


## ORIGINAL RESEARCH

# Surgiflo<sup>®</sup> hemostatic matrix versus NasoPore<sup>®</sup> nasal packing following potassium titanyl phosphate laser surgery for hereditary hemorrhagic telangiectasia: A randomized controlled trial

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**Abstract**

**Background:** To help ensure adequate hemostasis immediately following potassium titanyl phosphate (KTP) laser treatment, many centres treating hereditary hemorrhagic telangiectasia (HHT) routinely use nasal packing post-operatively. The purpose of this study was to compare hemostatic thrombin matrix with standard packing for postoperative bleeding, patient pain, and comfort.

**Methods:** A prospective, randomized, double-blinded, non-inferiority study was conducted with participants at an HHT centre of excellence (COE) and randomized to the treatment group with reconstituted thrombin gelatin matrix (Surgiflo<sup>®</sup>) or control group with a biodegradable synthetic polyurethane foam (NasoPore<sup>®</sup>). Adult subjects with confirmed HHT and moderate to severe epistaxis (a minimum calculated epistaxis severity score [ESS] of 4.0) warranting KTP laser treatment were recruited. Data was collected 2 weeks post operatively by a blinded reviewer completing a visual outcomes evaluation and each patient completing a subjective symptoms questionnaire. Non-parametric statistical analysis was employed.

**Results:** Twenty-eight adult patients were randomized to the treatment and control arms with comparable preoperative epistaxis severity scores. Postoperative nasal bleeding was equivalent. Significantly less pain was found in the treatment arm ( $p = .005$ ). While there were trends towards less obstruction and increased satisfaction in the treatment group as well as less crusting in the control group, these findings were not statistically significant. Allocation to the treatment group was associated with an approximately \$75 higher cost.

**Conclusions:** When compared to NasoPore<sup>®</sup> for hemostasis, Surgiflo<sup>®</sup> hemostatic matrix performed equivalently while causing less discomfort in HHT patients following nasal KTP treatment.

**Level of evidence:** 1b.

**KEYWORDS**

epistaxis, hereditary hemorrhagic telangiectasia, nasal packing

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## 1 | BACKGROUND

Hereditary hemorrhagic telangiectasia (HHT) is an autosomal dominant dysplastic condition affecting approximately 1:10,000.<sup>1</sup> It is associated with abnormal development of blood vessels which can occur in the sinonasal, respiratory or gastrointestinal mucosa, the skin, and/or as arteriovenous malformations (AVMs) elsewhere in the body.<sup>2,3</sup> As these individuals often form abnormal capillaries, a fragile region between vein and artery develops that is more prone to rupture. This can manifest as potentially life-threatening hemorrhage with major bleeding (such as epistaxis) occurring quite frequently. By the age of 40, almost 100% of HHT patients are significantly affected by epistaxis.<sup>4</sup>

The potassium titanyl phosphate (KTP) laser has been implemented in the treatment of numerous otolaryngologic diagnoses, including recurrent respiratory papillomatosis (RRP) and HHT.<sup>5</sup> It involves passing a 1064-nm Nd:YAG source through a KTP crystal in order to emit frequency-doubled light at a wavelength of 532 nm. This wavelength corresponds with the absorption peak of oxyhemoglobin, making its application to mucosal blood vessels relatively specific.<sup>5</sup> Moreover, it has been shown to improve quality of life outcomes for those suffering from HHT.<sup>6</sup>

Due to the high risk of bleeding for HHT patients in the immediate postoperative period following KTP laser treatment, many centres treating this population employ nasal packing routinely. Reported side effects from nasal packing included crusting, pain, obstructed nasal breathing, infections, eustachian tube dysfunction and atrophy of the nasal mucosa.<sup>7-13</sup> Mahoney et al are proponents for postoperative nasal packing (absorbable material soaked with Bactroban).<sup>14</sup> On the contrary, Bergler et al. feel that no packing is necessary following argon plasma coagulation.<sup>15</sup> Jung et al. conducted a randomized controlled trial in 2014 comparing NasoPore<sup>®</sup> with fibrin sealant for postoperative packing following functional endoscopic sinus surgery in 35 patients. They found that there were no differences in bleeding occurrence postoperatively, but the NasoPore<sup>®</sup> group reported significantly more subjective nasal obstruction<sup>16</sup> as well as more granulation and crusting in the early stages of the study.

