the operative notes,

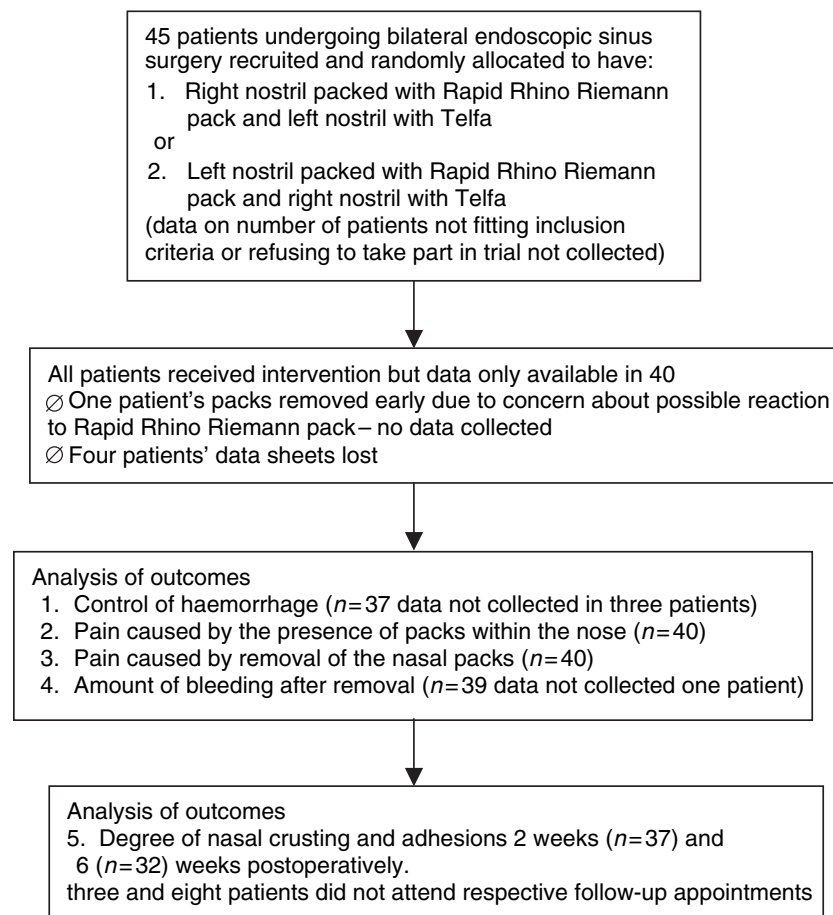


Fig. 1. Flow of participants.

Patient trial number	Rapid Rhino Riemann side	Telfa side
4	Septal deviation towards this side	
6	Grade 3 polyps	Grade 2 polyps
15		Septal deviation towards this side
22	Grade 1 polyps	Concha bullosa
24	Concha bullosa	
26	Grade 2 polyps	Grade 1 polyps
33	Concha bullosa + grade 3 polyps	Septal deviation towards this side + grade 1 polyps
35	Grade 1 polyps	Grade 2 polyps

Table 1. Differences in clinically assessed pathology between nostrils in those patients who had asymmetrical pathology

clinical assessment of nasal pathology was symmetrical in 32 of 40 patients (80%). Thirty-eight of 40 (95%) had nasal polyps. The differences in pathology between the sides of the remaining eight patients can be seen in Table 1.

The mean Lund–MacKay CT scores⁵ for the Rapid Rhino Riemann pack side was 8.6 and for the Telfa pack side 8.5. On two-tailed paired *t*-test there was no significant difference between the scores for the sides packed with each type of nasal pack ($P = 0.68$). There was also no statistically significant association between Lund–MacKay CT score and incidence of bleeding or adhesion formation postoperatively.

The surgery carried out was the same on both sides in 36 of 40 patients (90%). For the four patients with asymmetric surgery, the differences were patients 1 and 24 had excision of the middle turbinate on the side of the Rapid Rhino Riemann pack, patient 8 had excision of the middle turbinate on the side of the Telfa, and patient 38 had frontal recess surgery on the side of the Rapid Rhino Riemann pack.

Statistical assessment method

The patients' experience of discomfort with the packs in place and on removal, as demonstrated on a visual analogue scale, conformed to a normal distribution as tested with Normality plots and Kolmogorov–Smirnov testing. These were, therefore, analysed with paired *t*-test. The remaining variables were non-parametric and Wilcoxon sign rank testing was used for analysis.

Outcomes

Primary. (1) The pain caused by the presence of packs within the nose.

Table 2. Pain felt while nasal packs were in the nose recorded on a 10 cm visual analogue scale

	Mean (cm)	<i>n</i>	SD	SE
Rapid Rhino Riemann	1.73	40	1.85	0.29
Telfa	2.00	40	1.98	0.31

$P = 0.371$ (95% confidence interval of the difference -0.33 to $+0.87$ cm).

