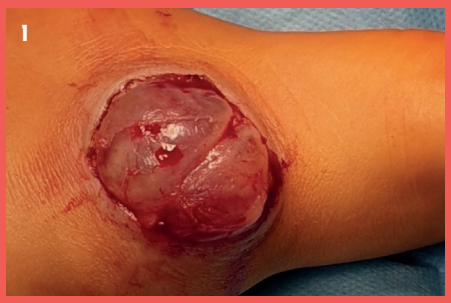
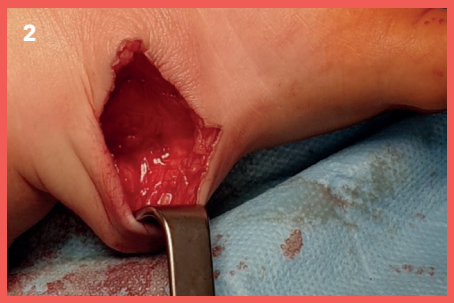
TachoSil SEALANT MATRIX

Case example:
Use of TachoSil® for efficient hemostasis and sealing after tumor resection in an 11-month-old child

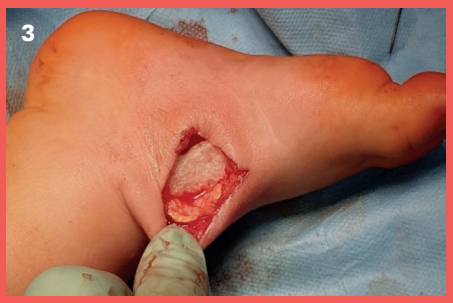
Removal of a lymphatic and venous malformation tumor in the metatarsal region.



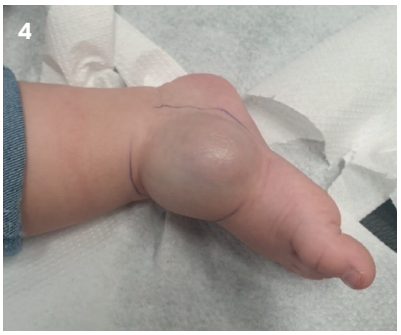
1: Lymphatic malformation during surgical removal.



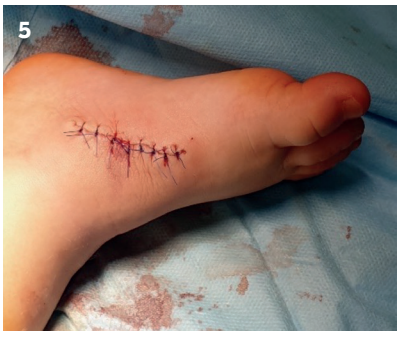
2: Site after removal of the lymphatic malformation.



3: TachoSil® 3 x 2.5 cm was gently pressed onto the wound surface. After 5 minutes, the success of the localized hemostasis was confirmed and the sealing of the lymphatic vessels.



4: Lymphatic malformation of the right metatarsal region – preoperative status.



5: The right metatarsal region – postoperative status.

Preliminary remarks:

- Lymphatic vascular malformations are developmental vascular lesions that result from a disruption of normal vascular morphogenesis.[1]
- In 90% of children the defect manifests itself by the age of two.[2]
- Vascular malformations grow rapidly as a result of filling with fluid or due to bleeding into the cystic spaces.
- Well-defined lesions can be surgically treated and removed.
- TachoSil® can reduce the incidence of postoperative complications, such as bleeding and the formation of lymphadenopathy or lymph cyst.[3-5]
- Tissue sealants, in addition to fulfilling a hemostatic function, may play an effective role in sealing lymphatic vessels.[6-9]

Patient history:

- An 11-month-old boy with a tumor of the medial dorsal area of the right metatarsal.
- The lesion is present since birth but increasing in size since the first month of life.
- The tumor is tight, covered with healthy skin, non-painful, non-movable relative to the substrate.
- Ultrasound: a fairly well-defined area measuring 40 x 16 mm with heterogeneous fluid/blood echogenicity with hyperechogenic areas. The lesion is consistent with a lymphangioma.
- Indication for a surgical intervention due to a significant limitation of the function of the child's foot.