Nasal packing practices following laser surgery for HHT vary between centres.<sup>1,17</sup> While some rhinologists may favor no nasal packing after these procedures, our experience in the early phase of the KTP laser treatment program demonstrated moderate to severe bleeding immediately following extubation which required intervention with intranasal hemostatic agents in all cases. As such, at our institution, which is an HHT centre of excellence (COE), the standard of care includes NasoPore<sup>®</sup> nasal packing as postoperative treatment following KTP treatment of intranasal HHT to maintain hemostasis in the early postoperative epistaxis. While better tolerated than non-resorbable packing, during the post-operative period, patients have complained of the associated nasal obstruction as well as the discomfort associated with debridement of persistent packing.

Surgiflo<sup>®</sup> Hemostatic Matrix is a Health Canada approved treatment option that is already in use hemostasis in several hospital settings,<sup>18-20</sup> including uncomplicated anterior epistaxis.<sup>21</sup> Surgiflo<sup>®</sup>

reconstituted thrombin matrix is a combination of a flowable gelatin matrix and human thrombin that accelerates the formation of a platelet plug and aids in fibrin and clot formation. It allows precise placement and conforms to tissue providing a tamponade effect. Surgiflo<sup>®</sup> builds on a patient's natural coagulation cascade as the thrombin component of Surgiflo<sup>®</sup> acts as a catalyst, activating the patient's endogenous fibrinogen and accelerating fibrin clot formation. A recent study found that non-HHT patients preferred recombinant thrombin for controlling hemorrhage in comparison to traditional nasal packing based on comfort and pain measures.<sup>21</sup> Further, the consistency of the gelatin matrix compared to the polyurethane foam may be less uncomfortable to debride postoperatively.

There is a paucity of data evaluating the comfort and complication rate of Surgiflo<sup>®</sup> compared with NasoPore<sup>®</sup> when used for postoperative packing following laser treatment of HHT. This study aimed to compare a hemostatic human thrombin matrix with NasoPore<sup>®</sup> packing following KTP Laser surgery in the HHT patient population.

## 2 | METHODS

### 2.1 | Design and participant selection

A prospective, randomized, double-blinded non-inferiority study design was conducted at the University of Alberta Hospital in Edmonton, Alberta, Canada. Adult subjects were recruited who had been diagnosed with HHT, were referred to an otolaryngologist—head and neck surgeon for KTP laser treatment, and had a minimum calculated epistaxis severity score (ESS) of 4.0 (Figure 1). Subjects were excluded if they were on any anticoagulation medication, if they had a diagnosis of a bleeding dyscrasia(s), and if they had signs of active infection at the time of surgery. Only one side of the septum was operated on per procedure as per standard of care to minimize the risk of septal perforation. The control group consisted of those whose nose was packed with NasoPore<sup>®</sup>, and a standard 8 cm piece of material was utilized. The treatment group consisted of those who were packed with Surgiflo<sup>®</sup>. This is distributed in a standard size of 8 mL, and this is the dosing which was used in the study.

### 2.2 | Participant numbers

To obtain our cohort numbers, an ad hoc power calculation was performed assuming a non-inferiority study with a power of 0.80 and non-inferiority limit of 15% and alpha of 0.05 giving us a sample size of 28 (14 per group).