Table 3. Pain felt on removal of nasal packs recorded on a 10 cm visual analogue scale

	Mean (cm)	<i>n</i>	SD	SE
Rapid Rhino Riemann	1.96	40	2.11	0.33
Telfa	3.70	40	2.43	0.38

$P = 0.001$ (95% confidence interval of the difference 0.76 – 2.71 cm).

No significant difference was found in reported discomfort between the two packs while in the nose (Table 2).

(2) The pain caused by removal of the nasal packs.

The main difference between the packs was on removal. The Rapid Rhino Riemann pack caused significantly less pain on removal compared with the Telfa (Table 3).

Secondary. (1) Control of haemorrhage.

The assessment of the bolster dressings suggested bleeding while the packs were *in situ* was equal from both packed nostrils in 17 of 37 (44.7%). In 13 of 37 (34.2%) bleeding was greater on the side with the Rapid Rhino Riemann pack and in eight of 37 (21.1%) it was greater on the side containing the Telfa. The dressing bolster was changed on average 1.8 times for each patient. Data for this outcome failed to be collected in three patients.

(2) The amount of bleeding after removal.

There was no bleeding after removal of 31 of 39 (79.5%) of the Rapid Rhino Riemann packs and no bleeding after removal of 29 of 39 (74.4%) of the Telfa packs. After removal of the Rapid Rhino Riemann pack there was an average of 0.3 min of bleeding and after removal of the Telfa 1.3 min of bleeding. This difference was mainly because of one patient who bled for 30 min after removal of the Telfa pack. There was no statistical difference in bleeding between the packs ($P = 0.234$ Wilcoxon sign rank). No patients required repacking of their nose.

(3) The degree of nasal crusting and adhesions 2 and 6 weeks postoperatively.

At 2-week follow up ($n = 37$), there was significantly more crusting on the Rapid Rhino Riemann pack side than the Telfa side. At 6 weeks ($n = 32$), this was no longer significant (Table 4). With regard to adhesions, more were noted on the Telfa than the Rapid Rhino Riemann pack side at both 2 ($n = 37$) and 6 weeks ($n = 32$). At 6 weeks, there were no adhesions seen on the Rapid Rhino Riemann side but three of 32 (9.4%) patients had adhesions on the Telfa side. The difference, however, at both 2 and 6 weeks was not statistically significant (Table 5).

Discussion

Postoperative care after endoscopic sinus surgery is important both to minimize discomfort for the patient and to obtain the best outcome. The first step in this care is the decision as to whether to pack the nose and if so with what. Not packing the nose has the advantage of avoiding the discomfort caused by packs being in the nose and by their removal. Patients often report that removal of the nasal packs was the worst part of their surgical experience.¹ There is, however, inevitably some bleeding from the nose following surgery even with meticulous nasal preparation and surgical technique. Orlandi and Lanza⁹ have suggested that packing is mostly unnecessary but warn patients that postoperative bleeding will mean 'they could use more than a box of tissues on the day of surgery'. To achieve good control of bleeding and improve the patient experience, packs are being developed that are more comfortable and cause less pain on removal.

A variety of nasal packs have been compared mainly following septal or turbinate surgery rather than endoscopic sinus surgery. Garth and Brightwell² on a trial of 48 patients reported that packing the nose using paraffin

Table 4. Crusting noted in each side of the nose 2 and 6-weeks following surgery

	0 (%)	1 (%)	2 (%)	Median	Interquartile range (25–75%)
Two weeks, $n = 37$					
Rapid Rhino Riemann	19/37 (51.4)	10/37 (27.0)	8/37 (21.6)	0	0–2
Telfa	25/37 (67.9)	9/37 (24.3)	3/37 (8.1)	0	0–1
Six weeks, $n = 32$					
Rapid Rhino Riemann	25/32 (78.1)	6/32 (18.8)	1/32 (3.1)	0	0–0.5
Telfa	28/32 (87.5)	4/32 (12.5)	0/32 (0)	0	0–0

Scored according to Kennedy–Lund grading⁸: 0, absent; 1, mild; 2, severe (2 weeks $P = 0.021$; 6 weeks $P = 0.102$).

