



Use of fibrin sealant (Vivostat®) in skull base surgery

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ABSTRACT

Introduction:

Fibrin sealants are widely used as topical hemostatic agents, sealants and tissue adhesive that contain fibrinogen and thrombin. A large number of clinical applications are referenced in medical literature, from closures of fistula to seroma prevention; they have become a valuable adjunct in a broad range of surgical procedures (especially neurosurgery, and skull base surgery).

One of these sealants is Vivostat® (only available in Europe), which has the advantage of being a patient-derived hemostat and sealant (autologous) with an efficient component mixture and a delivery dosage control.

The aim of this study is to analyze how accurate this sealant is to control bleeding, to seal and to promote tissue growth and repair.

Material and methods:

We present our experience with Vivostat®, which was used in 36 patients that were operated on for skull base or sinus pathology. The experience encompasses selar tumors (pituitary adenomas), CSF leaks, vestibular schwannomas, cholesteatoma, carcinoma and endoscopic sinus surgery.

Results:

Our outcomes were satisfactory, obtaining an adequate sealing and haemostatic control. No complications were seen regarding the use of this product.

Conclusions:

Fibrin sealant Vivostat® has been used as a useful sealant and tissue adhesive with enhanced elasticity and tensile strength that allows a safer and better performance of wound management, especially in skull base surgery.

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INTRODUCTION

Fibrin sealants (FS) have been conceived to aid closure of a variety of tissues throughout the body. They are a complement to conventional techniques in order to improve sealing after surgical procedures.¹ FS contain fibrinogen and thrombin, which are widely used to achieve haemostasis and to seal air and fluid leaks in a broad range of surgical interventions.² They have become a valuable adjunct in general neurosurgery and skull base surgery to control bleeding, to provide a firm seal and to promote tissue growth and repair. A large number of clinical applications are referenced in medical literature³, from closures of cerebrospinal fluid (CSF) fistula to seroma prevention.

CSF leaks represent one of the most common complications of skull base surgery (6-12% cases reported) and are responsible for significant patient morbidity and mortality. To diminish the incidence of these events additional steps are needed. Therefore, the use of FS as a temporary sealant, in conjunction with fat or muscle flap has proved to be extremely useful for preventing this complication.¹

A number of FS have been described to date; a novel fibrin-sealant application system (Vivostat ®) has been employed so as to ascertain its advantages in endoscopic skull base surgeries.

The aim of this study is to analyze how accurate this sealant is to control bleeding, to seal and to promote tissue growth and repair for endoscopic skull base surgeries.