### 2.3 | Procedure

Participants were block randomized with allocation revealed only to a third-party individual who was not part of the patient treatment process to ensure double blinding. Once the laser portion of the

Question	Response	Multiplied by:		Coefficient	Result
1	Less than monthly	0	x	0.14 (0.70 Den)	
	Once per month	1			
	Once per week	2			
	Several per week	3			
	Once per day	4			
Several per day	5				
2	< 1 minute	0	x	0.25 (1.00 Den)	
	1-5 minutes	1			
	6-15 minutes	2			
	16-30 minutes	3			
	> 30 minutes	4			
3	No	0	x	0.25 (0.25 Den)	
	Yes	1			
4	No	0	x	0.30 (0.30 Den)	
	Yes	1			
5	No	0	x	0.20 (0.20 Den)	
	Yes	1			
6	No	0	x	0.31 (0.31 Den)	
	Yes	1			
TOTAL =				Denominator (Sum Den)	Raw Score

**FIGURE 1** Epistaxis severity score table. The color spectrum at the bottom demonstrates highlights the range of scores required for a participant to be eligible to take place in the study.

$$\text{Normalized HHT-ESS} = \left[ \frac{\text{Raw Score}}{\text{Denominator (2.71)}} \right] \times 10$$



procedure was completed, the primary surgeon exited the room, and the OHNS resident placed the nasal packing material according to the subjects allocation on the operated side, the procedure was concluded, and a standard postoperative course was resumed. All patients were discharged home from hospital on the day of surgery.

Participants were seen in follow-up approximately 14 days after their procedure. During this visit, the subject's nose was examined, debrided and data collection was conducted on objective measures questionnaire based on the domains of adhesions, bleeding, crusting, infection, and granulation (Appendix S1). This was adapted from previous literature<sup>16,21-26</sup> and modified to fit this study. The questionnaire was based on an ordinal scale from 0 (none/absent) to 3 (severe/gross). Each participant was then asked to fill out a subjective comfort measures questionnaire (Appendix S2) based on the domains of pain affecting behavior, pain following the procedure, pain during packing debridement, facial pressure, nasal obstruction, nasal bleeding, and general satisfaction. This was also adapted from previous publications on patient reported pain scales.<sup>17,27</sup> The behavioral rating aspect of the questionnaire was based on a categorical scale ranging from no pain (scaled as 0) and pain present, cannot be ignored, rest or bedrest required (scaled as 5). A box scale from 0 (being the least) and 10 (being the worst) was utilized for the domains of pain following treatment (0-14 days after surgery), pain during packing removal,

facial pressure, nasal obstruction, and nasal bleeding. For the domain of general satisfaction, the 0-10 same box scale was used, however 10 represented the most satisfied whereas 0 represented the least satisfied. This was clarified with the participant prior to completion of the questionnaire. The subject did not view the questionnaire until after the debridement had taken place. Our primary endpoint of hemostasis following nasal packing was determined via the patient questionnaires.

### 2.4 | Statistical analysis

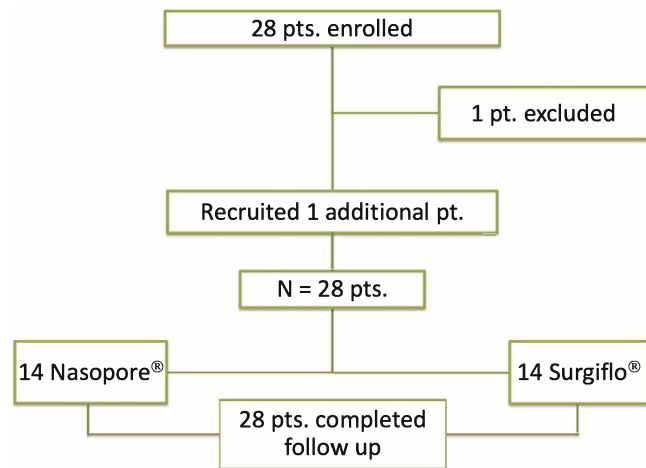
For statistical analysis, we performed an independent samples *t*-test to compare demographics and subjective and objective outcomes. This was done utilizing SPSS® statistics version 25 (IBM, Armonk, NY). A *p*-value of less than .05 was considered statistically significant.

