## **Cook Biotech patient story**



## Mia's story

Thirteen hours after she was born, Mia had her first surgery for an extensive esophageal atresia, a birth defect that left her with an esophagus that had not developed properly in the womb. In addition, Mia's stomach sphincter had not formed correctly, and she also suffered from a tracheoesophageal fistula.

Because of these serious congenital malformations, there was no complete connection from Mia's mouth to her stomach, and she couldn't eat or swallow properly.

This situation was a matter of life and death for the newborn; her parents said goodbye as she was whisked away for her first surgery. They had no idea what her future would hold.

During Mia's initial surgery, surgeons separated the esophagus and trachea and sewed the two unconnected esophageal parts together. Mia was also given a stomach tube for artificial nutrition and a trachea tube for artificial respiration.

Although Mia survived this first operation, it was not long before there were significant problems. Her initial situation was complicated, but it got even worse after the primary reconstruction of her esophagus failed. Other malformations caused additional problems, and specialists at the hospital were not sure what to do to help Mia. Specialist Prof. Uwe Friedrich came back from vacation early to help with this extremely urgent case.

Left with few good options, the surgical team discussed the possibility of creating an esophageal replacement out of a biological material called small intestinal submucosa (SIS) and asked Mia's parents if they were in favor. The hope was that this graft, an extracellular matrix (ECM) that would incorporate itself into Mia's body, would be a permanent solution to her esophageal challenges. Mia's parents had never given up hope that Mia could live a normal life despite all the setbacks, and they agreed to move forward with the biological graft.

The surgery to recreate the esophagus with the graft succeeded. Mia was able to swallow liquid food three months after the surgery. Nine months after the surgery, she was eating food normally. Everyone felt like the graft was a miracle because this solution worked long-term.

Even though the surgery was a success, Mia still had a long road ahead of her. The weeks after included intensive therapy and many smaller operations. Some procedures included expanding the esophagus where the graft was located to prevent shrinkage.



Mia and Prof. Friedrich

After five months of hospitalization, Mia's parents were finally allowed to take her home during the daytime hours, but Mia had to return to the hospital in the evenings. Mia's mother was determined to take Mia home for Christmas. She had to learn how to operate Mia's oxygen and feed her through a stomach tube, but it paid off. Mia was finally allowed to go home for good on Christmas Eve, six months after her birth. It felt like she had finally become a full member of the family.

Mia needed many other surgeries for her digestive tract. Her mother stopped counting anesthesia authorizations after the eightieth, all of which happened before her third birthday!



It all paid off because Mia is now a thriving 16-year-old.\* The graft has done its work, and it is still having a positive impact on her all these years later. She still has some minor problems related to the conditions she was born with, but she takes just one drug now, and her visits to the doctors are now a minimal part of her life.

Because Prof. Friedrich saved Mia's life with the SIS surgery, Mia's parents asked him to be her godfather. He had never done this for a patient before, but he was happy to do it for this special case. He suffered right along with Mia's parents and felt that he had become an honorary member of the family. Mia and Prof. Friedrich are still in touch, and he has had the joy of watching her grow into a happy, healthy teenager.

## Prof. Friedrich's version of Mia's story

Esophageal surgery in children is still a challenge. Common procedures like the Foker procedure, gastric pull-up, and intestinal interpositions are associated with side effects like surgical complications, patient discomfort, and leakage, and there is not always a straightforward path to a successful outcome for the child.

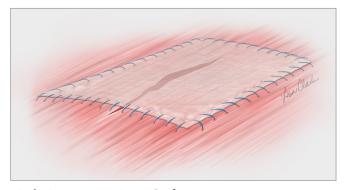
Mia was born with a type 3B esophageal atresia with hypoplasia of the esophageal segments. Primary reconstruction of the esophagus failed, causing dehiscence of the esophageal segments. Malformations in the pylorus and anorectal region were additional factors that complicated her situation.

Left with few good options to help Mia, the surgical team considered a biological graft to form an esophageal replacement for her, a solution they hoped would be long-term. The clinic had successfully used this method with several other patients in emergency situations.

Biomedicine can offer new therapeutic approaches for patients like Mia. SIS provides an ECM with a framework where cells can invade, leading to capillary growth and the formation of a new replacement structure.

After a thorough operative cleaning of the entire area, a four-layer SIS matrix (4 x 7 cm), Biodesign® 4-Layer Tissue Graft, was sewn into the defect, and then the transplant was sealed. The last step in the operation was thorough drainage of the space. The SIS implant did its job and was completely incorporated by three months after the operation.

There were some minor problems with shrinkage near the graft, but periodic esophageal dilatation until Mia was around a year old helped with the situation.



**Biodesign 4-Layer Tissue Graft** 

Mia could swallow liquid food three months after the first surgery and then eat orally without problems nine months after the implant. However, she needed additional surgeries, in part to correct a malformed colorectum. By the time she was old enough to enroll in school, all organ systems were fully functional.

Considering the desperate initial situation, the problem-free transformation of the implant into a fully functioning esophagus is remarkable and shows that a reconsideration of conventional surgical techniques for children is urgently needed. Prof. Friedrich went on to use SIS grafts in 42 pediatric cases since 2002.

## **Final thoughts**

Thank you to Mia and Prof. Friedrich for sharing this remarkable story about SIS. Cook Biotech was founded to serve patients and improve lives like Mia's. Cook Biotech's advanced tissue-repair products are used to manage multiple types of wounds, including burns, diabetic ulcers, venous ulcers, and trauma wounds. Surgical applications include hernia repair, fistula repair, otologic repair, and soft-tissue reinforcement, and our proprietary technologies and manufacturing processes have produced more than 6 million advanced tissue-repair products for global distribution.

\*As of 2022 publication date.



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