Surgical procedure:

- Resection of the whole lymphatic malformation and thorough hemostasis of the residual surgery site.

Reference: According to information and estimates from Dr. n. med. Anita Kalińska-Lipert and Dr. n. med. Marzena Nosek-Kościołek. Department of Paediatric Surgery and Traumatology, Prof. Antoni Gębala University Children's Hospital in Lublin: Case report: Use of TachoSil during removal of a lymphatic and venous malformation tumour from the metatarsal region in an 11-month-old child.

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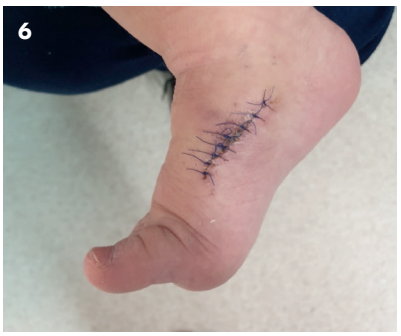
Case example:

Use of TachoSil® for efficient hemostasis and sealing after tumor resection in an 11-month-old child. Removal of a lymphatic and venous malformation tumor in the metatarsal region.



6: The right metatarsal region: Appearance of the wound on postoperative day 15. No exudate is visible.

- Decision to apply the TachoSil® due to persistent venous bleeding from the surface of the site.
- After 5 minutes, the bleeding site was inspected and successful localised hemostasis was confirmed.

Conclusion:

- The healing after surgery was uncomplicated, including in terms of postoperative wound healing.
- The child was discharged on postoperative day 4 in a good general and localised condition.
- Visits on postoperative days 9 and 15 showed normal wound healing. An subcutaneous exudate was not seen.
- The use of TachoSil® was effective and safe for improving hemostasis and promoting tissue sealing in this child.

Sources: 1. Fishman SJ, Mulliken JB. Haemangiomas and vascular malformations of infancy and childhood. Pediatr Clin North Am 1993; 40(6): 1177-200. 2. Donnelly LF, Adams DM, Bisset GS. 3rd Vascular malformations and hemangiomas: a practical approach in a multidisciplinary clinic. AJR Am J Roentgenol 2000 174(3):597-608. doi: 10.2214/ajr.174.3.1740597. PMID: 10701595. 3. Grimm C et al. A collagen-fibrin patch (TachoSil®) for the prevention of symptomatic lymphoceles after pelvic lymphadenectomy in women with gynecologic malignancies: a randomized clinical trial. BMC Cancer 2014;14:635. 4. Navarro-Rodriguez E et al. Effectiveness of an absorbable fibrin sealant patch to reduce lymphoceles for mation after axillary lymphadenectomy for breast cancer: a matched-pair analysis. Am J Surg 2014;208(5):824-30. 5. Minig L et al. Use of TachoSil to prevent symptomatic lymphocele after an aggressive tumor. Gynecol Obstet Invest 2016;81(6):497-503. 6. Tineli A et al. Limfoceleprevention after pelvic laparoscopic lymphadenectomy by a collagen patch coated with human coagulation factors. Int J Gynecol Cancer 2013;23(5):956-63. 7. Simonato A et al. The use of a surgical patch in the prevention of lymphoceles after extraperitoneal pelvic lymhadenectomy for prostate cancer: a randomized prospective pilot study. J Urol 2009;182:2285-90. 8. Buda A et al. The use TachoSil for pre90 vention of postoperative complications after groin dissection in cases of gynecologic malignancy. Int J Gynaecol Obstet 2012;117(3):217-9. 9. Cippolla C et al. Does the use of fibrin glue prevent seroma formation after axillary lymphadenectomy for breast cancer? A prospective randomized trial in 159 patients. Journal Surg Oncol 2010;101:600-3.

