Synthetic tendons made from bicomponent fibres

Organs are not the only things to be transplanted. Sometimes tendons also need to be replaced. At St. Gallen-based Empa (Swiss Federal Laboratories for Materials Science and Technology), an interdisciplinary team of scientists is working on the development of synthetic tendons for surgical applications. The synthetic tendons are made of bicomponent fibres that decompose efficiently in the body after implantation.

The researchers' goal is to develop a synthetic tendon that supports a torn tendon while it repairs itself, and degrades in the body after a certain period of time. The properties of the synthetic tendon, for example its tensile strength, must be as close as possible to that of a natural tendon. To achieve this, the Achilles tendons of sheep were mechanically tested to determine the required characteristics of the final product.

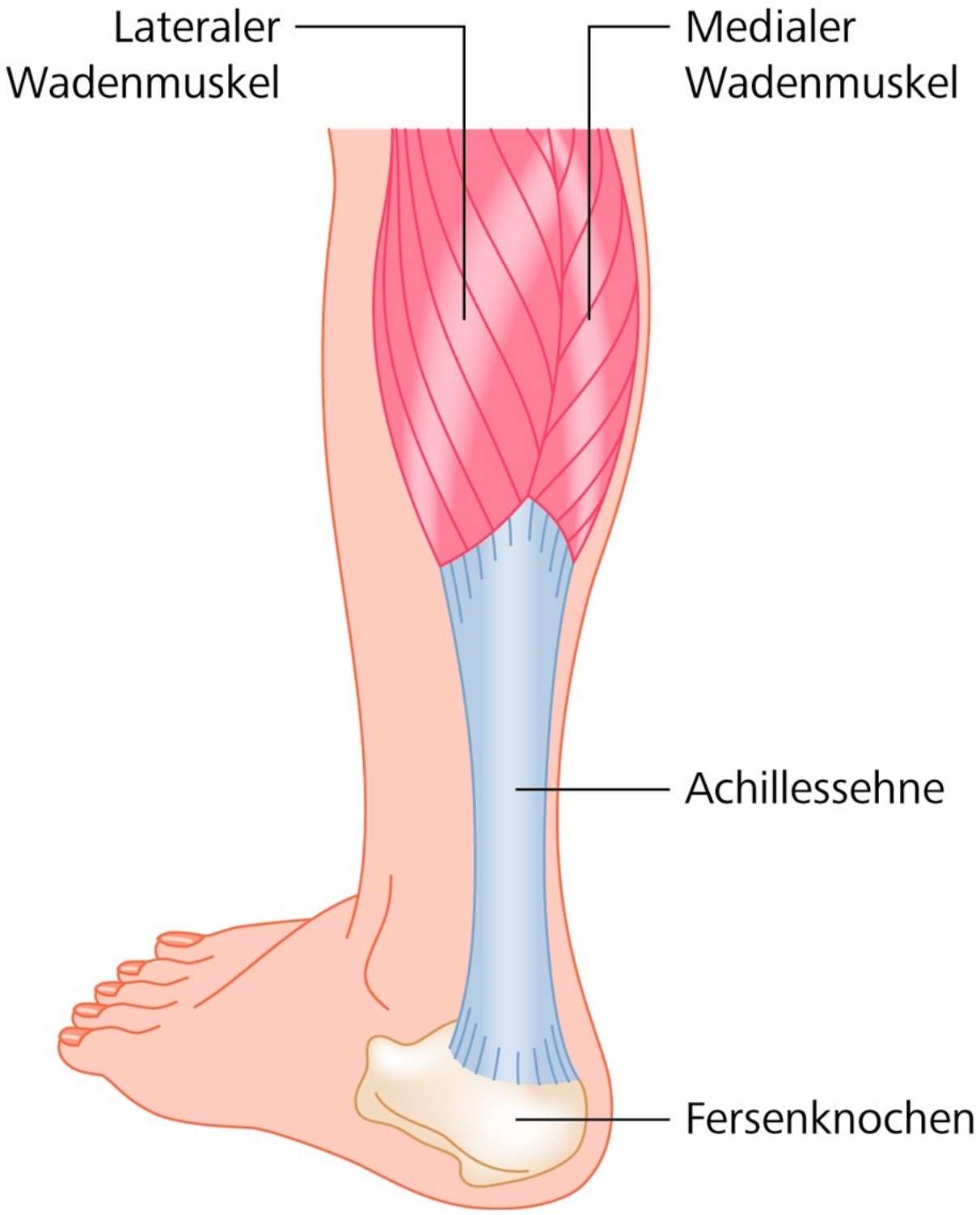
Bacteria play an important role in the production of bicomponent fibres

