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# Foam nasal packs: a prospective, randomised, patient-controlled study*

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SUMMARY

***Objectives:*** *To compare the efficacy of Spiggle and Merocel foam packs following routine nasal surgery.*

***Design:*** *Prospective, randomised, single-blind, paired study.*

***Participants:*** *Twenty adult patients undergoing elective nasal surgery.*

***Intervention:*** *At the end of nasal surgery patients were randomised to have a Spiggle pack inserted in one nasal cavity and a Merocel pack in the other. Packs were removed the following morning.*

***Main outcome measures:*** *The primary outcome measure was pain due to the presence of packs in the nose and pain associated with their removal. This was measured using a visual analogue scale. Secondary outcome measures were bleeding, crusting and adhesion formation.*

***Results:*** *Both packs were effective at preventing postoperative haemorrhage. Bleeding following removal was minimal. There were no significant differences between the packs in terms of levels of discomfort experienced 6 hours after surgery or the following morning prior to removal (p=0.3 and p=0.3 respectively). However, the Spiggle foam pack caused significantly less pain on removal compared with the Merocel foam pack (mean difference 1.4; 95% CI 0.4 to 2.4, p=0.005). There were no significant differences in terms of crust and adhesion formation.*

***Conclusions:*** *In this study, both the Spiggle and Merocel foam nasal packs were well tolerated while in the nose. Both provided good postoperative haemostasis and were not associated with bleeding on removal. The Spiggle foam pack had the advantage of causing significantly less pain on removal. However, it must be borne in mind that in this study the Spiggle pack was more likely to be positioned in the non-incised nasal cavity, the side that would generally be expected to be associated with less pain.*

*Key words: nasal, surgery, packs, postoperative, trial*

## INTRODUCTION

Nasal packs are often inserted at the end of endonasal surgery in order to control postoperative bleeding. The type of pack chosen is largely determined by inherited practice and departmental provision. Since patients usually cite pack removal as the worst part of their operation it would make sense to choose a pack that minimises the amount the pain experienced during this process.

A wide variety of nasal packs are available to insert into the nose following nasal and sinus surgery. Traditionally, BIPP (Bismuth, Iodoform, and Paraffin Paste) and Vaseline ribbon gauze packs were used, mainly due to familiarity of their use in the management of epistaxis. However, their main drawback is that they are painful while in place and cause even more discomfort on removal [1,2].

Foam packs were introduced in the 1980's and are simple to use, highly absorbent and very effective at controlling bleeding. These factors led to their widespread use in cases of epistaxis and following nasal surgery. Merocel (Medtronic Xomed, USA) is one example of a foam pack. It is made of polyvinyl acetal and is packaged in a compressed, dehydrated state to allow ease of insertion. It requires rehydration with normal

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saline to activate it. Its mean pain score while in-situ and on removal has been shown to be lower than both BIPP and Vaseline ribbon gauze [1,2]. However, in a more recent study, Merocel was associated with a significantly higher mean pain score on removal when compared to the Rapid Rhino pack [3].

Packs are continually evolving as manufacturers strive to design a pack that possesses the 'ideal' characteristics. Each of these newcomers requires evaluation with regard to their efficacy and safety. A relatively new foam pack manufactured by Spiggle & Theis (Germany) has been designed with a non-stick, non-absorbent, latex-free smooth cover. Given the overall effectiveness of foam packs in general, the presence of these additional characteristics prompted us to evaluate this pack and compare it with the widely used Merocel, looking primarily at the level of discomfort experienced on removal.

The pack manufactured by Spiggle & Theis does not have a formal name and so for the purpose of this paper it is referred to as the 'Spiggle' pack. It is packaged in non-compressed form and so has to be squashed between tilley dressing forceps to allow it to be introduced into the nasal cavity, after which it springs open to its original size. It does not require activation with normal saline. The Spiggle pack is available in different sizes. Our study compared the 8cm latex-free Spiggle nasal pack with the 8cm standard Merocel nasal pack.

## MATERIALS AND METHODS

This single-blind, randomised, patient-controlled trial was conducted at Fairfield General Hospital between May and October 2005. Local Research and Ethics Committee approval was granted prior to the start of the study and informed consent taken from each participant.

### *Eligibility criteria*

Patients undergoing elective bilateral nasal surgery were enrolled into the study. Exclusion criteria were the patient being under the age of 18 years, those undergoing unilateral surgery, and patients unable or unwilling to give consent. Patients with haemostatic disorders were also excluded from the study.

