

# Multi-center, Comparative Clinical Assessment of Products for Hemostasis and Wound Healing in Endoscope Sinus Surgery

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## ABSTRACT

**Objective:** To assess the efficacy in endoscopic sinus surgery (ESS) in tissue healing and symptom improvement of three products indicated for this application; BloodSTOP<sup>®</sup> iX Hemostatic Matrix, SURGICEL<sup>®</sup> Absorbable Hemostat, and Vaseline<sup>®</sup> gauze strip.

**Materials and Methods:** Post-ESS surgery assessments were conducted on patients presenting with chronic sinusitis and nasal polyps type-II (II term). All patients were treated via the Messerklinger (1997) operative procedure<sup>1</sup>. Follow-ups were primarily performed within 3-6 months post-op (in some instances, the follow-up period was >1 year). A total of 218 patients (318 sides), 153 male and 65 female were enrolled, ranging from 11 to 62 years with an average age of 36.5 yrs. 72 were single-sided and 146 were dual-sided nasal cavities. Cases were randomly divided into three groups according to the materials applied post-surgery: Group A: BloodSTOP<sup>®</sup> iX Hemostatic Matrix (LifeScience PLUS, Inc.); Group B: Surgicel<sup>®</sup> Absorbable Hemostat (Johnson & Johnson); Group C: Vaseline<sup>®</sup> gauze strip. Evaluations of the materials for efficacy of healing and symptom management were performed following the ESS curative standard (1997)<sup>2</sup>.

**Results:** The incidence of Grade I healing (84%) of Group A was much higher than the other two groups (65%); the number of Grade III healing was much lower than the other two, P<0.05. The other two groups are similar to each other, P<0.057. The incidence of Grade I symptom improvement of Group A is much higher than the other two, P<0.05, the second degree of it is much less than the other two groups P<0.017. Group B&C are similar P<0.05.

**Conclusions:** BloodSTOP<sup>®</sup> iX Hemostatic Matrix demonstrated the ability to improve the formation of epidermal tissue and healing following ESS, improve the symptoms and reduce the frequency and intensity of post-surgical medical management. Per these metrics, BloodSTOP<sup>®</sup> iX yielded superior results to the other materials tested.

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<sup>1</sup> Endoscopy of the Nose, Messerklinger, W., 9780806712116, <https://books.google.com/books?id=fr1sAAAAMAAJ>, 1978, Urban & Schwarzenberg

<sup>2</sup> Branch of Chinese Medical Society of Otolaryngology, ENT Journal Editorial Board. Chronic sinusitis, nasal polyp type and stage of clinical evaluation standard endoscopic sinus surgery (1997, Haikou) [J]. Journal of Otolaryngology Journal, 1998, 33 (3): 134.

## **1. Introduction**

ENT surgeons commonly use Surgicel<sup>®</sup> Hemostat and Vaseline<sup>®</sup> gauze strips in the management of the post-ESS surgical patient. The procedure typically requires 5 – 7 post-surgical cleaning and debridement processes of the nasal cavity. Having used an etherified, oxidized regenerated cellulose material (BloodSTOP iX) for hemostasis and wound healing in other indications, it was the authors' objective to determine the efficacy of that material in ESS applications. A review of the literature revealed no prior publications referencing these materials, leading the authors to develop this comparative study.

Utilizing a consistent protocol, data were collected from multiple medical centers from 2000-2003. A total of 218 patients (318 sides) with chronic sinusitis, type-II nasal polyps (II term) and recurrent nasal polyps were treated. Cases were randomly assigned to receive one of the three materials noted. Post-surgical follow ups were conducted over a 3-6+ month period. The primary assessments were tissue healing and symptom improvement.

## **2. Materials and methods**

### **2.1 Clinical information:**

A total of 218 patients (318 sides), 153 male and 65 female, aging from 11 to 62 yrs with average age of 36.5 yrs. 72 single side nasal cavity, 146 dual side nasal cavity. All patients classified as chronic Sinusitis and Nasal Polyps type-II (II term) according ESS (1997) clinic standard, totaling of 318 sides nasal cavity operations, were randomly organized into three groups as Group A (BloodSTOP<sup>®</sup> iX Matrix), Group B (Surgicel<sup>®</sup> Hemostat), and Group C ( Vaseline<sup>®</sup> gauze strip).

### **2.2 Treatment method:**

All patients were treated with Messerklinger (1997) operation procedure. Three different materials were applied in nasal cavity post-op. Images were taken one-month post the surgery.

