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Titel
An open-source digital fabricated sensor-based diabetic foot monitoring system usable for orthoses treatment

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Zusammenfassung
Treatment of diabetic neuropathic osteoarthropathy is a challenge due to missing sensitivity of the patient. An open-source diabetic foot monitoring and feedback system detects disease progression by measurement of temperature and pressure. An application gives an insight into the health status.

Hintergrund
Diabetic neuropathic osteoarthropathy is a chronic and progressive disease that can have serious consequences on affected feet. Without proper treatment, the disease can lead to destruction of the foot skeleton, ulceration and even amputation. Treatment includes immobilization and complete pressure relief of the foot. Due to polyneuropathy, overloads and infections may not be noticed by the patient and are therefore often recognized and treated too late, making therapy a challenge. Measurements of the pressure distribution on the plantar foot are important to inspect the fitting of the orthosis. Current pedobarography is not designed for long-term use or permanent embedding so that therapy progress cannot be continuously monitored. This work presents the development of an open-source diabetic foot monitoring system customizable for patients, along with an application to monitor and help to avoid worsening of an existing case.

Material Methode; Durchführung/ Prozess
An open innovation process is executed between a FabLab and a medical supply store to find proven and commonly used materials and approaches for digitalization in the production routine of a workshop. Therefore, various digital manufacturing processes and machines are tested in terms of viability and time efficiency. Different self-made pressure sensors and commercial

temperature sensors are utilized in various combinations of positional placement, layout and number of sensors used. They are attached onto layers of fabric via conductive and non-conductive thread using an embroidery machine. The created insole is then embedded into a provided orthosis and tested for functionality and durability. It is placed below the top layer of a diabetic foot bedding (closed-cell EVA foam). The data is recorded and processed via a self-developed circuit board that is integrated in an electronical box placed in the frame of the orthosis and connected via cables with the insole.

Ergebnisse

For pressure sensors, tests show that an embroidered self-made matrix variation is the most suitable solution. It is easy in production, cost efficient, can be customized and digitalized, as well as not being significantly impacted by the deep drawing procedure during the embedding process. Additionally, technical testing shows that such sensors with a size < 1 cm^2 provide good pressure readings and perform reliably and consistently on par with other commercial sensors. In tests with larger sensors (up to 4 cm^2), the measured values already reached their maximum at minimum load. Therefore, they are unsuitable for plantar pressure measurement. The temperature sensors should be positioned individually under the foot according to existing inflammations or vulnerable regions. As a solution, six commercial sensors can be placed by the technician (three to four at inflammation site and the rest far away from pressure peaks). By embedding the insole below the top layer of the closed-cell EVA foam, no further pressure points occur on the plantar side of the foot that could affect the healing process. Testing shows that the sensors are reliable and have high linearity to detect temperature differences up to 0.1°C below the foam. To have a contactless system, the circuit board communicates data via WIFI. The software application visualizes pressure and temperature values and gives warning feedback. The system can further be used to monitor if the orthosis is worn regularly.

Diskussion/ Schlussfolgerung; Fazit für die Praxis

An open-source monitoring and feedback system for diabetic patients was developed to measure pressure peaks and temperature with the novelty of permanent embedding in an orthosis. The main advantage is that it allows measurements over the entire time span of the fitting process. The implementation is simple and customizable and offers new manufacturing

possibilities with digital machines. The use of fabrics and an embroidering solution makes the self-made insole flexible and thin and does not interfere with diabetic sole. Comparing this system with commercial sensors, the self-made solution has wider possibilities for individualization, and lower material costs, but is also more time-consuming. The application gives the doctor, the technician, and the patient an overview of the state of health. Records of wearing time can also be helpful for health insurance coverage.
Long-term monitoring of foot pressure and temperature with the ability to provide feedback is a promising development for treatment and could reduce the costs for the health care system. This innovation offers a new additional care option in diabetic treatment that will be available to every medical supply store and its patients.