### *Participant allocation*

Using a random sequence generated by a computer, patients were randomly assigned to have a Spiggle pack placed in one nostril and a Merocel pack in the other.

### *Concealment of allocation*

The instructions for each patient were placed and sealed in sequentially numbered opaque envelopes, to be opened only at the end of the operation.

### *Intervention*

Patients were informed of the trial during the preoperative assessment visit. Written information regarding the trial was also provided at this time and consent taken from those wishing to take part.

Operations were performed under general anaesthetic by four different surgeons. At the end of surgery an independent observer would open the next sealed envelope and would instruct the surgeon accordingly. Following Merocel insertion the pack was activated with normal saline. The Spiggle pack was compressed between tilley dressing forceps to allow insertion.

Nasal packs were removed by a member of the nursing staff on the ward on the first post-operative day. Merocel packs were soaked with 10 mls of normal saline prior to removal 5 minutes later. The right pack was always removed first followed by the left pack.

### *Blinding*

Patients were blind to the type of pack inserted in each nostril. In order to maintain blinding of the patient during pack removal, saline was also applied to the Spiggle pack prior to its removal 5 minutes later (although in reality this is not required). Patients were also asked to close their eyes during pack removal to eliminate the possibility that differences in pack colour and appearance may have altered the perception of pain associated with their removal. The operating surgeon and nursing staff looking after the patients could not be blinded as the Merocel pack is white in colour and the Spiggle pack blue.

### *Outcome measures*

Our primary outcome measures were pain levels while the packs were in the nose and pain associated with their removal. Patients were asked to record the severity of pain experienced in each nostril on a graduated horizontal visual analogue scale, with a range of 0-10, 0 being no discomfort and 10 representing worst pain imaginable. The scores were recorded at three different times; six hours after operation while the packs were in-situ, prior to removal the following morning and immediately after pack removal.

Our secondary outcome measures were control of bleeding while the packs were in situ and the amount of bleeding once they had been removed. Nurses were asked to monitor and record evidence of bleeding using the following grading system: no bleeding=0, bleeding for less than 3 minutes=1, bleeding that settled with ice packs=2, bleeding that required repacking=3.

The nasal cavities were examined endoscopically at 6 weeks to assess the degree of crusting and adhesion formation. Each of these findings was scored as follows: absent=0, mild=1 or severe=2.

Any complications such as difficulty in pack removal or pack fragmentation were also noted.

### *Power calculations*

Statistical support was obtained prior to the trial. When devising this study, we considered that a difference of 2cm in a 10cm visual analogue scale would be clinically relevant. It was

Table 1. Type of operation performed.

| Procedure | Number of patients (%) |
|---|---|
| Septoplasty and submucous diathermy to inferior turbinates | 14(70) |
| Septoplasty and bilateral antral washouts | 1(5) |
| Septoplasty | 2(10) |
| Polypectomy | 1(5) |
| Septorhinoplasty | 2(10) |

Table 2. Side of incision.

| Side of incision | Number of patients (%) |
|---|---|
| Left | 15(75) |
| Right | 2(10) |
| Full transfixation | 2(10) |
| Not applicable (Polypectomy) | 1(5) |

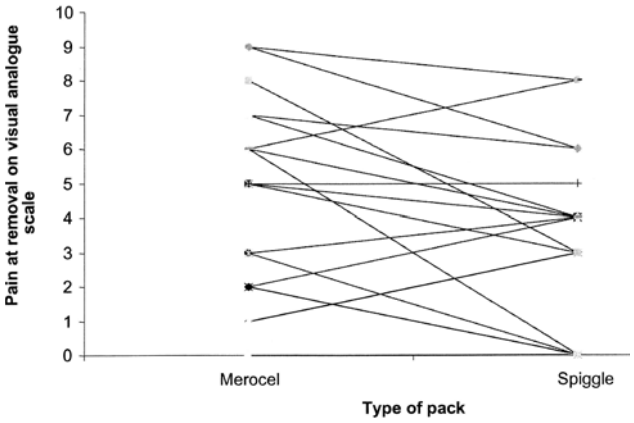


Figure 1. Pain on removal, linked by individual.

calculated that to have a 90% chance of detecting a difference of 2cm or more on the visual analogue scale, if it truly existed, at a 5% level of significance would require 19 patients to be recruited (assuming a standard deviation of 2.5).

