MERIT Startup Challenge Report

Department of Bioengineering, School of Engineering, MERIT 13th Cohort Sekino Laboratory, Anna Iino

Entrepreneurial Challenge Period: October 7, 2024 – March 31, 2025

Title: Development of New Medical Devices Based on Design Thinking

Commercialization Concept:

Issue: There is currently no treatment available to halt the progression of disease in patients with HFpEF.

Heart failure with preserved ejection fraction (HFpEF) is a type of heart failure in which the heart cannot pump sufficient blood throughout the body. This is due to reduced elasticity or stiffness of the myocardium, which hinders the heart from filling with enough blood during diastole (Figure 1). Common symptoms include shortness of breath, fatigue, and edema.

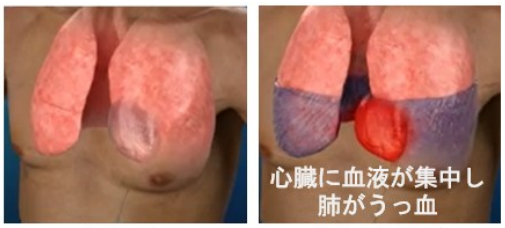

Figure 1 Pathophysiology of Patients with HFpEF

Most HFpEF patients experience recurrent hospitalizations and a gradual worsening of their condition. However, no effective treatment exists today. In fact, approximately 220,000 patients (26% of all HFpEF patients) are hospitalized for HFpEF, with hospital stays ranging from 7 to 10 days. This suggests a market size of approximately 171.6 billion yen (220,000 × 780,000 yen per hospitalization).

Solution: By providing a treatment device for HFpEF, we aim to improve prognosis and reduce readmission rates.

The main pathology in HFpEF is pulmonary congestion caused by elevated left atrial pressure. If we can develop a device that continuously reduces left atrial pressure, we can expect to improve patient outcomes. The applicant is developing a novel device to reduce left atrial pressure. This device aims to provide curative treatment in a single procedure, thereby preventing readmissions. If successful, this treatment could improve the prognosis not only of HFpEF patients but also of 1.2 million heart failure patients in Japan. We are currently developing a cryo-catheter that promotes sustained reduction in left atrial pressure (Figure 2).

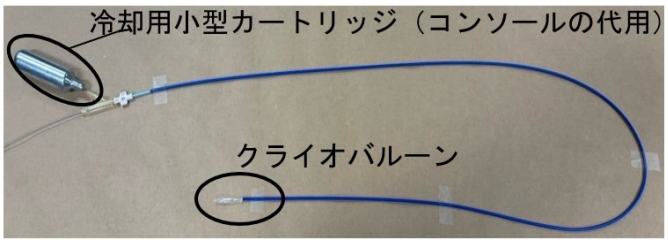

Figure 2 Prototype of Cryo Catheter

Activities During the Biodesign Fellowship (Prior to the Stanford Training)

Our project team consists of four members: a cardiologist, a cardiovascular surgeon, a member with a business background, and myself (Figure 3). We were selected as the 10th cohort of the Tokyo Biodesign Fellowship, organized by the University of Tokyo's Faculty of Medicine, and formed our team through this program.

Tokyo Biodesign is a medical device development program that aims to practically teach the mindset and skills necessary for creating innovative medical technologies. The process is rooted in identifying unmet clinical needs and employs a design thinking approach.

Figure 3 Team Members

Our team began activities in May. At the start of the program, we spent nearly every day for two weeks observing surgical sites and intensive care units at the University of Tokyo Hospital, identifying clinical needs from the medical frontlines. From approximately 270 identified clinical needs, we evaluated each based on the following quantitative indicators:

- Degree of understanding of the pathology
- Market potential
- Value delivery to stakeholders such as patients, their families, and healthcare providers
- Team interest

Based on these criteria, we selected the most promising need, which was:
"A method to relieve shortness of breath in heart failure (HFpEF) patients by sustainably lowering left atrial pressure."
For the selected need, we further defined criteria from the perspectives of:

- Effectiveness
- Invasiveness
- Cost
- Usability

These criteria were categorized into "Must-have" (essential to meet) and "Nice-to-have" (desirable to meet) standards.

