

A novel Kaolin-coated surgical gauze improves hemostasis even in presence of anticoagulation

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Abstract

Background: Bleeding is a major indicator of morbidity and mortality in surgery and the wide spread use of anti-coagulation has raised the risk associated with surgical procedures. We introduce a novel kaolin-coated hemostatic surgical gauze and we evaluate its efficacy in controlling bleeding in normal and anticoagulated hosts. **Methods:** In vitro testing employed free kaolin (n=36) and kaolin-coated gauze (n=15) in a modified PT test. In vivo studies in pigs were conducted in normal clotting animals (n=10) and in animals treated with Plavix (n=5) and Coumadin (n=5). A model of severe bleeding injury was employed including: liver (n=15) and spleen (n=13) lacerations, mesenteric injury (n=11) and complete femoral artery and vein transection (n=7). Standard surgical gauze was used as control (n=10) and complete clotting within 5 minutes was compared. Finally, the kaolin gauze was tested for efficacy and safety in 66 human pediatric adeno-tonsillectomies and 7 cases of epistaxis. **Results:** Both kaolin alone and kaolin-coated gauze significantly decreased clotting time in vitro when compared to untreated control blood (2.7 ± 0.11 vs. 10.92 ± 0.30 minutes $p < 0.001$ and 1.88 ± 0.15 vs. 10.92 ± 0.30 minutes $p < 0.0001$, respectively). In vivo the novel gauze controlled bleeding in 100% injuries within 1-5 minutes in normal clotting animals and is significantly superior to standard surgical gauze in anticoagulated hosts. Excellent hemostasis was also achieved following 66 pediatric adeno-tonsillectomies and epistaxis. **Conclusion(s):** Kaolin-coated gauze offers outstanding efficacy in controlling bleeding even in presence of severe anticoagulation and represents a promising new therapeutic choice for surgeons.

Introduction

The aim of this study is describe the clinical experience using a Kaolin-based hemostatic gauze in surgical procedures of oropharynx and nose.

Material and Methods

Kaolin-Gauze:

- patients undergone adenoidectomy and tonsillectomy
- patients with epistaxis and resection of nasosinusual tumor.

Safety and Efficacy:

- **Oropharynx Intraoperative:** time to hemostasis, hemostatic success (defined as cessation of bleeding within 10 minutes), operative time, intraoperative blood loss (it was estimated assuming that 1 mL of blood weighs 1 g).
- **Recovery:** throat pain, vomit, oral and intravenous analgesis doses, time to first drink (h), time to normal diet, edema peritonsillar.
- **Nasal cavity:** time to control epistaxis, uni or bilateral nasal packs, duration of nasal packs, recurrence of epistaxis.

Patient Demographics

	Oropharynx	Nasal Cavity
Age, mean \pm SD	6.8 \pm 3.5	46.1 \pm 18.6
Male	43	3
Female	47	4
Indications	Adenotonsillar chronic and hypertrophic	<ul style="list-style-type: none"> • Epistaxis • Epistaxis post septoplasty • Resection naopharyngeal angiofibroma