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Image: Image 1 Digital design for embroidery machine_180.png

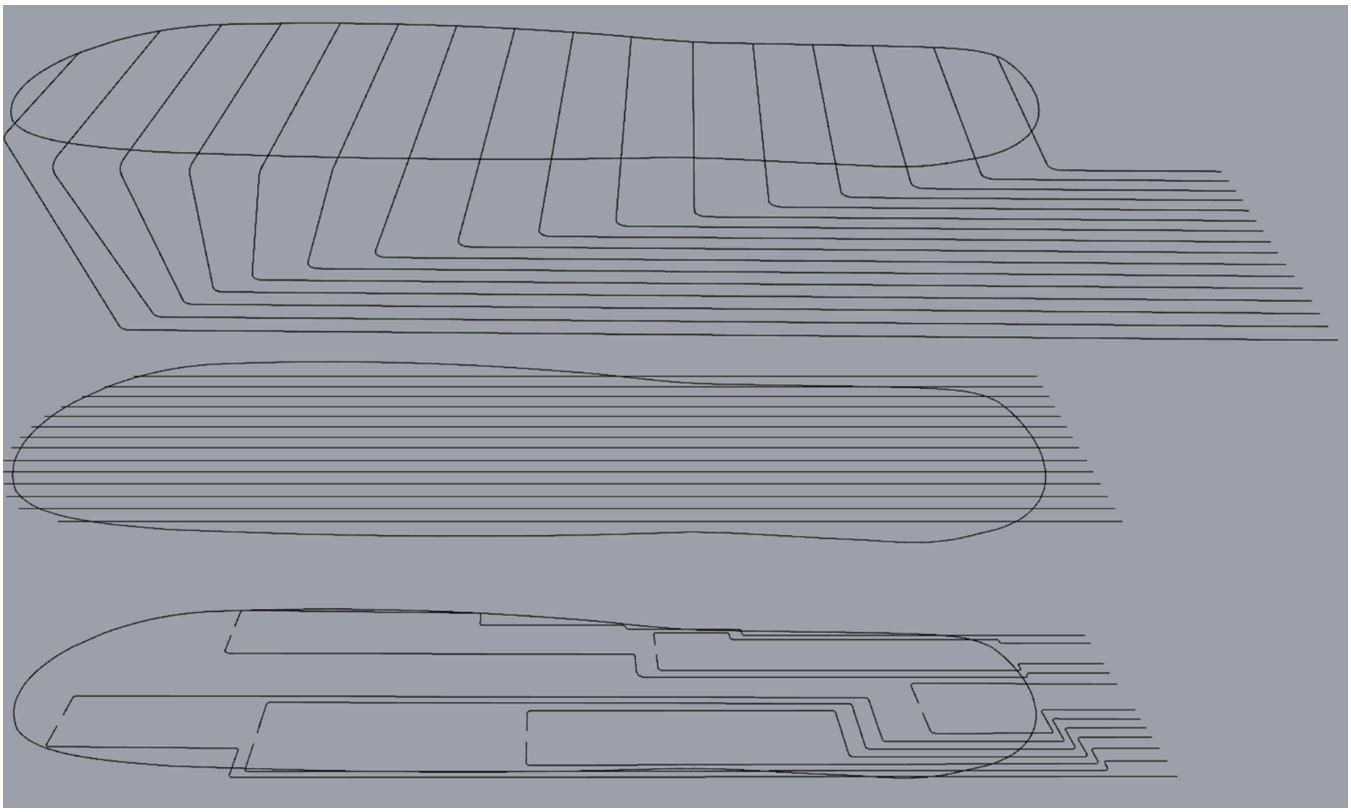

Image: Image 2 Embroidered fabrics with conductive and non-conductive thread for pressure and temperature sensosrs_181.jpg