To address the identified need, we conducted team brainstorming sessions to generate ideas (Figure 4). During brainstorming, we deliberately disregarded feasibility and other constraints, encouraging free and uninhibited ideation. As a result, the team generated approximately 100 potential solutions.
We then screened the ideas to determine which met the predefined Must-have criteria. Among those, we further evaluated:

Figure 4 Ideas Generated from Brainstorming

- Patentability
- Regulatory approval difficulty
- Insurance reimbursement complexity
- Business model viability
- Product feasibility

Through this comprehensive process, we concluded that the most suitable solution was the cryo-catheter shown in Figure 2.

Training at Stanford University

As the culmination of the Biodesign program, from February 10th to 14th, we had the opportunity to present our

project and receive feedback at Stanford Biodesign, the home of the Biodesign methodology. One of the most valuable takeaways from this experience was learning the basics of catheter manufacturing and reaffirming the importance of intellectual property and patent strategy.

Figure 5 Presentation at the Consulate-General of Japan in San Francisco

During our stay, we were also invited to the Consulate-General of Japan in San Francisco, where we presented the progress of our project (Figure 5).

In addition to receiving feedback on our own project, we visited an organization that supports the development of medical device startups. There, we attended a presentation by developers of a cryo-catheter (targeting a different disease) similar to ours. The subsequent discussion with them helped resolve some of our critical questions regarding development direction and strategy—an invaluable experience (Figure 6).

Figure 6 Visit to an Organization Supporting Medical Device Development for Startups, Where We Were Shown the Cryo Catheter Under Development

Before traveling to the U.S., we had searched in Japan for companies or laboratories that could manufacture cryo-catheters, but we were unable to find any and felt uncertain due to unresolved issues. However, while at Stanford, we secured meetings with two startup companies that manufacture cryo-catheters and were able to speak directly with their CEOs.

The abundance of medical device development professionals in Silicon Valley and the openness of the environment to newcomers were both surprising and inspiring. This experience made me seriously consider living and developing products in such an environment at some point in the future.

Future Funding Plans

For the future development of our project, we plan to utilize government grants. We are currently applying for, or planning to apply for, the following funding programs:

- **Sōgyō Program** (a JST initiative aimed at cultivating deep-tech startup leaders and supporting the creation of startups capable of IPOs and M&As)
- **Translational Research Program** (a support program for university-based medical startups by AMED)
- **Support Program for R&D-based Startup Founding and Management Talent / Entrepreneur Development Program in the Deep-Tech Sector (NEP) / Frontier Track "NEDO-Front-Runner (FR)"** by NEDO
- **IJIE-GAP Fund Program 2024 (Step 1: "Pre")** by IJIE

We have already been selected for the first stage of the **Sōgyō Program**, and are currently working toward advancement to the second stage. If selected for Stage 2, we will receive development funding of 5 million yen.

Patentability

We conducted a patent search using **J-PlatPat** and **Google Patents** to investigate similar products not only in Japan but also globally (Figure 7). Through this process, we confirmed that there is a reasonable expectation that the novel aspects of our development could demonstrate **inventive step**.

We also consulted with a patent attorney who specializes in medical devices to discuss these findings. As a result, we confirmed that the likelihood of infringing upon existing patents is low, and that our concept has a strong potential for **patentability**.

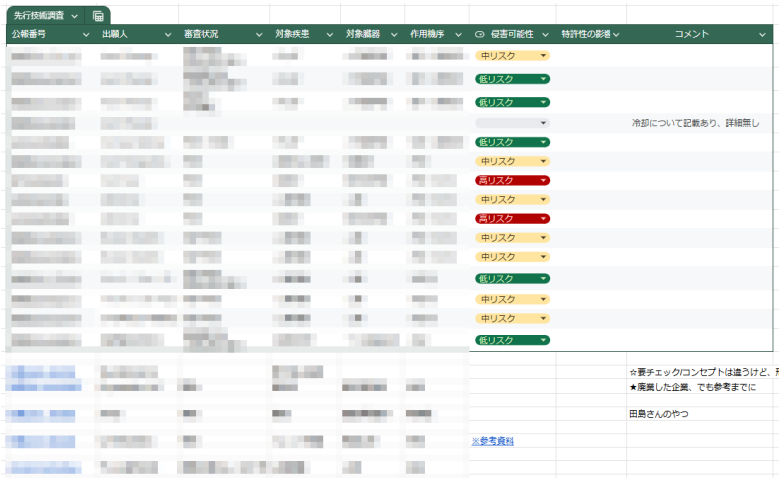

Figure 7 Prior Patent Search