Results

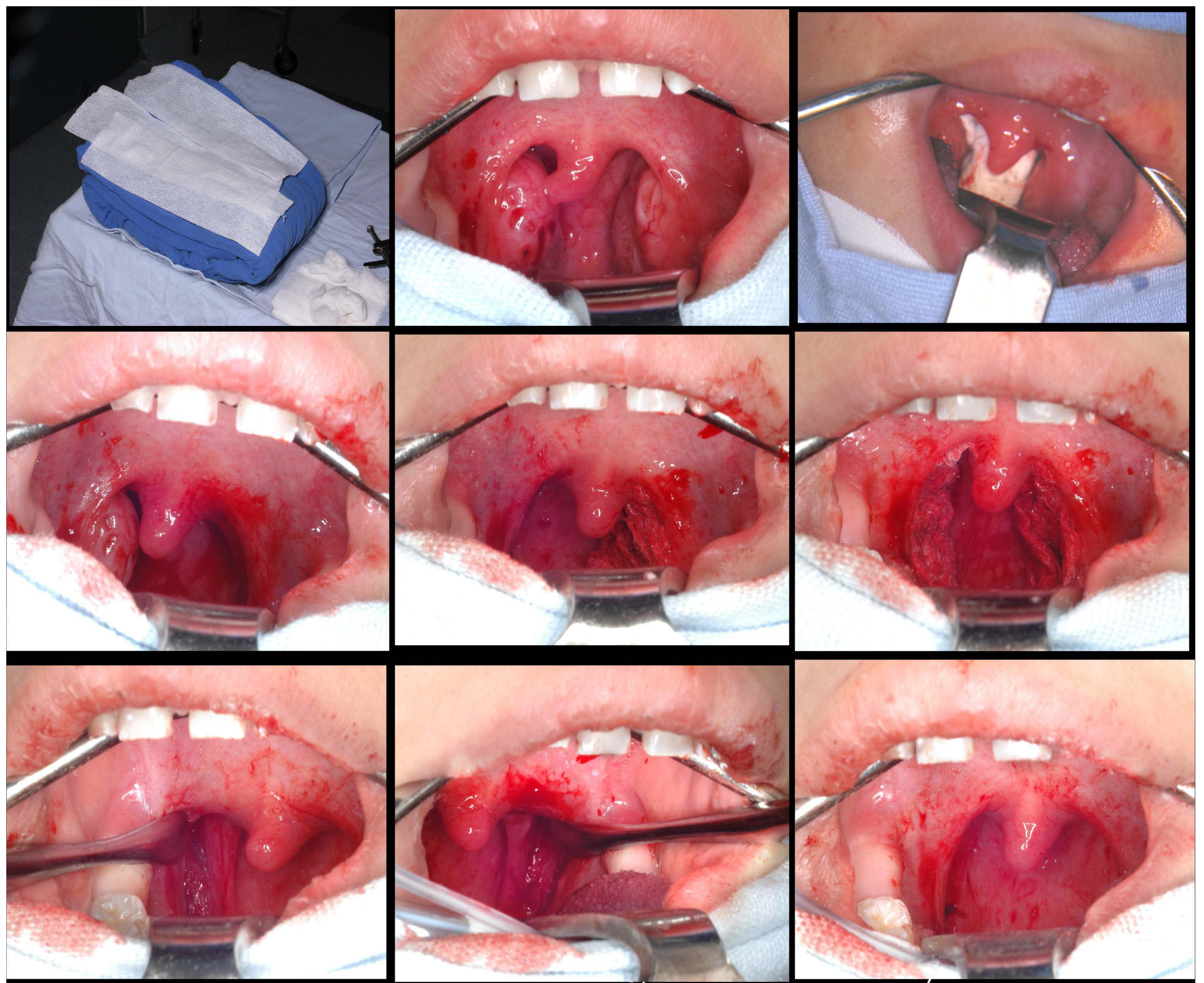
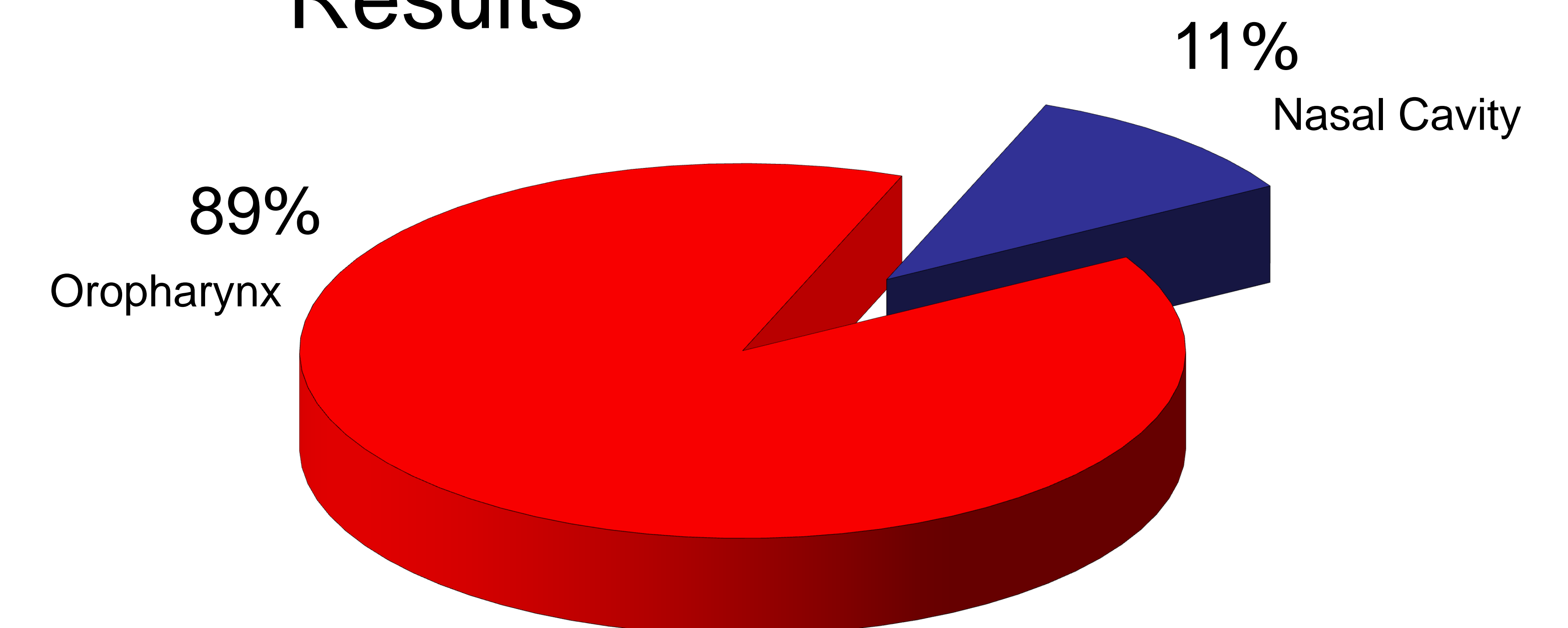


