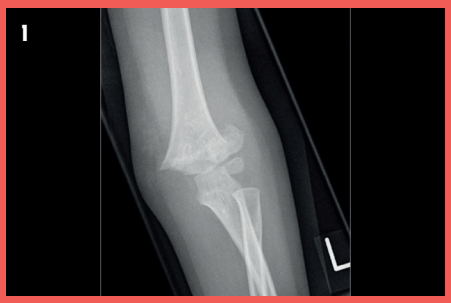
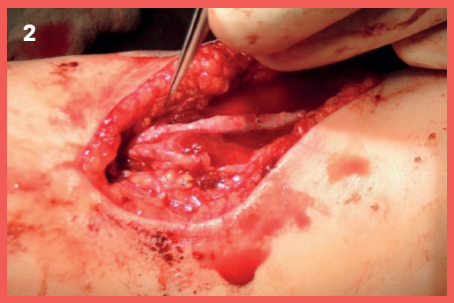
TachoSil SEALANT MATRIX

Case example: Use of TachoSil® for sufficient sealing of a vein interposition for acute occlusion of the brachial artery in a 5-year-old child

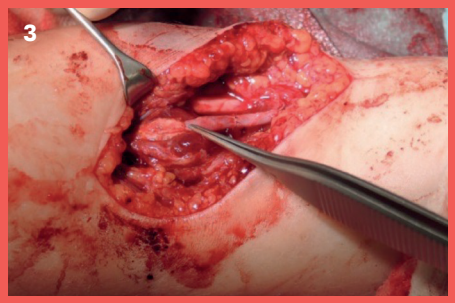
Open treatment of a left supracondylar humerus fracture.



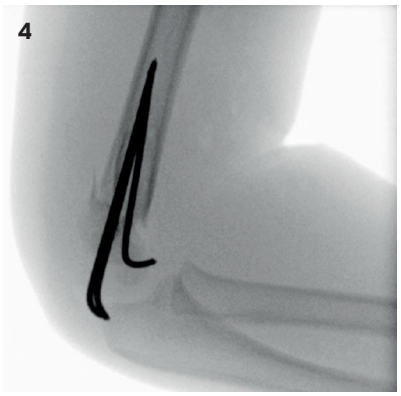
1: X-ray image preoperatively: Completely dislocated supracondylar humerus fracture on the left side with nonpalpable peripheral pulses.

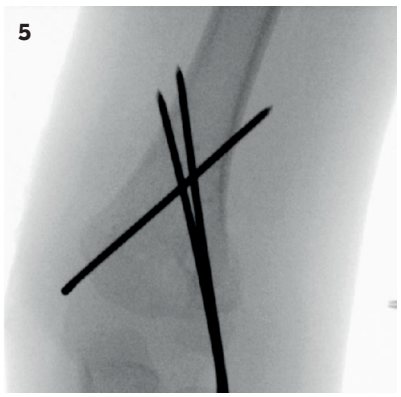


2: Surgical site: Vascular anastomosis in the area of the brachial artery before application of TachoSil®.



3: Surgical site: Additional sealing of the venous interposition in the area of the brachial artery with TachoSil® (2 pieces: 1 cm x 0,5 cm).





4-5: X-ray images postoperatively: condition after reduction and successful osteosynthesis with crossed Kirschner wires above the fracture area.

Preliminary remarks:

- Supracondylar fractures of the distal humerus account for approximately 15% of all pediatric fractures.[1] The median age of presentation is six years.[1]
- Falls from play equipment are frequently the reason.[1]
- All around the world, the most commonly used classification system is the Wilkins-modified Gartland classification of supracondylar humerus fractures. Currently, the decision to operate or to do conservative treatment with plaster cast is taken on basis of this classification system.[2]
- Supracondylar humerus fractures are known to have a potential to cause significant acute morbidity and complications such as nerve injuries, compartment syndrome and vascular injuries.[2]
- In the context of surgical treatment of vascular injuries, the use of TachoSil® can promote sealing and suture support.

Patient history:

- 5-year-old patient with left supracondylar humerus fracture and acute occlusion of the left brachial artery.
- Diagnosis according to ICD-10 code: S42.41.
- Accident while sliding on a playground.
- No increased risk of bleeding.
- No comorbidities.
- Indication for emergency surgery.

Sources: 1. Duffy S et al. Overview of the contemporary management of supracondylar humeral fractures in children. European Journal of Orthopaedic Surgery & Traumatology. 2021; 31:871-881. 2. Shah M et al. Supracondylar Humerus Fractures: Classification Based Treatment Algorithms. Indian Journal of Orthopaedics (2021) 55:68-80.

Reference: According to information and estimates from Joachim Suß, M.D., Chief of Surgery, Catholic children's hospital Wilhelmstift gem. GmbH, Hamburg-Rahlstedt, Germany.

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Case example:

Use of TachoSil® for sufficient sealing of a vein interposition for acute occlusion of the brachial artery in a 5-year-old child. Open treatment of a left supracondylar humerus fracture.

Surgical procedure:

- Open reduction of the fracture and treatment with Kirschner wires.
- Three wires ensure biomechanically high stability.
- In the absence of evidence of peripheral pulses in the radial and ulnar arteries, exposure of the brachial artery, which showed massive vasospasm.
- Indication for a vein interposition with a vein from the surgical area.
- Since the distal anastomosis was fragile and showed signs of leakage, an additional application of TachoSil® (2 pieces: 1 cm x 0,5 cm) was performed to support the vessel sealing.

Conclusion:

- The use of TachoSil® prevented the occurrence of postoperative bleeding in this young patient.
- Peripheral pulses were detectable here, thus ensuring distal (forearm/hand) blood flow.
- By using TachoSil® as a method to secure the vascular anastomosis surgical time was reduced by 60 minutes for this child.
- In addition, the use of a Sealant Matrix made it here possible to operate in a way that was gentle on the tissue.
- The use of a patch in this case reduced the likelihood of postoperative complications.

Reference: According to information and estimates from Joachim Suß, M.D., Chief of Surgery, Catholic children's hospital Wilhelmstift gem. GmbH, Hamburg-Rahlstedt, Germany.

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/