## 3 | RESULTS

A total of 28 subjects were initially recruited in rolling fashion. One subject had to be removed from the pool due to active infection noted at the time of surgery thus an additional subject needed to be

recruited. This yielded a total of 14 subjects per cohort (Figure 2). The two groups were similar in terms of their demographics with no significant differences observed. Further, both groups had similar epistaxis severity scores. There was one notable bleeding episode reported which occurred after a subject in the Floseal® group blew his nose aggressively - despite preoperative counseling - and removed his packing himself before follow-up due to discomfort. This bleed was self-limiting and did not require further packing or medical intervention (Table 1).

Visuals depicting the preoperative intranasal mucosa as well as post-KTP treatment, post-Nasopore® packing and post-Surgiflo® placement are detailed in Figure 3A–D. In terms of the objective measures questionnaire, there were higher scores for adhesions, bleeding and crusting in the control group while the treatment group had greater scores for local infection and granulation. However, these relationships were not significant (Table 2). On review of the subjective comfort measures questionnaire, there were trends towards lower pain scores in the treatment group, although this was only perceived as significant in the behavioral rating scale (1.50 vs. 0.5,  $p = .005$ , CI 0.34–1.66). There were no differences observed between the two groups for facial pressure, nasal obstruction, and general overall satisfaction (Table 3).



**FIGURE 2** Participants who underwent laser treatment for intranasal hereditary hemorrhagic telangiectasia.

**TABLE 1** Participant demographics.

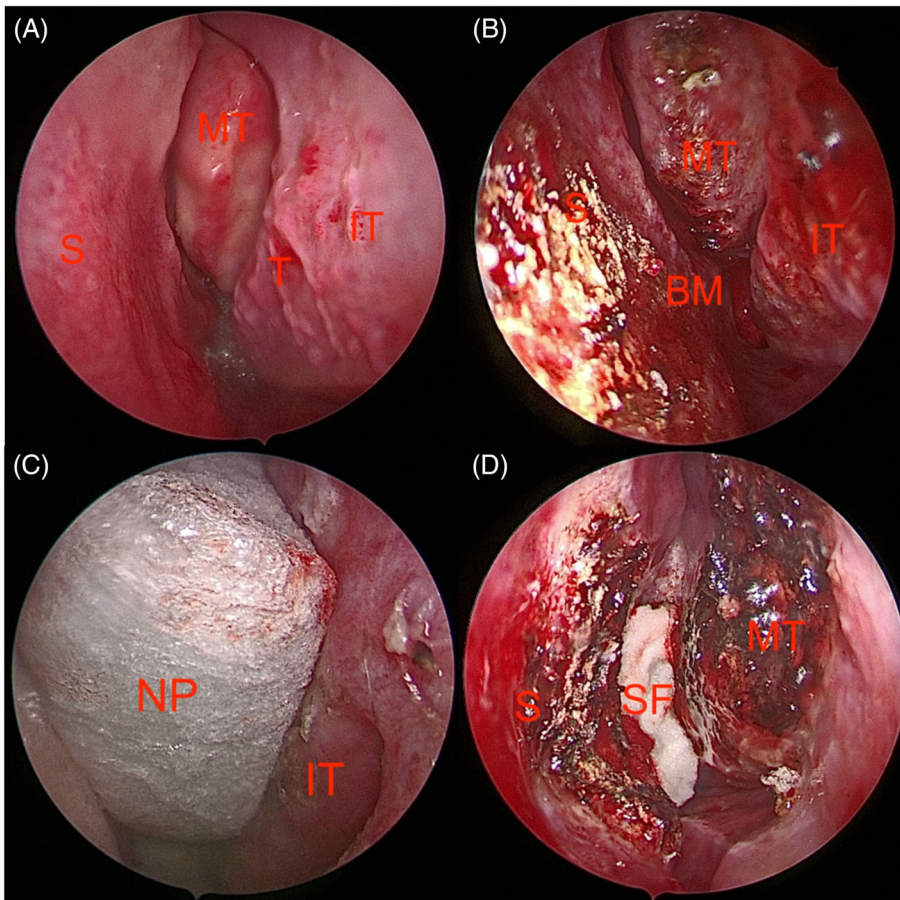
Variable	Total	NasoPore®	Surgiflo®	p	CI
Age, years (mean)	54.54	56.57	52.5	.49	–7.96 to 16.10
Sex (M/F)	15/13	7/7	8/6	.7	–0.45 to 0.30
ESS (mean)	5.84	5.97	5.71	.67	–0.98 to 1.49
Days to follow-up (mean)	16.64	18.71	14.57	.15	–1.57 to 9.85
Major complication (mean)	0.04	0	0.07	.31	–0.22 to 0.076
Minor complication (mean)	0	0	0	1	-

