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A New Gelatine-based Hemostat for Sinonasal Surgery: A Clinical Survey

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Abstract. *Background: To ensure more effective hemostasis in surgical procedures, a novel sponge of pharmaceutical-grade chemically cross-linked gelatine, characterized by a high pore density, reduced ligaments and a high nanoscale roughness of the surface has been developed. Patients and Methods: A questionnaire-based survey was carried out at seven ENT centers in Germany to collect clinical data. A total of 62 patients undergoing nasal and sinus surgery were treated with the new product to test its efficacy as a hemostat, its absorptive capacity, its handling in general, and its subsequent biodegradation. Results: In summary, performance regarding the above parameters was very good. No adverse events were observed. The major advantages of this sponge in comparison with other available products were fast hemostasis and that there was no need for removal of the dressing because of its biodegradation.*

Nasal packing materials are indispensable in sinonasal surgery. There is an increasing number of products on the market utilizing different materials (1). Nasal packs are designed to provide hemostasis in epistaxis or surgery, to provide support for the cartilaginous and bony nasal structure, nasal conchae and soft tissue (*i.e.* sliding flaps), and to prevent adhesion or stenosis, especially following sinus surgery (1). To overcome the risk and disadvantages of conventional nasal packs (2, 3), hemostatic packing materials (HP) have been designed. When applied to the wound surfaces in the ethmoid and possibly in the opening of further sinuses, they allow the patient to breathe normally, resulting in a significant increase in patient comfort. The materials disappear due to a number of effects that are difficult to quantify: dissolution, suction, drainage etc. Different combinations of materials may lead to different effects (1): Hemostasis, placement of tissue through adhesion, barrier function, improved wound healing and sealing of surfaces or spaces.

Gelatine has been used since many years to control postoperative bleeding in endonasal sinus surgery (4-7).

A novel gelatine-based product called X-Blod® (Gelita AG, Eberbach, Germany) is now on the market. It is made of a purified fraction of pharmaceutical-grade gelatine as previously described (8). Under electron microscopy, it was found to have higher porosity and a rough surface compared to other gelatine sponges (8). It also showed a high absorption capacity for blood under study conditions (Figure 1). In the same *in vitro* study, a venous hemorrhage model showed rapid hemostasis with decreased blood loss compared to standard gelatine sponges. The rapid hemostasis may be explained by platelet adhesion and activation of the coagulation system on the rough surface of the X-Blod sponge, and by the shear stress inside the capillary network of the sponge; this could well induce more effective platelet activation. It could also be hypothesized that the gelatine lamellae provide attachment sites for proteins such as fibrin. According to the manufacturer, X-Blod dissolves completely in a mucosal model within two to five days and disappears completely within 14 days.

The objective of this survey was to evaluate the performance and safety of X-Blod in sinonasal surgery.

Patients and Methods

For the evaluation of efficacy and tolerance of X-Blod, a clinical survey was carried out. A questionnaire was developed to be completed by the surgeon after using X-Blod in one of the following indications: Sinus surgery, turbinoplasty, septoplasty and rhinoplasty.

The questionnaire asked for information about the treating physician (name, position in the hospital, address), anonymous patient data (age, gender), indication (as above) and any coagulation-inhibiting medication or other relevant drugs taken by the patient. These general questions were followed by a five-stage rating of the product (very good, good, satisfactory, moderate, poor) regarding the following parameters: Efficacy of the product in general, efficacy as a hemostat, absorptive capacity (blood/fluid), general handling, ease of application and adaption to surrounding

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Table I. *Number of patients and indications (combination of indications/procedures for some patients) at each participating institution.*

ENT Department	No. of patients	Turbinoplasty	Epistaxis	Sinus surgery	Septoplasty	Rhinoplasty
Kliniken der Stadt Köln (Holweide)	5	1	2	2	2	
Klinikum Kassel	11			11		
Lister Krankenhaus Hannover	5	1		2	3	
Paulusklinik Dören	10	10		2	6	
Paracelsius Klinik Karlsruhe	10	8		7	10	2
St. Vincentius-Klinik Karlsruhe	11	8		8	4	
Theresienkrankenhaus Mannheim	10			10	9	

Table II. *Results of evaluation.*

	Very good	Good	Satisfactory	Moderate	Poor
General efficacy	73.8%	24.6%	0%	1.6%	0%
Hemostatic efficacy	57.4%	41%	1.6%	0%	0%
Absorption capacity	56%	40%	4%	0%	0%
General handling	40%	51.7%	6.7%	1.7%	0%
Application	40.3%	43.6%	12.9%	1.6%	1.6%
Adaption to surrounding tissue	50%	46.78%	0%	1.61%	1.61%
Resorption	72%	24%	2%	0%	2%

tissues, resorption and patency of the nasal airway. In addition, five questions were included addressing adverse reactions, removal ahead of schedule, currently used product(s) for this indication, benefits and disadvantages of the new sponge in comparison to the previous products and a question regarding the application of X-Blod as a prospective standard for this indication.