*Statistical analysis*

The difference in pain scores between interventions, measured using a visual analogue scale, conformed to a normal distribution was therefore analysed with paired t-test. The remaining outcome measures were analysed using non-parametric methods. Statistical significance was accepted at the $p < 0.05$ level.

## RESULTS

*Participants*

Twenty consecutive patients from the waiting list were entered into the trial. No patient refused entry or was excluded. Data was collected on all patients. Ten were randomised to have a Spiggle pack inserted in the right nostril and a Merocel in the left. The remaining 10 patients had a Merocel pack in the right and a Spiggle in the left nasal cavity. Thirteen were male and 7 were female. The mean age of the patients was 37.7 years with a range of 17 to 68 years.

The types of nasal surgeries performed are shown in Table 1. The vast majority of patients underwent septoplasty with submucous diathermy to inferior turbinates. Septorhinoplasty was carried out in two cases. One patient had bilateral nasal polypectomy. In the vast majority of cases a left hemi-transfixation incision was performed (Table 2).

None of the patients were taking regular aspirin or anticoagulants. Analgesic requirements were noted but did not vary significantly between patients.

*Outcomes*

*Primary*

No significant difference was found in pain scores between the two packs while in the nose. However, a difference was noted on removal (Table 3). The Spiggle pack caused significantly less pain on removal when compared with the Merocel. Individual responses during pack removal are shown in Figure 1.

*Secondary*

No bleeding occurred while either pack was in the nose. There was no bleeding following removal of 18 of 20 (90%) of Spiggle packs and no bleeding after removal of 19 of 20 (95%) of Merocel packs ($p > 0.99$, McNemar test). None of the patients required ice to stop bleeding or needed repacking.

At six-week follow-up in clinic, 19 of 20 (95%) nostrils on the Spiggle pack side had no crusting evident compared with 19 of 20 (95%) nostrils on the Merocel pack side ($p > 0.99$, McNemar test). No patients had severe crusting.

Table 3. Mean pain scores.

| | Merocel Mean (standard deviation) | Spiggle Mean (standard deviation) | Mean difference [Merocel-Spiggle] (95% Confidence Interval) | p-value from paired t-test |
|---|---|---|---|---|
| Pain score 6 hours after operation | 3.3 (2.5) | 3.8 (2.8) | -0.6 (-1.7 to 0.6) | 0.3 |
| Pain score prior to removing pack | 3.1 (2.7) | 3.7 (2.9) | -0.6 (-1.9 to 0.7) | 0.3 |
| Pain score on removal of pack | 4.7 (2.7) | 3.3 (2.6) | 1.4 (0.4 to 2.4) | 0.005 |
| Change in pain score during removal | +1.6 (1.8) | -0.4 (2.6) | 2.0 (0.9 to 3.1) | 0.002 |

Table 4. Pain scores comparing incision side with non-incision side (n=17).

| | **Incision side ("more pain expected") mean (SD)** | **Non-incision side ("less pain expected") mean (SD)** | **Mean difference [Incision-Non-incision] (95% Confidence Interval)** | **p-value from paired t-test** |
|---|---|---|---|---|
| Pain score 6 hours after operation | 4.3 (2.7) | 3.8 (2.4) | 0.6 (-0.9 to 2.1) | 0.44 |
| Pain score prior to removing pack | 4.2 (3.0) | 2.9 (2.4) | 1.2 (-0.2 to 2.6) | 0.08 |
| Pain score on removal of pack | 4.8 (3.0) | 3.4 (2.5) | 1.4 (0.1 to 2.6) | 0.03 |

Table 5. Bleeding scores.

| **Outcome** | **Merocel n (%)** | **Spiggle n (%)** | **p-value*** |
|---|---|---|---|
| **Grade of bleeding with pack in-situ** | | | > 0.99 |
| 0 - no bleeding | 20(100%) | 20(100%) | |
| 1 – less than 3 mins | 0(0%) | 0(0%) | |
| 2 – settled with ice | 0(0%) | 0(0%) | |
| 3 – required packing | 0(0%) | 0(0%) | |
| **Grade of bleeding after pack removal** | | | >0.99 |
| 0 - no bleeding | 19(95%) | 18(90%) | |
| 1 – less than 3 mins | 1(5%) | 2(10%) | |
| 2 – settled with ice | 0(0%) | 0(0%) | |
| 3 – required packing | 0(0%) | 0(0%) | |

*Comparing number with bleeding present/absent via McNemar test

Table 6. Crust and adhesion scores.

| **Outcome** | **Merocel n (%)** | **Spiggle n (%)** | **P-value*** |
|---|---|---|---|
| **Crust formation** | | | |
| 0 - absent | 19(95%) | 19(95%) | >0.99 |
| 1 – mild | 1(5%) | 1(5%) | |
| 2 – severe | 0(0%) | 0(0%) | |
| **Adhesions** | | | |
| 0 - absent | 20(100%) | 20(100%) | >0.99 |
| 1 – mild | 0(0%) | 0(0%) | |
| 2 – severe | 0(0%) | 0(0%) | |

*Comparing number with outcome present/absent via McNemar test

At six weeks, neither the Merocel pack side nor the Spiggle pack side was noted to have any adhesions.

