



Toward the development of new ultrasound diagnostic technologies

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There have long been calls for the development of new innovative medical devices. In the domain of diagnostic ultrasound, what should we start with when attempting to create such an innovative device? Unfortunately, I do not have a clear answer to this question. However, I assume that there are the following possible general approaches in the development of medical devices.

The first is a sort of traditional approach in which one searches for a clinical application for which seeds of technology developed by an engineer or developer look like they could be useful. With this approach, I think that the development of technology often starts by searching for a technologically interesting topic while keeping in mind the fact that it should be clinically useful. Participating in conferences is an indispensable part of searching for new technologies and exploring current technological trends. One representative international conference related to ultrasonics is the annual IEEE International Ultrasonics Symposium. Subjects related to medical ultrasonics have tended to account for the majority of presentations in recent years, which gives us a strong sense that the medical application of ultrasound is a matter of global interest. At last year's online conference, there were too many presentations related to technological topics to name them all here, but some examples are Super-Resolution Imaging, Photoacoustic Imaging, Functional Ultrasound and Brain Imaging, New Methods in Elastography, and Deep Learning-Based Imaging. At first glance, some appear to be technological topics that have been around for a long time, but they include technologies that have seen a revival as of late with the introduction of new techniques such as deep learning and advances in peripheral technologies like improvements in computational speed.

Another approach is to begin development of a technology after identifying a medical need. Several years ago, I was seconded to the Medical and Assistive Device Industries Office, Ministry of Economy, Trade and Industry, Japan, where I was involved in the revitalization of Japan's medical device industry from a policy perspective. The Japan Agency for Medical Research and Development (AMED) was established just at that time, and I was also involved in transferring the operations of the Ministry of Economy, Trade and Industry's Medical Device Development Assistance Program. An issue that we were aware of at the time in terms of policymaking was medical device manufacturers not finding a big enough market for the medical devices they had developed. That is, as a matter of policy, technological development based on marketing was recommended, not starting technological development based on a medical need proposed by one doctor. This was also around the time that the Stanford Biodesign Program would be started in Japan. According to my understanding, Biodesign refers to the process where engineers or developers embed themselves in a clinical site and uncover unmet needs that might be useful for clinical procedures by watching procedures of physicians, come up with a product concept by narrowing down their ideas through brainstorming, and commercialize the product after proof of concept. Here, an unmet need refers to a potential need that neither the physicians nor technicians who use medical devices have noticed.

I imagine there is a diverse range of opinions regarding which approach is better when developing new ultrasound diagnostic technologies, starting with seeds of technology or starting with medical needs. Nevertheless, one could say that The Japan Society of Ultrasonics in Medicine (JSUM), which has evolved through close collaboration between engineering and medicine, is a rare entity that is capable of starting with either approach. For example, even if researchers in the field of engineering cannot immediately embed themselves in a clinical site to search for a medical need, they can read medical papers in the JSUM's Journal of Medical Ultrasonics (JMU), and

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they can also listen to medical presentations at JSUM's annual meeting. I do not think it is an exaggeration to say that JSUM has been practicing medicine-engineering

collaboration since before the advent of Biodesign. I think that this is JSUM's strength and that we must make an effort to continue this collaboration.

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