Cupriavidus necator and Pseudomonas putida are bacteria of the lowest biosafety class that play an important role in the production process of a perfect synthetic tendon. The biocomponent fibres produced at Empa consist of polymers generated by the aforementioned bacteria. "Cupriavidus necator is excellently suited for the production of thermoplastic polyhydroxyalkanoates, while Pseudomonas putida is also able to produce functional elements that are suitable for matrix functions," commented Dr. Manfred Zinn, project manager and head of the biomaterials group at St. Gallen-based Empa.

Bicomponent fibres consist of two components: poly-3-hydroxybutyrate-co-3-hydroxyvalerate (PHBV) mantled with L-polylactid (PLLA). The combination of these two compounds enables the researchers to control the properties of the artificial tendons, in particular the degradation rate in the human body. "PLLA is degraded much more quickly than PHBV. The degradation rate of the fibres can be precisely determined by combining specific quantities of PLLA and PHBV," said Dr. Manfred Zinn. In contrast to many other tissues, artificial tendons usually remain in the body for at least six months.

The tendons are created by melting the biopolymers produced by the bacteria in the "melt spinning plants" of the "Advanced Fibres" department at Empa. The open-pore structure of the filaments enables the natural tendon tissue to grow through and regenerate.

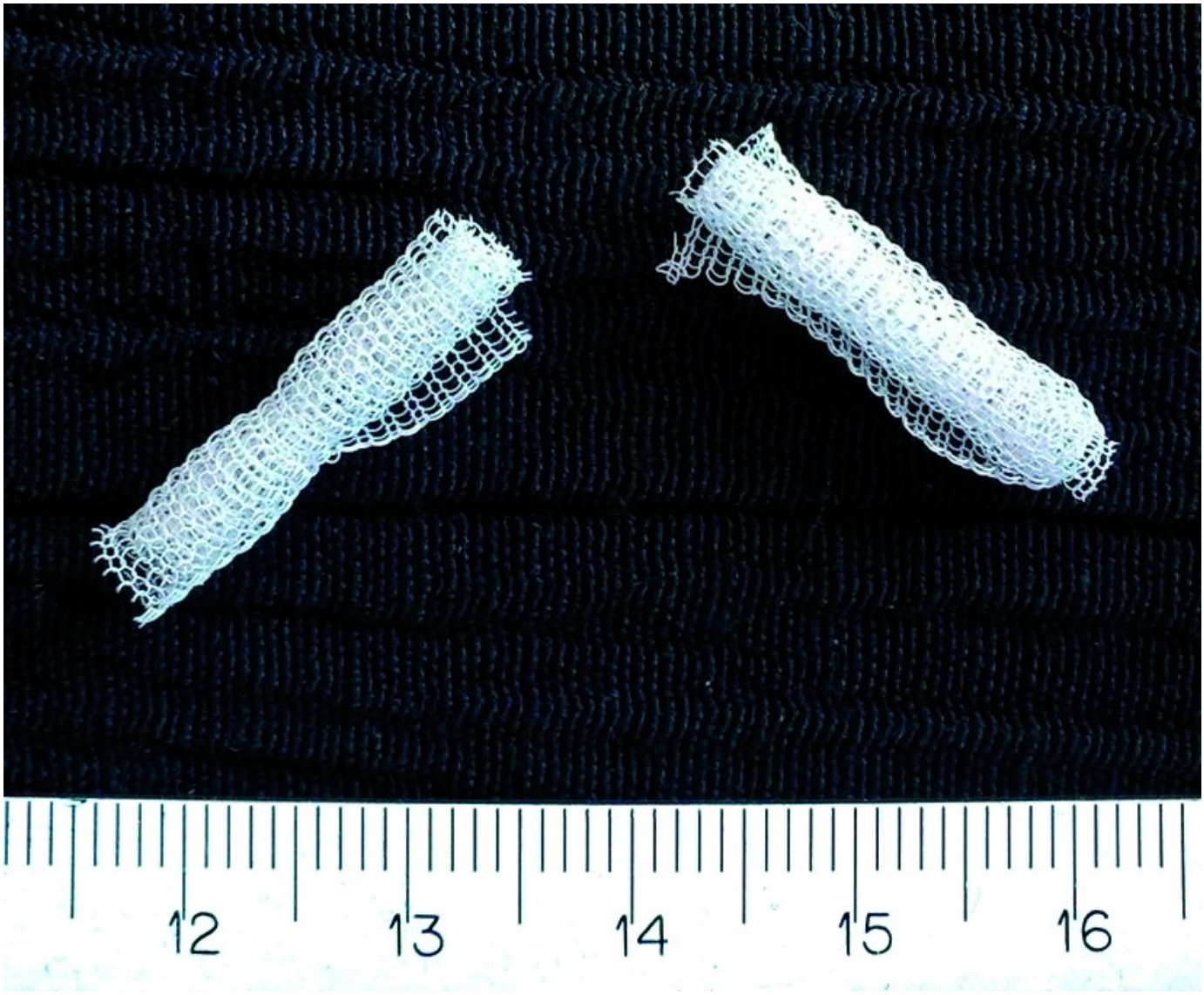
Purity: the fundamental priority in the production of medical implants is