**2.2.1 Post-surgery Group A (BloodSTOP<sup>®</sup> iX) (LifeScience PLUS, Inc.):** In the first week post-op, except for the use of antibiotics, only regular nasal-mirror observations were required. All patients used 0.9% saline to wash nasal cavities daily for 15 days. Endoscopic exams at one month revealed very little residue of BloodSTOP<sup>®</sup> iX. Follow-up endoscopy at 2-3 months revealed, 95% of epidermis of nasal sinus had epithelium; 5% of patients had minor swelling. All sinuses opened well, there was minor secretion and no blood significant scab or crust formation. There were no reports of pain, headaches or sense of distension within eyes.

**2.2.2 Post-surgery Group B (Surgicel<sup>®</sup> Hemostat) (Johnson & Johnson) –** During the first week post-op, cleaning once with endoscope was required to remove clots, crusted blood and some Surgicel residue. Nasal protein mucous secretions, significant bloody secretions and partially-dissolved gauze were found. Nasal cavities and sinuses were

generally swollen and unable to open well. Local anesthesia with 2% lidocaine was utilized applied in order enable the removal of the debris without significant discomfort to patients. Dressing changes were generally required 5-6 times within the 3 month post-op period.

**2.2.3 Post-surgery Group C (Vaseline®)** - The Vaseline-regular gauze strip, in all instances, required removal within three days post-op due to swelling and tendency for the swollen tissue to adhere to other tissues within the nasal cavity. This required cleaning of affected tissues within 72 hours post-op. Daily dressing changes were required in an effort to minimize this effect. Endoscopic cleaning at one week was required to remove bloody secretions, newly formed polyps, and mucous secretions. Endoscopic cleaning was generally required 5-6 times in the subsequent 2-3 month post-op period. Most patients were antibiotic injections for 3-7 days followed by an oral antibiotic regimen for 2 weeks. Daily 0.9% saline rinse was ordered in most instances.

## **2.3 Evaluation Standards**

### **2.3.1 Healing Evaluations**

According to the endoscope exam in three months after the operation, the healing can be classified as 3 grades.

I: healed, the operated cavity epidermis of nasal sinus had epithelium, there were no secretions.

II: healing, most part of the operated cavity epidermis of nasal sinus had epithelium, has some chronic infection or small amount secretions.

III: symptoms have recurred, operated cavity had polyp-type mucous membrane swelling, there is large amount of secretions, sinus or operated cavity is closed.

### **2.3.2 Symptom Improvement Evaluations**

According to the symptom improvement of patients, it classified as 4 grades:

I: very satisfied, all symptoms disappeared, nasal cavity opens and smells well

II: satisfied, 75% symptoms disappeared

III: some satisfied, 50% symptoms have been disappeared

IV: not satisfied, the symptoms have not been improved.

### 3. Results:

**Table 1: Healing evaluations:**

Group	Cavities	Grade I (%)	Grade II (%)	Grade III (%)	Post-op total washings
<b>A</b> (BloodSTOP® iX)	118	99 (84.0)	17 (14.4)	2 (1.7)	0-2
<b>B</b> (Surgicel® Hemostat)	120	78 (65.0)	33 (27.5)	9 (7.5)	50
<b>C</b> (Vaseline® Gauze)	80	52 (65.0)	21 (26.3)	7 (8.75)	50

The incidence of Grade I healing (84%) of Group A was much higher than the other two groups (65%); the number of Grade III healing was much lower than the other two,  $P < 0.05$ . The other two groups are similar to each other,  $P < 0.057$ .

**Table 2: Symptom improvement evaluations:**

Group	Cavities	Grade I (%)	Grade II (%)	Grade III (%)	Grade IV (%)
<b>A</b> (BloodSTOP® iX)	118	108 (91.5)	10 (8.5)	0 (0)	0 (0)
<b>B</b> (Surgicel® Hemostat)	120	88 (73.3)	28 (23.3)	4 (3.5)	0 (0)
<b>C</b> (Vaseline® Gauze)	80	62 (85.0)	8 (10.0)	4 (5)	6 (7.5)

The incidence of Grade I symptom improvement of Group A is much higher than the other two,  $P < 0.05$ , the second degree of it is much less than the other two groups  $P < 0.017$ . Group B&C are similar  $P < 0.05$ .

**4. Conclusions:** The therapeutic efficiency of Group A demonstrated comparatively favorable results for healing and symptom improvement than Groups B and C. As well, Group A required considerably less daily maintenance and medical management than the other groups

BloodSTOP® iX Hemostatic Matrix demonstrated the ability to improve the formation of epidermal tissue and healing following ESS, improve the symptoms and reduce the frequency and intensity of post-surgical medical management.