Results

Between June and November 2010, the sponge was used in sinonasal surgery in 62 patients in the seven centers listed (Paracelsius Klinik Karlsruhe, Kliniken der Stadt Köln (Holweide), Paulusklinik Dören, St. Vincentiusklinik Karlsruhe, Lister Krankenhaus Hannover, Klinikum Kassel, and Theresienkrankenhaus Mannheim).

Surgery was performed for sinus diseases, septal deformities, turbinate hypertrophy and nasal deformities (Table I).

The results are summarized in Table II (expressed as a percentage of participants).

In 73.8% of all surgical cases under investigation, X-Blod showed a very good efficacy. No surgeon reported satisfactory or poor efficacy. Similar to general efficacy, the product had a very good to good hemostatic effect (98.4%), being rated only satisfactory in 2% of cases. Moreover, the absorptive capacity for blood or liquids was assessed by the surgeons as satisfactory or better in all procedures. These findings demonstrate an excellent absorption capacity. Handling in general (ready-to-use) was classified as being satisfactory or better in 97.4% of the cases enrolled. Regarding the different indications general handling was rated as follows: very good in 29.6% of turbinoplasties, 50% of rhinoplasties, 34.4% of septoplasties and 48.7% of sinus surgery cases; good in 51.9% of turbinoplasties, 50% of rhinoplasties, 53.3% of septoplasties and 48.7% of sinus surgery cases. In most cases, the application of X-Blod was rated as being good (83.6%), indicating an easy handling of the product. The application in turbinate surgery was found to be very good or good in 67.8%, in rhinoplasty in 100%, in septoplasty in 79.4% and in sinus surgery in 90.3% of cases. In 16% of all cases, application was rated as not optimal. Excellent adaptation of the novel sponge to the surrounding tissue would seem to be one of the benefits of the product. In 97% of surgical indications a very good or good adaptation of X-Blod was reported (turbinoplasty 96.5%, rhinoplasty 100%, septoplasty 94%, sinus surgery 95%).

The question of resorption was very interesting since the removal of a hemostat can lead to recurrence of bleeding. Thus, it was noted that in 96% of the patients good or very good biodegradation was observed. Patency of the nasal airway after application of the product was classified as good to very good in about 75% of indications. Detailed analysis of the data revealed that only one ENT physician reported a decrease in nasal airflow after the application of X-Blod. Furthermore, no adverse reactions were observed. Removal ahead of schedule was necessary in fewer than 2% of cases without any provided reason. Individual evaluation of the