*Adverse events*

No adverse events occurred for either pack during the study.

## DISCUSSION

*Interpretation*

A trial by Von Schoenberg compared pain levels in patients with packs and those without following nasal surgery [(2)]. During the first 24 hours of surgery the mean pain score in the non-packed group was 2.75 (compared to 4.2 in the packed group). In relation to this non-packed figure, the packed mean pain scores in our study were only slightly higher, particularly with regard to Merocel (3.3 and 3.1, at 6 hours and prior to removal respectively). This suggests that both packs were well tolerated while in the nose. Indeed, the morning after surgery, six Merocel and five Spiggle packs were reported as causing no discomfort whatsoever (visual analogue scores of zero).

The level of discomfort caused by the presence of each pack did not change significantly over time; the mean pain score the morning after surgery for each pack was only marginally lower compared to that recorded 6 hours after operation. One might have expected the scores to have dropped more substantially given that more time had elapsed since surgery. Interestingly, Buchanan et al did note a reduction in pain scores during the first 6 hours postoperatively [(4)]. The pain scores at 6 hours may therefore reflect attainment of a baseline level of pack discomfort.

There was no evidence of a difference between the Spiggle and Merocel packs in terms of discomfort experienced by the patient 6 hours after operation. Similarly, no significant difference was noted the following morning prior to removal (Table 3).

Significant differences between packs occurred during removal. The change in pain score between the times immediately before and immediately after pack removal was compared (Tables 3). The mean pain score during removal of the Merocel pack increased by 1.6 from 3.1 to 4.7 (an increase of 66%), whereas the mean change in pain score for Spiggle pack dropped by 0.4, a difference between treatments of 2 (95% CI 0.9 to 3.1, $p = 0.002$).

Comparing the two packs, the Merocel was on average 1.4cm more painful on removal, on the visual analogue scale, than the Spiggle pack (95% CI 0.4 to 2.4, $p = 0.005$) (Table 3). To

put this figure into context, Kelly found that the minimum *clinically* significant difference in VAS pain scores was 0.9cm [5]. The lower mean pain score associated with removal of the Spiggle pack may be attributable to its non-stick, latex-free cover allowing it to slide more easily out of the nasal cavity. In contrast, the Merocel has an open foam cell structure that may permit more mucosal adherence [6,7]. One might expect the newer 'Merocel 2000' nasal pack, with a non-stick polyethylene coating, to be associated with a lower mean pain score on removal. This pack was not evaluated in this study.

Both packs fulfilled their primary role of providing haemostasis while in position. Furthermore, there were no significant differences between the packs in terms of bleeding following pack removal and crust formation at six weeks. Neither pack was associated with adhesion formation during the follow-up period (Table 5 and 6).

*The literature*

It is interesting to note that our mean pain score on removal of the Merocel pack (4.7 of 10) is lower when compared with other studies evaluating packs after nasal surgery; Garth & Brightwell 1994 (6.0 of 10) [7], Shinkwin 1996 (50.72 of 100) [1] and Arya 2003 (5.6. of 10) [3]. There could be a number of reasons for this observed difference. It may relate to the type of nasal surgery performed, variation in soaking of packs prior to removal, the exact timing of removal or the technique of withdrawal. In the absence of standard deviations relating to these figures it is not possible to determine whether the apparent differences in mean pain scores between studies are statistically significant.

The mean pain score on removal of the Spiggle pack in our study (3.3 of 10) is higher when compared to the Rapid Rhino pack; Arya 2003 (Rapid Rhino Goodman pack=1.64 of 10) [3] and Cruise 2006 (Rapid Rhino Riemann=1.96 of 10) [8]. It does however appear to be better than Telfa; Von Schoenberg 1993 (Telfa=4.33 of 10) [2] and Cruise 2006 (Telfa=3.7 of 10) [8].

