May 21, 2024
Sanyo Chemical Industries, Ltd.
Hiroshima University

Investigator Initiated Trial Confirms Safety of Silk-Elastin for Meniscus Injury

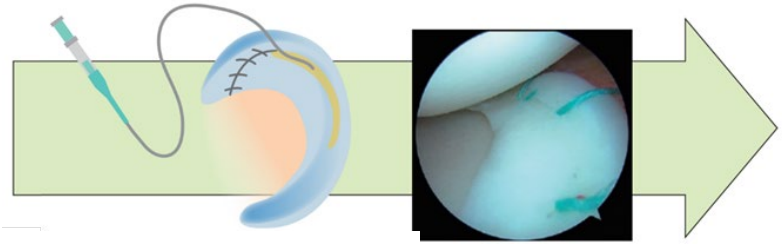
- Multi-Center Collaborative Corporate Clinical Trial
to Seek Approval for Meniscal Repair and Regeneration Medical Devices-

Sanyo Chemical Industries, Ltd. and Hiroshima University are pleased to announce that an investigator-initiated clinical trial was conducted targeting patients with meniscus injuries (meniscus suture) using new treatment method using Silk-Elastin at Hiroshima University Hospital, and its safety was confirmed. Silk-Elastin is a functional protein with high potential as a scaffold for promoting repair and regeneration of living tissue.

Based on these results, Sanyo Chemical, together with Hiroshima University and others, will conduct a corporate clinical trial to confirm its efficacy and promote research and development toward commercialization.

[Outline]

The Department of Orthopaedic Surgery, Graduate School of Biomedical and Health Science Medical Sciences (Medicine), Hiroshima University ("Hiroshima University") under the leadership of Professor Nobuo Adachi, has discovered the efficacy of Silk-Elastin in promoting meniscal regeneration through collaborative research with Sanyo Chemical Industry, Ltd. ("Sanyo Chemical"). Based on these results, an investigator-initiated clinical trial was conducted at Hiroshima University Hospital from June 2022, and the safety of Silk-Elastin (P47K-WAS-MR) was confirmed.



1.Implanting Silk-Elastin at the tear **2.Suturing**

Silk-Elastin is injected into the tear

Based on these results, we will transition to a corporate clinical trial focusing on the efficacy evaluation from spring 2025. This trial will be supported by the Japan Agency for Medical Research and Development (AMED) as part of the "Development and Commercialization of Innovative Therapeutic Technology for the Radical Cure of Meniscus." Details are as follows.

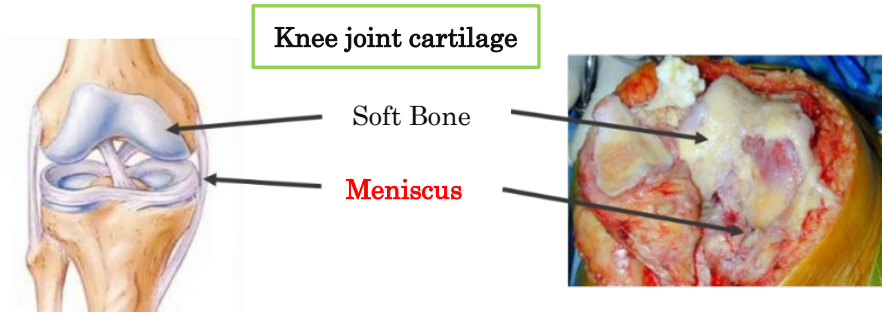
Project name: FY2024 Medical Innovation Promotion Project
Project Title: Development and Commercialization of Innovative Therapeutic Technology for Ultimate Cure of Meniscus
Researchers: Sanyo Chemical Industries, Ltd, Hiroshima University, Kagawa University and Koryo Chemical Industry Co., Ltd.
Period: May 2024 - March 2027 (planned)
Plan: Conduct corporate clinical trials based on investigator-initiated clinical trials
Design the product forms with high usability (design of containers and packaging materials, etc.)

[Background]

The function of the knee and other joints declines with age and obesity, posing a risk of decreased mobility and greatly affecting the so-called "locomotive syndrome. In particular, the cartilage and meniscus of the knee joint, which governs walking, are important tissues that act as cushions to absorb the shock of movement, reduce joint friction, and enable smooth movement of the knee. However, damage or deformity to the cartilage and meniscus occurs due to factors such as aging or sports, leading to the knee osteoarthritis and chronic pain that interferes with daily life.