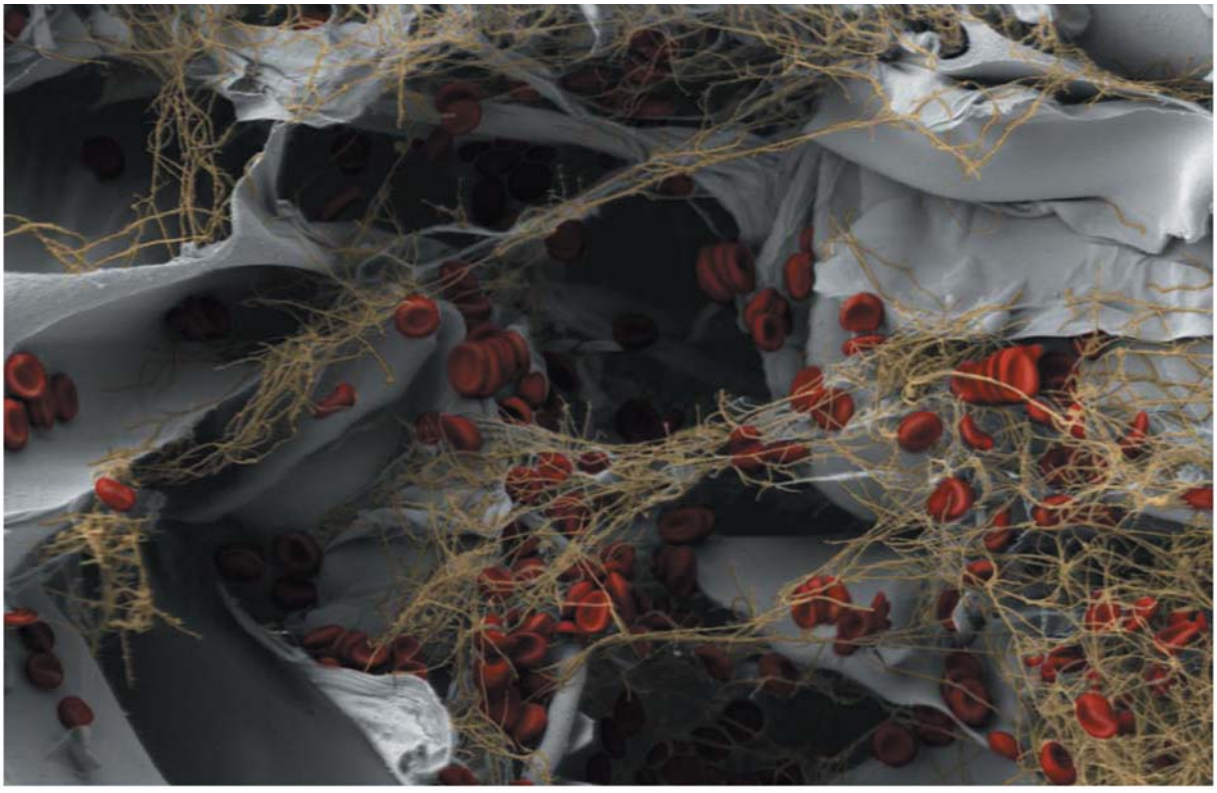

Figure 1. *Scanning electron microscopy of X-Blod® after blood uptake (colorized illustration). An accumulation of blood cells is evident. Gelatin lamellae with blood-binding profiles partially in conjunction with fibrin-like fibers indicating initial hemostasis. © Gelita AG, Eberbach, Germany.*

advantages of the new sponge showed an interesting ranking. Most votes were given to good hemostasis followed by less pain/pressure, decreased turgor and better wound healing. The next votes were for good nasal airflow, no pre-treatment, good biodegradation, no need for additional nasal packing and ease of handling. In very few cases were there individual votes for low pressure, bad application and poor hemostasis.

Discussion

Hemostatic nasal packing materials have been proven to be effective in providing hemostasis in sinonasal surgery and epistaxis (1). They are designed to enhance the comfort of the patient (9). The results here confirmed good efficacy of the new gelatine-based sponge for all indications tested. X-Blod is made of pharmaceutical-grade chemically cross-linked gelatine characterized by a high pore density, reduced ligaments and a high nanoscale of roughness of the surface. This is the first questionnaire-based survey of this new gelatine-based product. In a publication from 2010 (8), the *in vitro* blood uptake assays of X-Blod revealed a rapid absorption of human blood. It has been shown to be two- to three-times faster than that of comparative hemostats. This good absorbing property was also confirmed by the surgeons in this survey. In the same publication (8), it was found that *in vitro* hemostasis was induced in less than one minute. This fast hemostatic effect would seem to be confirmed in this survey. These results show that the new sponge is reliable and effective as a hemostat in surgical procedures. It would seem to be safe as there were no negative findings or adverse reactions. Of course, this survey included only a small number of cases. Thus, the safety of the sponge needs to be evaluated in further studies. General handling was assessed to be very good or good in more than 90% of all cases. The reason for this could be its ready-to-use property as a dry hemostat. In daily routine, there is a need for an easy-to-apply and ready-to-use hemostat. Detailed analysis revealed that there is a dependence on the respective surgical indication. This is plausible as different areas within the nose vary in terms of their accessibility. In comparison with other gelatine-based products, this gelatine sponge does not have to be prepared before use, which is an added advantage in cases of acute and strong bleeding. These findings also show that the product is easy to apply to the bleeding site. The few negative results regarding application comfort were dependent on the surgical indication. Overall, the

performance of X-Blod in terms of handling and application would seem to be satisfactory in surgical interventions. As some hemostats sometimes adapt with some difficulty to the surrounding tissue, depending on the nature of the product and the tissue involved, it was interesting to see how the new sponge would perform. Adaptation was in fact very good over all surgical indications. These findings show that X-Blod is an option to be used in the daily routine of surgical interventions. One disadvantage of other hemostats is the need for removal after the bleeding has stopped; thus, a resorbable hemostat would be a major benefit. As the dressing does not have to be removed, the chance of recurrent bleeding is minimized and hence discomfort for the patient reduced. Therefore, a positive assessment on the part of the physicians regarding resorption was highly anticipated. Moreover, good biodegradation was one central aspect in an individual evaluation of the benefits of the new product. In spite of this advantage, the hemostat was removed ahead of schedule twice. It would have been interesting to know for what reasons but these were not stated. Another disadvantage of most nasal packs is the blocking of the nasal airway. Most surgeons did not report a blocked nasal airway after applying X-Blod. Chandra and Kern (7) in their review of studies examining absorbable packing materials stated that HP may be useful in achieving hemostasis and may lead to increased postoperative patient comfort for patients requiring stents and who do not tolerate conventional nasal packs. Nevertheless, it seems to be unclear whether the necessity for postoperative care is reduced when HPs are used. As some HPs induced increased granulation and adhesions after endonasal sinus surgery (10), this should be taken into account for developing any new material. In this survey, we did not find an increased rate of scarring and adhesions postoperatively. However, this was not the focus of our investigation and not specifically addressed. Limitations of the study were the lack of a control group and of longterm endoscopic examinations to identify the development of postoperative adhesions. This should be the focus of further studies.

Conclusion

Overall, the evaluated data demonstrate that the new gelatine sponge is safe and efficient as a hemostat in nasal surgery. The general handling of the product is user-friendly and, moreover, no adverse reactions in the course of the application were reported. The novelty of this medical device lies in the immediate hemostasis achieved and in the increased comfort for the patient due to its biodegradation. This biophysical property makes it unnecessary to remove the dressing. Additional studies are required to further evaluate the safety and efficacy of the new sponge in sinonasal surgery and epistaxis.

Disclosure

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Conflicts of Interest

The Author declares that there is no conflict of interests.

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