The highest mean pain score recorded on removal belongs to BIPP (7.3 of 10) [2]. This is likely to be related to the tightness and quantity of packing that is required with this method.

*Our study design*

Our study was purposely designed so that patients would act as their own controls rather than allocating one type of pack to a particular individual. We therefore avoided bias that would be incurred from differences in pain thresholds between individuals, variations in surgical and anaesthetic technique, differing analgesic requirements and psychological factors that can influence pain.

We used the visual analogue scale for pain scoring as it is widely used, easily understood by most patients and readily reproduced on successive presentations. Its ratio scale properties lend itself to statistical analysis unlike multidimensional pain scales.

It is feasible that removal of the first pack could have altered the subsequent perception of pain associated with removal of the second. For example, one might expect that following removal of the first pack the patient would be more 'psychologically' prepared to face removal of the second and so would report this pack as causing less pain. However, this bias was overcome by randomly assigning the packs to the nasal cavities and making certain that the person removing them did not preferentially choose to remove one first over the other. With regard to the latter, this could be ensured by either randomising pack removal or, as in our study, stipulating from the outset that the pack on the right side would always be removed first.

In our study 17 patients underwent surgery that involved a unilateral incision. One could quite rightly surmise that pain scores on the side of incision would be expected to be higher compared with the non-incised side. However, it has been shown that there is no significant difference in pain scores between the incised and non-incised sides on pack removal [9]. To verify this, we performed a similar analysis with our data set. We also evaluated the data obtained while the packs were in position. We found that, irrespective of the type of pack used, the differences between the incised and non-incised sides in terms of reported pain scores was not significant at 6 hours or immediately prior to removal (Paired t-test, $p = 0.44$ and $p = 0.08$ respectively; Table 4). However, on removal, the incised side was associated with a significantly higher mean pain score compared with the non-incised side (4.8 versus 3.4, $p = 0.03$). This is in contrast to the findings by Lavy [9]. Further analysis reveals that the Merocel pack was on the same side of the incision in 11 out of these 17 cases. Given the assumption that the incised side is associated with more pain we should interpret any data obtained during pack removal from this study with caution, as there is potential for bias in favour of the Spiggle pack. The overall estimate of effect (in this case, the mean difference in pain scores on pack removal) did ultimately favour the Spiggle pack by a magnitude of 1.4 out of 10cm on the visual analogue scale. Thus, if one is to be totally impartial we must conclude that there is insufficient evidence to state with certainty whether one pack was more painful on removal than the other.

*Our experience*

The Spiggle pack was more difficult to insert as it is packaged in non-compressed form. At first we tried compressing the two lateral sides of the pack but this tended to cause the pack to acquire a dumbbell shape that was difficult to insert. We ultimately settled on compressing the narrower top and bottom surfaces. This did allow easier insertion but the sides of the pack tended to rub against the septum medially and the nasal wall laterally. We would therefore expect it to cause more discomfort compared to compressed packs when being inserted in the non-anaesthetised individual, such as a patient presenting with acute epistaxis (Note: Spiggle & Theis do manufacture foam packs package in compressed form that would be more

suited to this clinical situation).

The evaluation of any new product being introduced into a health care system involves consideration of its cost. The packs used in this study differed slightly in price. The Merocel pack costs £2.94 compared with £2.51 for the Spiggle pack.

*Generalisability*

Our study purposely permitted the inclusion of any type of bilateral nasal surgery as we wanted the findings to be applicable to a broad target group. However, the vast majority of patients recruited underwent septal surgery. As a result, the generalisability of the findings of this study should be limited to patients having this type of intervention.

*Criticisms of our method*

The study could be criticised for not evaluating patients undergoing nasal surgery that would be more likely to be associated with bleeding or pain during the postoperative period, such as trimming of inferior turbinates or endoscopic sinus surgery. This would have been a sterner test of each packs haemostatic capabilities and comfort levels.

If a similar trial were to be designed in the future we would suggest stratifying randomisation to the incised and non-incised sides to obviate the risk of bias that could be incurred by not doing so.

## CONCLUSION

Both the Spiggle and the Merocel packs performed well in our study. They were well tolerated while in the nose and fulfilled their primary role of haemostasis. In our trial, the mean pain score on removal of the Merocel pack was lower compared to that reported in other studies. The Spiggle pack was associated with significantly less discomfort on removal. However, the result must be interpreted with caution as the Spiggle pack was more likely to be placed in the non-incised nasal cavity, the side generally expected to be associated with less pain on pack removal.

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