Figure 1. Bleeding control following Kaolin-gauze application during adenoidectomy and tonsillectomy. The photographs shown minor blood during the surgery. The tonsil bed after 3 minutes of application of kaolin-gauze looks clean. There is no evidence of alterations on adjacent structures.

Kaolin-Gauze Hemostatic effects

Adenoidectomy and Tonsillectomy Measures	
Intraoperative	
Bleeding Control	
3 min	73%
5 min	27%
Time the hemostasis	
1 to 10 min (complete hemostasis)	85%
11 to 15 min	15%
Surgery time, min	19.1 ± 3.5
Intraoperative blood loss (ml.)	36.5 ± 11.2
Recovery *	
Pain	65%
Vomit	6%
Mean oral analgesic doses	2.0 ± 0.6
Mean intravenous analgesic doses	1.3 ± 0.5
Time to first drink, h	3.3 ± 1.5
Time to first steps, h	6.2 ± 1.9
Peritonsillar edema, very slight	75.7%
Mean, days near normal diet	2.9 ± 0.9
* 18-hours hospital stay	

In vivo hemostasis in anti-coagulated animals

•Kaolin-gauze vs Control

•Coumadin Pigs n=5

INR 3.2-12.4

	Pass	Fail	Total
•Test	52	3	55
•Control	9	29	38
•Total	61	32	93
•Chi-Sq =	7.030 + 13.400 + 10.175 + 19.395 = 50.000		
•DF = 1, P-Value = 0.000			

Kaolin-gauze vs Control

•Plavix Pigs n=5

	Pass	Fail	Total
•Test	52	5	57
•Control	11	26	37
•Total	63	31	94
•Chi-Sq =	4.984 + 10.128 + 7.677 + 15.602 = 38.391		
•DF = 1, P-Value = 0.000			

Treatment effect on nasal cavity

Control epistaxis	%
3 min	72
5 min	28
Anterior nasal packs	
Unilateral	57
bilateral	43
Duration nasal pack	
0-24 h	15
2-5 days	57
6-8 days	28
Recurrence Epistaxis	0

Conclusions

In our experience the use of kaolin-gauze to control bleeding during tonsillectomy and following epistaxis was superior to conventional methods (manual compression, ligature). The kaolin-gauze is safe and its efficacy was demonstrated by achieving immediate hemostasis, maintaining the operative field clean, reducing operating time and intraoperative blood loss. In addition, using the kaolin-gauze allowed faster pain control, diet introduction and maintained peritonsillar edema low. Also, using the kaolin-gauze within the nasal cavity following epistaxis was safe and achieved the desired hemostatic effect very quickly. Finally, pre-clinical data also show that the kaolin-gauze is superior in controlling bleeding in anti-coagulated hosts (Plavix and Coumadin) when compared to standard surgical gauze.

In conclusion, these findings in surgical procedures of the oropharynx and nasal cavity support the use of the kaolin-gauze in ENT procedures and make it an excellent candidate for surgical hemostasis overall.

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