Table 5. Adhesions noted in each side of the nose 2 and 6 weeks following surgery

	0 (%)	1 (%)	2 (%)	Median	Interquartile range (25–75%)
Two weeks, $n = 37$					
Rapid Rhino Riemann	29/37 (78.4)	8/37 (21.6)	0/37 (0)	0	0–0
Telfa	32/37 (86.5)	4/37 (10.8)	1/37 (2.7)	0	0–0
Six weeks, $n = 32$					
Rapid Rhino Riemann	32/32 (100)	0/32 (0)	0/32 (0)	0	0–0
Telfa	29/32 (90.6)	2/32 (6.3)	1/32 (3.1)	0	0–0

Scored according to Kennedy–Lund grading⁸: 0, absent; 1, mild; 2, severe (2 weeks $P = 0.453$; 6 weeks $P = 0.102$).

gauze (Jelonet) or Telfa caused significantly less discomfort and bleeding on removal as compared with Merocel (foam rubber tampon) and bismuth iodoform paraffin paste (BIPP) gauze ($P < 0.05$). The authors gave preference to Telfa as occasional paraffin granulomata have been reported following packing with paraffin gauze.¹⁰

Watson *et al.*¹¹ in a trial of 106 patients compared packing the nose post-surgery with a pneumatic balloon, paraffin ribbon gauze (Jelonet) and polythene glove fingers filled with ribbon gauze. They found the Jelonet was significantly more uncomfortable than the other two packing methods ($P < 0.005$), but in this trial the surgeons packed a length of Jelonet ribbon firmly into the nose rather than the technique of inserting a roll of Jelonet used in the trial reported by Garth and Brightwell.² Watson *et al.*¹¹ found that the pneumatic balloon, although easy to insert and relatively comfortable, caused a significantly higher incidence of debris accumulation, adhesion formation and nasal obstruction. They felt that this might have been because of mucosal ischaemia as a result of uneven pressure caused by the balloon.

Packs incorporating a ventilation tube have also been assessed to find if some air passage through the nose increases patient comfort. Illum *et al.*¹² compared finger-stall packs filled with gauze (32 patients) with a Merocel pack with a ventilation tube (27 patients). They reported that patients felt little benefit from the ventilation tube and that there was significantly more bleeding on removal of the Merocel pack than the fingerstall pack ($P = 0.02$). They felt this was related to greater adherence of the foam rubber pack to the nasal mucosa. This may be because of larger perforation size of the foam rubber pack allowing in-growth of granulation tissue.¹³

Von Schoenberg *et al.*³ in a trial of 95 patients undergoing septal or turbinate surgery found packing with ribbon gauze impregnated with BIPP or Telfa to be significantly more painful than no packing ($P < 0.001$). They also found greater frequency of complications in the BIPP group. They, therefore, proposed that nasal packing is unjustified and if it is to be done Telfa should be used. Their trial, however, was not randomized as all patients undergoing septal surgery were placed in the groups to be packed.

Packs with procoagulative properties have been proposed. Sirimanna *et al.*,¹⁴ in a trial involving 92 patients, compared calcium sodium alginate fibre (Kaltostat), trousered paraffin gauze (Jelonet) and glove finger packs following inferior turbinectomy. Kaltostat releases calcium ions, which stimulate both platelet aggregation and whole blood coagulation. They found no significant difference in bleeding while the packs were in place, but following removal of the Kaltostat pack, there were significantly

fewer bleeding nasal cavities ($P < 0.02$) and significantly less severe bleeding ($P < 0.003$) than after removal of the other two packs.

Shinkwin *et al.*⁴ compared Surgicel Nu-Knit with Vaseline ribbon gauze in 30 patients and Merocel packs in a further 30 patients. Surgicel is oxidized regenerated cellulose and is procoagulative both through platelet aggregation and activation of intrinsic and extrinsic clotting pathways. They found Surgicel Nu-Knit caused significantly less discomfort while in position and on removal than Vaseline gauze ($P < 0.01$). Compared with Merocel sponges, Surgicel Nu-Knit caused significantly less discomfort on removal ($P < 0.01$). Bleeding following removal of Surgicel Nu-Knit was also significantly less compared with the other packs. They did, however, have concerns about the tendency of the Surgicel Nu-Knit to fragment on removal and one patient had the Surgicel Nu-Knit fragments removed from their nose under general anaesthetic.

There has been one trial looking at one of the Rapid Rhino range of nasal packs, the Goodman pack. This pack has the same structure as the Riemann pack but is longer, 5.5 cm rather than 4 cm. It is intended for use following turbinectomy, septoplasty and polypectomy. Arya *et al.*¹⁵ compared the Goodman pack with the Merocel pack in fourteen patients, nine undergoing septal and/or turbinate surgery and five having endoscopic sinus surgery. They found significantly higher pain levels associated with Merocel pack removal than with Rapid Rhino Goodman pack removal (average pain scores 5.64 *versus* 1.64, $P < 0.001$).

Our trial seeks to compare Telfa, a pack shown by the above trials to cause less discomfort and other complications than many packs commonly used following nasal surgery, with the relatively new pack, the Rapid Rhino Riemann. Telfa (The Kendall Company, Boston, MA, USA) consists of a layer of cotton fleece enclosed in a perforated inert water-repellent plastic film. This dressing has been adapted from surgical wound care and can be cut to fit the patient's nose. The cotton fleece provides absorbency and the outer layer is non-adherent and by its occlusive effect keeps the wound moist, promoting epithelialization.