Lower thigh and foot.

that implants must be bacteria-free

Implants must be biocompatible. Biocompatibility refers to the behaviour of biomaterials and indicates whether a material elicits an immune response or not, and can thus be used for medical applications or not. “The American Food and Drug Administration (FDA) has set a maximum number



The biopolymers are turned into fibres in the institute's melt spinning plant and subsequently used for the production of textiles.

of endotoxins allowed in an implant at less than twenty endotoxin units per implant," said Zinn pointing out that it required a lot of work before the researchers managed to comply with this limit.

The researchers used a special LAL bioassay, which measures the clotting of the blood of the horseshoe crab (Limulus polyphemus), to determine the amount of endotoxin units. The researchers also carried out tests with in vitro cultures and experimental animals. "Experiments with rats are an excellent indication of whether a material is biocompatible or not; these experiments clearly showed whether the animals reacted to the implant as a foreign body and provided us with important information on the adhesion and acceptance of cells on the surface of the material," said Zinn. It was also necessary to develop a new method that enabled the researchers to effectively purify polyhydroxyalkanoates in order to prevent contamination during the bacterial production process. These efforts led to a purity of less than twenty endotoxin units per gramme of implant, which conformed with FDA purity requirements.

The artificial tendons were configured in such a way as to satisfy the material requirements of the final product: The result was a tendon whose elasticity, flexibility and tensile strength were identical to that of natural tendons.

Dr. Manfred Zinn is a researcher at the St. Gallen-based Empa.

Interdisciplinary cooperation makes progress possible

The development of the synthetic fibres involved researchers from many different disciplines: biologists, engineers, medical professionals and of course material scientists. “The greatest hurdle the interdisciplinary team had to overcome was the development of a common language,” said Zinn. The large number of medical terms was quite a challenge for the Empa researchers. Polymer chemists, material engineers and cell biologists also had to deal with challenges they had not been used to in their field of research, for example dealing with the sterility of materials. Once the team had dealt with all these challenges, the project was successfully terminated and follow-up projects were initiated.

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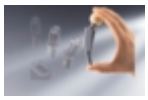

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