

NexStat® Topical Hemostat in Endoscopic Sinus Surgery

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Purpose:

Hemostatic products and nasal packing are routinely used for bleeding control after endoscopic sinus surgery. NexStat topical hemostatic powder is a novel agent to control bleeding in the nasal cavity. This study examines the safety and efficacy of NexStat topical hemostatic powder after endoscopic sinus surgery.

Methods:

50 adult patients undergoing traditional bilateral or unilateral endoscopic sinus surgery were enrolled in the trial. A total of 89 topical applications of the product were examined. 29 patients (58%) were male and 21 patients (42%) were female. The average age of the participants was 44.66 (20-84 years old).

NexStat was applied at the conclusion of the procedure. Endoscopic observation for breakthrough bleeding was assessed after 5 minutes. Patients were then assessed at 1 post operative day and again at 14 post operative days +/- 7 days for bleeding and/or adverse events.

Results:

Hemostasis without breakthrough bleeding at 5 minutes was achieved in 81 of 89 applications (91%). On day 1 and 14 post surgery, patients were asked to self-report bleeding on a scale from 0-10, 0 representing no bleeding, and 10 representing severe or constant bleeding. On day 1, patients reported an average score of 2.25 of 10. On day 14, patients reported an average score of 0.68 of 10. No patients reported severe or constant bleeding requiring medical intervention at either time interval. Self reported data was not obtained in 5 applications.

Patients were physically assessed at 14 days post surgery for nasal inflammation, scar tissue formation, and post-operative infections. Nasal

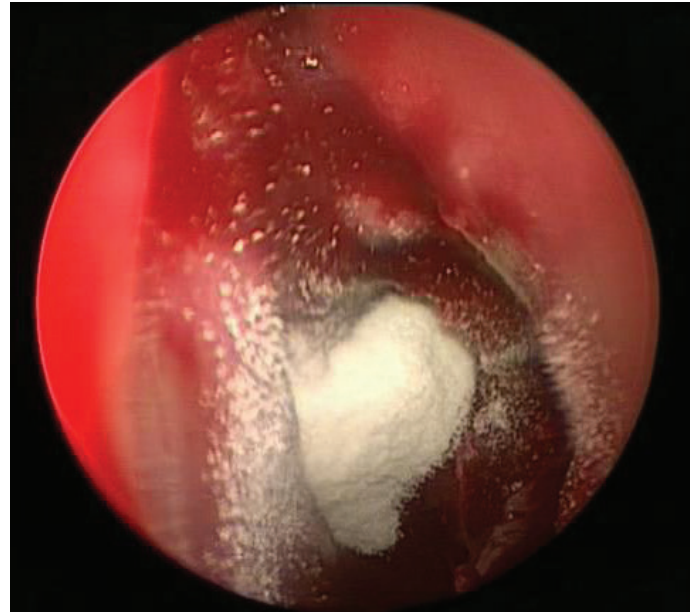


Figure 1: NexStat applied to the middle meatus of left nasal cavity

inflammation was categorized as none, mild, moderate, and severe. 19 cases (21.3%) were reported as none. 52 cases (58.4%) of applications were reported as mild. 18 cases (20.2%) were reported as moderate. No cases were reported as severe. Presence of scar tissue was categorized as none, mild, moderate, and severe. 80 cases (89.9%) were reported as none. 9 cases (10.1%) were reported as mild. No cases were reported as moderate or severe. The nasal cavity was assessed for the presence or absence of post operative infections. 87 cases (97.8%) were reported as none, with 2 cases (2.2%) found to have discolored mucus. No patients were found to have fever or required treatment with a second course of antibiotics.

Conclusion:

NexStat topical hemostatic powder performed well in the setting of post operative application after endoscopic sinus surgery. A high rate of hemostasis and a low profile of adverse effects were observed.