In recent years, it has become clear that in addition to repairing the knee joint cartilage, the repair and regeneration of the meniscus are crucial for the ultimate cure of knee joint disease. However, due to the limited blood flow at the meniscus and is difficult to repair once damaged, the mainstay of treatment is to remove the torn piece of the meniscus if unavoidable. Nevertheless, even the removal of a small portion of the meniscus can significantly impair knee function and potentially lead to osteoarthritis, thereby, limiting mobility and causing difficulty in bending, straightening, and walking. Therefore, it is desirable to preserve as much of the meniscus as possible.

Professor Nobuo Adachi and his research group at Hiroshima University, who have been leading in the field of knee joint injury treatment, have focused on osteoarthritis as a cause of locomotive syndrome. They are collaborating with Sanyo Chemical Industries to develop a treatment concept termed the "ultimate radical cure"' which aims to regenerate both knee joint cartilage and meniscus using Silk-Elastin. This collaboration aims to address the root cause of locomotive syndrome



This research and development was conducted with the following support from AMED.
・The "Acceleration Transformative Research for Medical Innovation Set-up scheme "ACT-MS" (Research on the development of an innovative approach for restoration of the meniscus) was started in September 2018.
・From August 2020, the " Acceleration Transformative Research for Medical Innovation (ACT-M)" (Research on development of an innovative approach for total solution of meniscus injury).

[Future plan]

The objectives of this investigator-initiated clinical trial were to confirm the safety of the Silk-Elastin sponge, to identify issues, and to establish an efficacy evaluation index, all of which were achieved.

The treatment method using Silk-Elastin is expected to become a new treatment method to preserve the meniscus and to repair and regenerate the meniscus for patients who previously had to have the meniscus removed. If its efficacy can be demonstrated in the corporate clinical

trials, it will have an extremely large impact on the world. We will confirm the efficacy of the product in the corporate clinical trials from spring 2025, and aim for early approval as a medical device.

<Reference>

(1) About Silk-Elastin

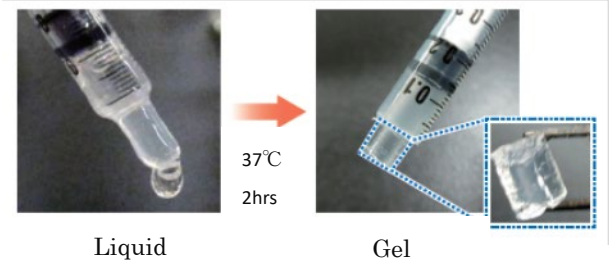
Silk-Elastin is an artificial protein produced by genetic recombination technology that mimics the naturally occurring proteins elastin*1) and silk fibroin*2). Silk-Elastin is suitable as a scaffold for promoting repair and regeneration of living tissues because of its high cell affinity and elasticity due to the large number of elastin sequences in the molecule, and is expected to be applied to various regenerative therapies.

*1) Protein that constitutes skin, *2) Protein that constitutes silk

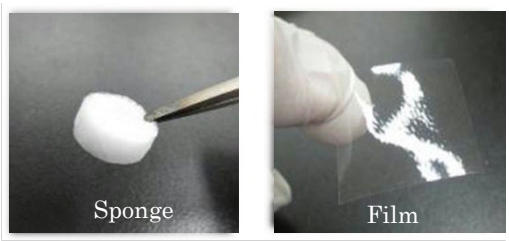
Structure of Silk-Elastin

*GVGVP is an amino acid sequence, G: glycine, V: valine, P: proline.

When aqueous Silk-Elastin solution is heated, the protein structure changes and solidifies (gels) in a hydrated state. Furthermore, Sanyo Chemical's proprietary surface control technology has made it possible to process Silk-Elastin into sponge (Silk-Elastin sponge) and film (Silk-Elastin film) forms that can be processed at various densities and thicknesses. Therefore, it is possible to design Silk-Elastin in the optimal shape for meniscus repair and regeneration.



Thermosensitive gelation of Silk-Elastin



Silk-Elastin's material formability

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