Abbreviation: CI, confidence interval for difference in means between groups; F, female; M, male.

## 4 | DISCUSSION

While several treatment options exist for the management of HHT epistaxis, it remains a difficult and challenging diagnosis for the clinician and the patient. Initial management methods include nasal humidification, topical creams, and barrier creams.<sup>28</sup> On the more radical end of the treatment spectrum, the Young's procedure, involving complete nasal closure has been performed in select cases, with patients reporting good control of epistaxis, and no effect on quality of life in terms of sleep or nasal obstruction, however the patient does lose the ability to breathe through the nasal passage.<sup>29</sup> Given the frequency of epistaxis, HHT patients typically undergo frequent nasal packing which is understandably associated with pain and discomfort. KTP laser for treatment of intranasal telangiectasias associated with moderate to severe epistaxis has yielded significant benefit for patients as they can avoid nasal packing, transfusion, hospitalization and more aggressive interventions for longer periods of time. A retrospective review of 64 patients who underwent laser treatment for HHT was conducted by Richmon et al. in 2007 comparing the use of sprayed fibrin matrix with traditional nasal packing (majority with Merogel®, INSTAT®, Surgisis®, Epistat®, RapidRhino® or Vaseline® Gauze for the rest). The authors found that 20% of the postoperative nasal packing group required readmission to hospital compared with just 3% in the fibrin sealant group ( $p = .04$ ), with an average cost of \$5914 per stay.<sup>30</sup> Additionally, the fibrin sealant group reported improved a higher level of comfort postoperatively. There were no reported bleeding complications.

We aimed to investigate the use of a potentially more comfortable post-operative nasal packing material by implementing a recombinant thrombin gelatin matrix instead of the standard bioresorbable foam. Yu et al. examined the use of a fibrin sealant and its effect on hemostasis and wound healing in comparison to polyvinyl acetyl sponge packing following functional endoscopic sinus surgery in a randomized controlled trial. They found that granulation, crusting, and the amount of bleeding and pain during debridement were lower for the fibrin group compared with the acetyl sponge group, and that the former had a higher degree of general satisfaction.<sup>25</sup> While our hypothesis was correct in that similar rates of postoperative bleeding were observed between the two groups, participants indicated a similar degree of comfort based on their questionnaire scores. Given that the treatment group had a significantly lower level of pain based on behavioral scores, and there were trends



**FIGURE 3** (A) Endoscopic intranasal view of left nasal cavity. IT, inferior turbinate; MT, middle turbinate; S, septum; T, telangiectasia. (B) Endoscopic intranasal view of left nasal cavity following KTP laser treatment. BM, bleeding mucosa; IT, inferior turbinate; MT, middle turbinate; S, septum. (C) Endoscopic intranasal view of left nasal cavity post-KTP laser treatment with NasoPore® nasal packing. IT, inferior turbinate; NP, NasoPore®. (D) Endoscopic intranasal view of left nasal cavity post-KTP laser treatment with Surgiflo® placement. MT, middle turbinate; S, septum; SF, Surgiflo®.

