July 1, 2024
Sanyo Chemical Industries, Ltd.
Kyoto University Hospital

Confirmation of High Safety and Efficacy of Artificial Protein Silk-Elastin® in Chronic Wound Healing

- Innovative Material for Chronic Wound Healing Moves Toward to Regulatory Approval-

Sanyo Chemical Industries, Ltd. and Professor Naoki Morimoto of the Department of Plastic and Reconstructive Surgery, Kyoto University Hospital, are pleased to announce positive results from a corporate clinical trial initiated in July 2021 for Silk-Elastin® Sponge, a novel healing material jointly developed for the treatment of chronic wounds[*1]. This collaborative R&D has led to the successful development of Silk-Elastin® Sponge, with clinical trials has been conducted since July 2021 to evaluate its efficacy and safety.

Based on the trial results, Sanyo Chemical has initiated the application for manufacturing and marketing approval of Silk-Elastin® Sponge for chronic wound healing, aiming for practical application within the next fiscal year.

[Outline]

In recent years, the increasing number of diabetic patients and the aging population have raised concerns about the growing prevalence of chronic wounds, such as diabetic skin ulcers. These chronic wounds, with their delayed healing due to various factors, are highly susceptible to bacterial infection, leading to a vicious cycle of further impedes recovery. The newly developed healing material, made from the artificial protein Silk-Elastin®, has shown efficacy in treating these vulnerable chronic wounds in animal studies and has undergone safety evaluations in investigator-initiated clinical trials at Kyoto University Hospital.

[Corporate Clinical Trial Results]

Based on the results of investigator-initiated clinical trials, Sanyo Chemical in collaboration with Kyoto University Hospital and Koryo Chemical Co., Ltd., conducted a corporate clinical trial from July 2021 to May 2023 at five medical institutions nationwide to verify the effectiveness of the Silk-Elastin® Sponge as a wound healing material.

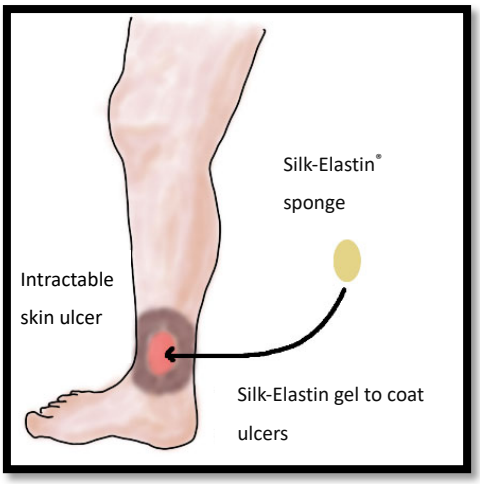
The trial was designed for patients with intractable skin defect wounds that were unresponsive or considered untreatable with existing standard treatments. This included 20 cases of chronic wounds (diabetic ulcers, venous stasis ulcers, pressure sores, etc.), and 5 cases of acute wounds (complicated wounds, second-degree burns or higher, localized wounds considered controllable and susceptible to resolution of infection).

In this trial, the Silk-Elastin® Sponge showed efficacy in 23 out of 25 cases, confirming its high effectiveness. Regarding safety, no new adverse events or malfunctions were observed since the investigator-initiated clinical trials, consistently affirming its safety profile.

This clinical trial was supported by the Development of Medical Devices through Collaboration between Medicine and Industry Project.[*4] of the Japan Agency for Medical Research and Development (AMED).

Silk-Elastin® sponge

Corporate Clinical Trials using Silk-Elastin® Sponge



[Impact and Future Plans]

Based on the results of the clinical trials, we plan to apply for regulatory approval for the Silk-Elastin® Sponge as a medical device for the treatment of chronic wounds and aim to launch it domestically in the next fiscal year.

Once approved, the Silk-Elastin® Sponge will become a new healing option for patients with chronic wounds that have not responded to conventional therapies, significantly improving their quality of life (QOL).

< Supplementary Information>

*1 About Chronic Wounds (Intractable Skin Ulcers)

When the skin is damaged due to burns, injuries, or the removal of skin cancer, the wounds usually heal with standard treatments if the body has the ability to heal them. However, wounds that lack this healing ability are referred to as chronic wounds (intractable skin ulcers). The main issue with chronic wounds is that they take a long time to heal or may not heal at all. Causes of chronic wounds include diabetes, venous insufficiency, pressure ulcers (bedsores), and collagen diseases. To treat chronic wounds, it is essential to keep the wound moist and prevent bacterial infection. This involves cleaning the wound daily, applying healing ointments, and regularly changing dressings. If the dressing is not changed for several days, bacteria can multiply and cause an infection.

*2 About Silk-Elastin® Sponge as a Chronic Wound Healing Promoting Material

Silk Elastin® is an artificial protein created using genetic engineering by combining sequences from silk fibroin*(1) and elastin*(2) (Figure 1). When aqueous Silk-Elastin® solution is heated, the protein structure changes and solidifies (gels) in a hydrated state (Figure 2). We discovered that Silk-Elastin® prevents bacterial infection and promotes wound healing

*3 About the Investigator-Initiated Clinical Trial

From February to December 2018, an investigator-initiated clinical trial using the Silk-Elastin® Sponge was conducted at Kyoto University Hospital, focusing on chronic lower leg

ulcers. This trial confirmed the safety of the material.

*4 Support from the Japan Agency for Medical Research and Development (AMED) for the Development of Medical Devices through Collaboration between Medicine and Industry Project.
Project Title: Support for the Development and Commercialization of Wound Healing Materials Using Innovative Protein Silk-Elastin®.
Link to the Japanese release: https://www.med-device.jp/developmentorg/01-303/

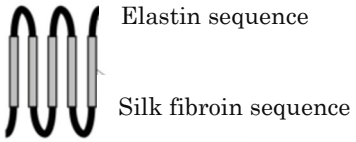


Fig.1 Structure of Silk-Elastin®

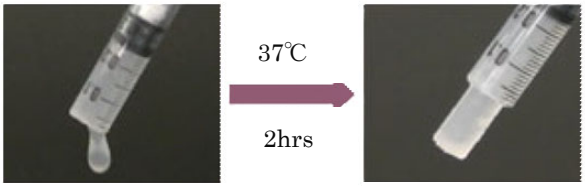


Fig.2 Thermosensitive gelation of Silk-Elastin®

(1) Silk-fibroin: It is a fibrous protein produced by silkworms and is the raw material for silk.
(2) Elastin: The primary protein constituting elastic fibers. The elasticity of skin, lungs, and arteries is due to the function of elastic fibers.

< Related Links>
1) Press release about the start of investigator-initiated clinical trial
"An investigator-initiated exploratory clinical trial for refractory skin ulcer of lower leg using silk-elastin sponge (P47K-WAS) to evaluate the safety"
https://www.amed.go.jp/news/release_20180205-01.html

2) Press release about the results of investor-initiated clinical trial
"Development of artificial protein to cure intractable wounds:
Industry-government-academia collaboration leads to investigator initiated clinical trials and then to corporate clinical trials."
https://www.sanyo-chemical.co.jp/archives/4820

3) Press release about the start of corporate clinical trials
"Corporate clinical trials for an artificial protein to heal intractable wounds will begin in July 2021 - Targeted for commercialization in 2023 as a revolutionary treatment for chronic wounds."
https://www.sanyo-chemical.co.jp/archives/8422

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