Rapid Rhino Riemann (Applied Therapeutics, Oberberg, Germany) has been specifically designed for use after endoscopic sinus surgery. It has a polyurethane foam core with a polyvinyl chloride (PVC) cover. This is covered by a hydrocolloid fabric which when wet creates a moist gel. In this way, it also keeps the wound moist promoting epithelialization and remains slippery for easy removal without damage to recovering tissues. The fabric coat is reinforced knitted carboxymethylcellulose (CMC)

fibre. CMCs have been shown to reduce adhesion formation post-surgery.¹⁶ CMCs also release calcium chloride, which promotes platelet aggregation and blood clotting.

Our results show both packs perform well. Bleeding was equally well controlled while the packs were *in situ*. Comparison of bleeding while the packs are in place is difficult and our method of looking at bolster dressings gave only an approximate result. A more accurate method would be a system of weighing dressings to assess bleeding. However, it is not possible to have separate dressings over each nostril with no cross-contamination. Both packs were well tolerated while in the nose as both scored an average of only two out of 10 on a visual analogue scale for discomfort while in place. The main difference between the nasal packs was on removal. The Rapid Rhino Riemann caused significantly less pain on removal than the Telfa pack with on average a visual analogue score (VAS) of only two out of 10 in comparison to 3.7 out of 10 for the Telfa ($P = 0.001$). Kelly⁹ found in a prospective descriptive study of 152 adult patients presenting to the emergency department with acute pain that the minimum clinically significant difference in VAS pain score was 0.9 cm. This was the change in VAS score that coincided with a descriptive change in pain of 'little better' or 'little worse' as opposed to 'a lot better' or 'much the same'. The minimum clinically significant difference was found to be independent of gender, age or cause of pain. Both packs caused little in the way of bleeding on removal. The Rapid Rhino Riemann caused less, with 79.5% of patients having no bleeding, but the difference between the packs was not statistically significant in this respect ($P = 0.234$).

Our main aim was to look at the issue of discomfort caused by nasal packing, but we also evaluated the two packs for their effect on healing, crusting and adhesion formation. In our trial, we removed the packs the morning after surgery. Many authors suggest leaving nasal packing for up to 7 days.¹² It would be expected that longer periods of packing would allow packing to have a greater influence on healing. Our assessment of crusting and adhesion formation after the two nasal packs surprisingly showed trends in opposite directions. At 2 and 6 weeks postoperatively the Telfa pack appeared to be associated with less crusting while the Rapid Rhino Riemann pack tended to cause less adhesions. We found that at 6 weeks there were no adhesions on the Rapid Rhino Riemann side, but 9.4% of patients had adhesions on the Telfa side. Owing to the small sample size no firm conclusions can be drawn about these differences.

A major strength of our trial was the fact that patients acted as 'their own controls' by having a different

pack in each nostril. This prevented error or bias created by psychological overlay or differences in pain tolerance in individual patients. Although different surgeons carried out the procedures and the patients did not receive a standardized anaesthetic or analgesia protocol, because in each patient the comparison was made between nostrils, these factors could not influence the result overall. As patients mostly had the same extent of surgery on each side of their nose this also provided a fair comparison between the packs. The study could be criticized for not testing inter-observer variability in assessment of crusting and adhesions. The assessment, however, was done blind to which pack had been used in each nostril and the paired nature of the trial will have minimized the effect of inter-observer variability.

Conclusion

Whether packs are always necessary following endoscopic sinus surgery is an ongoing debate. Studies will also be required to look at newer packs that do not require removal. This trial has demonstrated that both Telfa and Rapid Rhino Riemann packs fulfil their primary purpose of haemostasis and are well tolerated while in the nose. The Rapid Rhino Riemann pack has also been shown to cause little pain on removal and significantly less pain than a Telfa nasal pack. The Rapid Rhino Riemann pack may prevent adhesion formation, but a larger trial would be required to confirm this. Cost is an issue in national health care provision, which has to be balanced against best possible care for the individual. The Rapid Rhino Riemann pack costs £9.25 compared with the Telfa pack costing £1.17 (10 × 7.5 cm Telfa 18p and 2/0 silk suture £2.16 makes two packs).

Both the Rapid Rhino Riemann pack and Telfa pack can be recommended as packs that perform well following endoscopic sinus surgery, but the Rapid Rhino Riemann pack has the advantage of causing significantly less pain on removal.

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Conflict of interest

L. Badia and V. J. Lund would like to declare a possible conflict of interest as the manufacturer of the Rapid Rhino nasal packs provided a grant to the Rhinology Research Fund of The Royal National Throat, Nose and Ear Hospital.

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