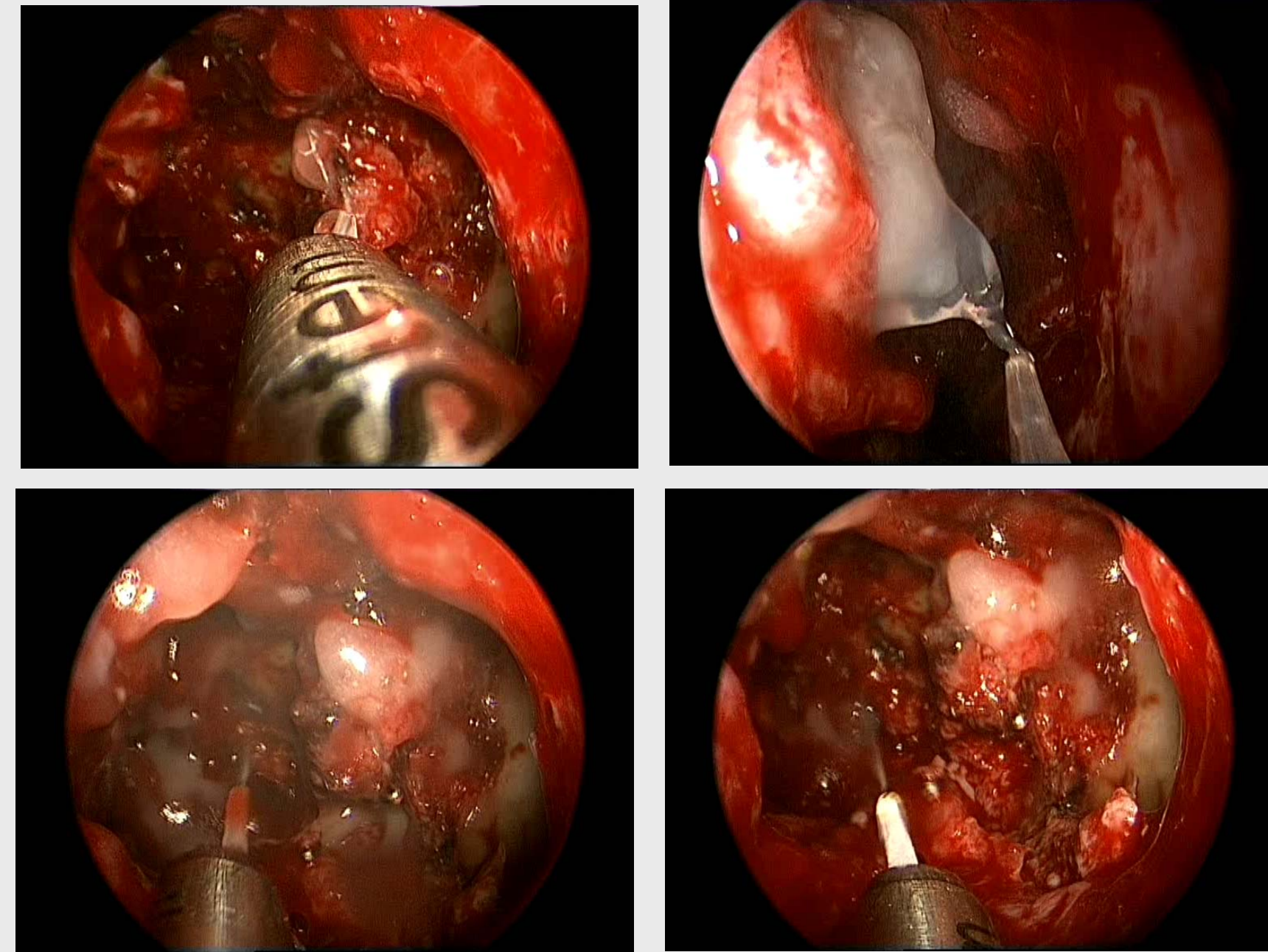


Figure 4. Application of autologous fibrin sealant in a sinus (ethmoid) endoscopic surgery.

METHODS AND MATERIALS

Thirty six patients underwent skull base surgery and Vivostat ® was applied either to achieve haemostasis or to seal air and fluid leaks depending on the procedure indicated.

Patients included were operated on between September 2008 and February 2010. Mean age was 55 years old (SD=18) and a female predominance 2:1 was described.

Vivostat® (Vivostat A/S, Alleroed, Denmark) is a system for the preparation and application of a sealant made from patient's own blood (Fig1-3). Autologous fibrin sealant was prepared with the Vivostat system and applied to the resection bed. This system is an automated medical device for the preparation of the fibrin sealant, generating around 5 ml of fluid out of 120 ml of patient's blood. The concentration of fibrin and the volume of sealant are stable; the sealant may be kept at room temperature for up to 8 hours before application without a loss of properties and effectiveness.

In cases of skull base surgery FS was applied in conjunction with fat or muscle flaps to enhance conventional techniques for closing tissues and avoid CSF leak or pneumocranium. For the rest of them, the sealant alone was utilized to minimize bleeding. (Fig 4)
Patients were followed-up for at least 7 months. Presence or absence of bleeding, CSF leak and pneumocranium were evaluated.

RESULTS

Indications for surgery were: pituitary adenomas (15), CSF fistulas (9), vestibular schwannomas (4), cholesteatoma (2), squamous cell carcinoma (2) and endoscopy sinus surgery for chronic rhinosinusitis (4).

A thin layer of fibrin was provided in all cases over the area to be closed or regenerated. For the former scenario, Vivostat was used in conjunction with a biological barrier such as a muscle graft or mucosal flap, serving as a primary seal (scab) until the biological implant has the opportunity to mature and be integrated into a permanent scar that will serve as a long term seal.

No complications regarding the use of this product were seen. Administration through a cannula proved to be favorable related to its efficient application system.

Patients have been periodically evaluated with fibroscopy and neuroimaging with no evidence of bleeding, CSF leak or pneumocranium in any case where the Vivostat was used.

DISCUSSION

To date a number of FS have been described. Their physical properties and surgical performance may vary depending on the manner of applying it.⁴ Vivostat system offers the following advantages compared to other FS: easy to use, reproducible with a high degree of control, can be deposited in repeatedly small amounts and has a lower airflow; therefore, the risk of causing air embolism is smaller. On the contrary, the disadvantages seen with its use are the preparation, as autologous Vivostat requires donation of 120 ml of blood from a patient undergoing surgery, and moreover it takes 30 to 40 minutes to be prepared.

Although its cost is around 747 USD per kit, it is less than the economic burden that an extended admission or a reoperation mean.

The use of an additional technique to improve tissue regeneration in areas where it is anatomically difficult to access is not controversial. Nevertheless, few references in the literature can be found to demonstrate the advantages of a conventional FS over the Vivostat system.⁵ This clinical study suggests that the use of Vivostat facilitates wound healing in surgical practice.

These experience encompasses the use of Vivostat ® for closure the exposed areas in craneofacial reconstruction, medial and lateral skull base defects, infratemporal approaches and endoscopic sinus surgery in order to avoid fistulas of the skull base and to promote adequate tissue regeneration and healing.

CONCLUSIONS

Fibrin sealant Vivostat® has been used as a useful sealant and tissue adhesive with enhanced elasticity and tensile strength that allows a safer and better performance of wound management in our skull base surgeries. Our initial experience with the Vivostat system has been encouraging.

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