Reference: According to information and estimates from Dr. n. med. Anita Kalińska-Lipert and Dr. n. med. Marzena Nosek-Kościołek. Department of Paediatric Surgery and Traumatology, Prof. Antoni Gębala University Children's Hospital in Lublin: Case report: Use of TachoSil during removal of a lymphatic and venous malformation tumour from the metatarsal region in an 11-month-old child.

TachoSil® sealant matrix (coated with human fibrinogen and human thrombin)

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: An off-white sponge coated with human fibrinogen 5.5 mg and human thrombin 2.0 IU per cm^2. The active side of the sponge is marked by a yellow color. Supplied, ready to use, in sterile packaging.

Indications: In adults and children from 1 month old, for supportive treatment in surgery for improvement of hemostasis, to promote tissue sealing, and for suture support in vascular surgery where standard techniques are insufficient; also in adults for supportive sealing of the dura mater to prevent postoperative cerebrospinal leakage following neurosurgical procedures.

Dosage & Administration: For epilesional use only. Use is restricted to experienced surgeons. The number of sponges to be used is governed by the size of wound area, and the underlying clinical need for the patient. In clinical trials the individual dosages have typically ranged from 1–3 sponges. Sponges should be used under sterile conditions and immediately after opening the inner sterile cover. Prior to application, the wound area should be cleansed, e.g. from blood, disinfectants and other fluids. The sponge should be pre-moistened in saline solution and applied immediately. The yellow, active side of the sponge is applied to the bleeding/leaking surface and held against it with a gentle pressure for 3–5 minutes. Pressure is applied with moistened gloves or a moist pad. If covered with blood, surgical instruments and gloves may be pre-moistened with physiological saline solution to avoid the sponge sticking to them. After pressing the sponge to the wound, the glove or the pad must be removed carefully. To avoid the sponge from being pulled loose it may be held in place at one end, e.g. with a pair of forceps. In the case of stronger bleeding, it may be applied without pre-moistening, while also pressing gently to the wound for 3–5 minutes. The sponge should be applied so that it extends 1–2 cm beyond the margins of the wound. Sponges should be overlapped if more than one is used and can be cut to the correct size and shaped if too large. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Contraindications: Intravascular use; hypersensitivity to the active substances or to any of the excipients.

Warnings & Precautions: No specific data available on the use of this product in gastrointestinal anastomosis surgery. Allergic type hypersensitivity reactions are possible, as with any protein product. If hypersensitivity reactions occur, the administration must be discontinued immediately. In the case of shock, the current medical standards should be followed. Standard measures to prevent infections from products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV and for the non-enveloped virus HAV. Measures may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (fetal infection) and for immunodeficient patients or those who have increased erythropoiesis e.g. hemolytic anemia. Risk of transmission of infective agents cannot be totally excluded, including pathogens of hitherto unknown nature. It is recommended to record the name and the batch number of the product administered to the patient.

Interactions: No formal interaction studies have been performed. In comparable products or thrombin solutions, the sealant may be denatured after exposure to solutions containing alcohol, iodine, or heavy metals.

Fertility, pregnancy & lactation: Safety use in human pregnancy or breastfeeding has not been established. Only administer to pregnant and breastfeeding women if clearly needed.

Undesirable Effects: Hypersensitivity or allergic reactions (in rare cases these reactions may progress to severe anaphylaxis; some cases of product residue causing granuloma); thromboembolism may occur if unintentionally used intravascularly, and adhesions and intestinal obstruction when used in abdominal surgery.

Refer to the SmPC for details on full side effect profile and interactions.

Marketing Authorization Holder: Corza Medical GmbH, Speditionstraße 21, 40221 Düsseldorf, Germany.

Marketing Authorization Numbers: EU/1/04/277/001-005.

Date of revision of the text: March 2023

Detailed information on this medicinal product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/