Variable (mean)	Total	NasoPore®	Surgiflo®	p	CI
Adhesions	1.61	1.79	1.42	.23	-0.16 to 0.88
Bleeding	1.04	1.21	0.86	.27	-0.17 to 0.89
Crusting	1.57	1.64	1.5	.77	-0.58 to 0.87
Infection	0.14	0.07	0.21	.5	-0.61 to 0.32
Granulation	1.29	1.14	1.43	.18	-0.75 to 0.18

Abbreviation: CI, confidence interval for difference in means between groups.

Variable (mean)	Total	NasoPore®	Surgiflo®	p	CI
Pain following treatment	1.43	1.71	1.14	.48	-1.06 to 2.20
Pain during debridement	1.79	1.93	1.64	.72	-1.31 to 1.88
Pain (BRS)	1	1.5	0.5	.005	0.34-1.66
Facial pressure	2.5	2.5	2.5	1.00	-2.71 to 2.71
Nasal obstruction	5.5	6.14	4.86	.34	-1.42 to 3.99
Nasal bleeding	2.29	2.57	2	.53	-1.27 to 2.41
General satisfaction	7.04	6.79	7.29	.64	-2.64 to 1.64

Abbreviation: CI, confidence interval for difference in means between groups.

towards lower pain following treatment and debridement, it is reasonable to suggest that these findings indicate an improved degree of comfort as well.

The debate surrounding debridement of the nasal cavity at some point during the postoperative period following intranasal surgery appears to be ongoing.<sup>31-33</sup> While most studies are cases series

**TABLE 2** Visual questionnaire results comparing mean scores between groups.

**TABLE 3** Comfort questionnaire results comparing mean scores between groups.

and/or retrospective reviews, a randomized controlled trial by Bugten et al. suggests that debridement of the nasal cavity following endoscopic sinus surgery is crucial to reduce the amount of crusting and fibrin clot, and subsequent adhesions that could otherwise arise.<sup>34</sup> Further, a systematic review examining nasal debridement following functional endoscopic sinus surgery highlighted that most studies showed that there was no observed difference between debridement and no debridement, but that the investigations by Bugten were the only literature that showed an improvement in visual analogue scores with the former.<sup>35</sup> However, Bugten did not place absorbable packing into the nasal cavity, rather allowed the mucosa to heal and achieve hemostasis independently.<sup>34</sup>

In terms of limitations, we recognize that the Surgiflo<sup>®</sup> treatment is approximately \$75 Canadian dollars more than the NasoPore<sup>®</sup> treatment. While we did not conduct a formal cost analysis, one may argue that the added decreased pain benefit of the former outweighs the down side of added cost. During our review, we did not identify any studies within the literature describing debridement following epistaxis treatment. However, the role for debridement in the setting of HHT patients following nasal KTP laser surgery is to improve nasal airflow as well as prevent the formation of intranasal synechiae, which has been known to occur after placement of nasal packing materials following nasal surgery.<sup>36</sup>

Patients have reported significant pain and bleeding during the debridement procedure, which has been observed in our institution as well. While methods to decrease this pain burden such as topical anesthetic and good nasal hygiene following surgery until follow-up may be beneficial, our hope was that a more fluid-like material would help to alleviate this further. Various factors such as patient pain tolerance and amount of topical anesthetic may have contributed to this, however we would have expected this to affect all pain measures equally.

## 5 | CONCLUSION

In conclusion, this is the first reported study investigating recombinant thrombin matrix for post-operative nasal packing following KTP laser treatment of intranasal HHT. When compared to NasoPore<sup>®</sup> for hemostasis, Surgiflo<sup>®</sup> hemostatic matrix performed equivalently while causing less discomfort in HHT patients following nasal KTP treatment. Future study may include a longer follow-up period to evaluate any late presenting sequelae within each group.

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### CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to disclose.

### DATA AVAILABILITY STATEMENT

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

### CONSENT FOR PUBLICATION

Consent for publication has been obtained from individual subjects where necessary.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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