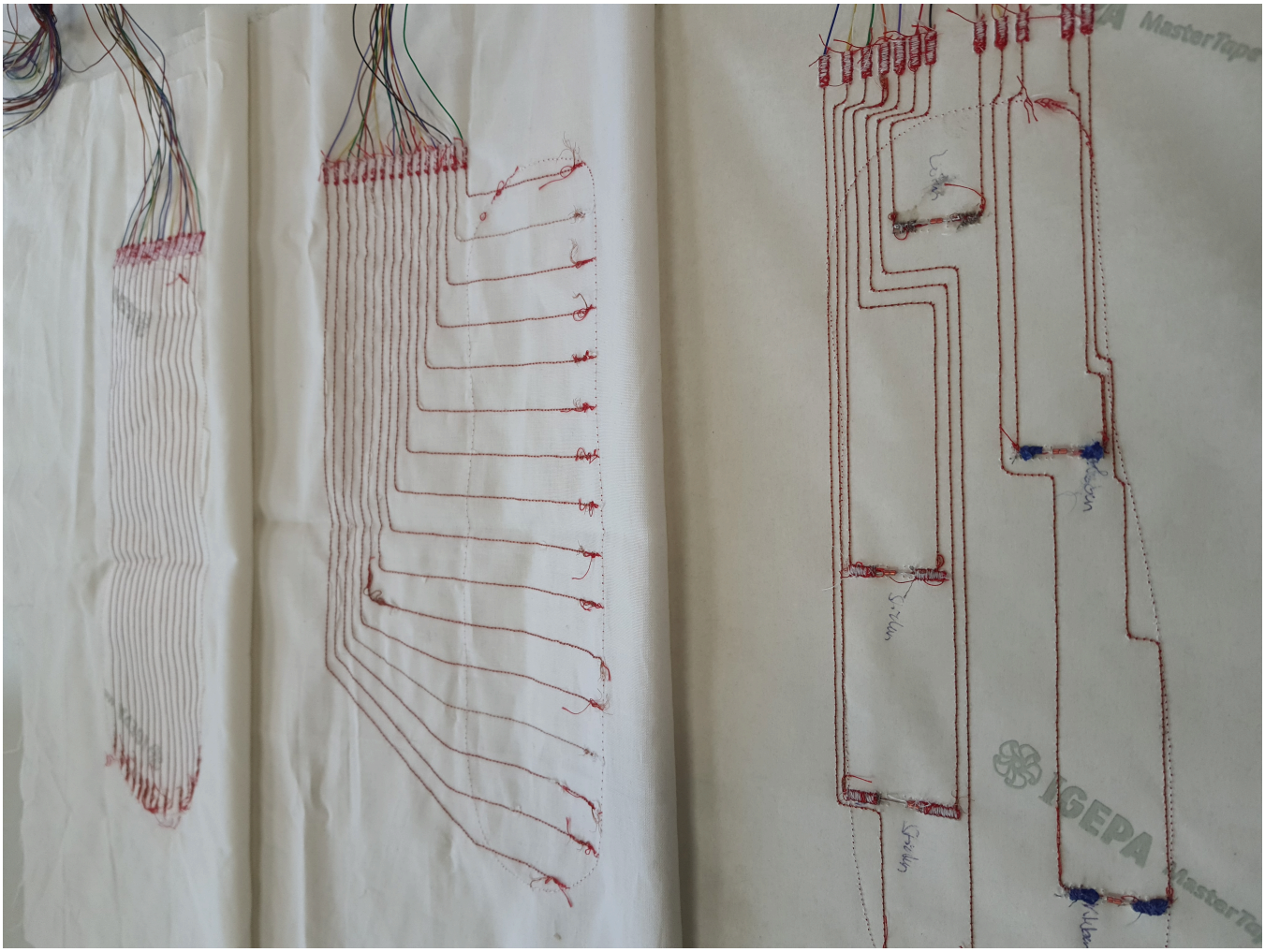

Image: Image 3 Prototype consisting of embroidered pressure sensors and commercial temperature sensors_182.png

Image: Image 4 Embedding situation with previous prototype version and positioning of electronical box and cables_183.png

Image: Image 5 Visualization of matrix (squares) and temperature sensors (question marks)_184.png