Repairing herniated discs is a clinical need that has still not been met. When the discomfort becomes unbearable, surgery can be performed and the intervertebral disc is generally removed. However, this can further reduce the patients’ quality of life. Scientists at DITF, in cooperation with the Spanish company NEOS Surgery S.L., have developed a textile-based device for treating herniated discs. The device is a minimally invasive “repair kit” that not only relieves patient suffering, but also ensures that the disc retains its shock absorbing function.

Herniated discs are usually caused by long-term wear and tear on the spine. As a result, the outer layer of the disc (anulus fibrosus) ruptures, causing the jelly-like inner layer to leak into the spinal canal and press on surrounding nerves. This can be extremely painful. In Germany alone, well over 100,000 people suffer from intervertebral disc herniation every year. The rupture does not heal by itself, and the affected disc no longer acts as a shock absorber in the spinal column.

Treatment is often conservative, involving physical exercise, relief, analgesic drugs and physiotherapy. Severe cases associated with the symptoms of paralysis need to be operated on. However, an operation cannot repair the disc. It is common practice to remove parts of the disc to enable adjacent vertebrae to grow together. It goes without saying that this further restricts mobility and also increases the strain on the other vertebral discs.

Scientists from the German Institutes for Textile and Fibre Research Denkendorf (DITF) and the Spanish company NEOS Surgery S.L. have developed a textile implant for the treatment of herniated discs in a Eurostars project called Ar-Tex, which is funded by the German Federal Ministry of Education and Research (BMBF). Using this implant, herniated discs can be repaired and maintained. The idea of closing the rupture in the intervertebral disc from within the disc originally came from NEOS. Together with a Spanish textile research institute, NEOS started designing the implant seven years ago. “However, the Spanish institute is not a specialist in the field of medical products and so they turned to us,” reports Prof. Dr. Michael Doser, who has led the research work at the DITF and is head of the Biomedical Engineering department at DITF.

For many decades, the DITF have been developing textile products for use in the medical technology sector, including suture materials and vascular prostheses. “We have also attempted to develop a complete, artificial intervertebral disc replacement,” says Doser going on to add, “but our new approach is completely different.” A competitive product from the United States is also very different from ours. Doser comments: “The American product can only be used for very large defects, is less
flexible, and only fills the rupture rather than actually closing it.”

“Umbrella” unfolds in the spinal column

The jointly developed implant closes the tear in the vertebral disc with a textile “umbrella” from within the disc. This only requires a minimally invasive procedure. The special device used in this procedure was developed by NEOS, the project's Spanish partner. “The instrument is inserted into the spinal column through the anulus fissure. This intervention is relatively complicated because the instrument has to be inserted relatively deeply into the disc. Furthermore, little space is available and the instrument has to be manoeuvred past the vertebral body and blood vessels without damaging them,” explains Prof. Doser. “The instrument is then used to place the implant into the centre of the disc and is unfolded. The textile umbrella then spans over the tear, even though the implant is very, very small - it has only a size of around 10 square centimetres. It is attached to the vertebral body with a small screw.”

The intervention leads to the tight closure of the outer layer of the intervertebral disc. The disc thus retains its shock absorbing function, which cannot be achieved with standard surgical methods. “The textile tissue is so tightly woven that the jelly-like inner layer is not squeezed out of the disc, and thus does not exert pressure on the surrounding nerves,” says Doser. The researchers have already demonstrated that the method works with intervertebral discs from pathology departments. These
trials were carried out in hospitals in both Spain and Germany, including the Institute of Orthopaedic Research and Biomechanics at Ulm University Hospital, where the load on the repaired disc could be realistically simulated. An artificial tear was induced and the spinal columns mounted in special devices and set in motion.

The final design required a great deal of development work

Since the beginning of the Ar-Tex project, over 20 implant design variants have been developed and tested at the DITF institute. Prof. Doser did not really like the first design, so the teams continued to work until the textile umbrella unfolded correctly and the textile tissue was sufficiently tight. Small tubes were subsequently woven into the textile. “The shape and structure of the textile has changed a lot during the project,” Doser says. “Only the last two design variants were deemed good enough and tested with pathological discs after initial tests had been carried out with spinal column models. And it goes without saying that we discussed the disc design in detail with doctors,” says Doser. The DITF researchers met at least three times a year with their Spanish partners. Doser also points out that developing the implant to achieve the final design was a very iterative process.

Implant will be produced in Denkendorf

Since the DITF also has a subsidiary, ITV Denkendorf Produktservice GmbH (ITVP) that is certified for medical device manufacture, which is totally unique for a research institute, it was possible to produce all samples in-house. “This is unique in itself. Our research institutes were certified at the same time as the company. This has now proved to be a huge advantage: first, our documentation complies with approval requirements, and second, ITV Denkendorf Produktservice GmbH was given authorisation to produce prototypes that can be implanted into humans,” says Prof. Doser.

It is therefore planned to manufacture the pilot series of the herniated disc implant at ITVP, and implant these into 30 patient spinal columns at the end of 2017 in order to assess safety and functionality. If these final clinical trials are also successful, the ITVP will continue to produce the textile part of the implant and NEOS will commercialise the device and the implant. If everything goes to plan, the first products will be available on the market by late 2018. DITF and NEOS were recently awarded the 2017 EUREKA Innovation Award in Madrid in the category “Inventors of Tomorrow” for developing this innovative product.
Tissue for the repair of herniated discs with inlaid tube for attaching the device to the disc.
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**Article**

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**Further information**

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Implants of the future: bioactive, corrosion-resistant and antibacterial