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Computer-Assisted Hip Joint Surgeries Improve Patients' QOL

IT innovation and digitalization are underway in a variety of fields. The field of medical devices is no exception, as it can now offer high-quality treatment through computer-assisted surgeries that are no longer dependent on a surgeon's experience.

In the past ten years, we have worked toward achieving accurate and minimally invasive hip joint surgeries. We have developed a new operative procedure allowing surgeons to view images on a monitor while simultaneously performing surgeries—not unlike using a car navigation system—and insurance coverage for this started from April 2012. This procedure enables less-experienced surgeons to perform accurate surgeries more easily, and also allows patients to sit on their knees or assume a sitting posture with ease after artificial hip joint surgeries.

Hip joint surgery navigation using 3D data

The hip joint is formed where the ball-like round femur head meets with the bowl-shaped concave surface of the pelvis (acetabulum). The Japanese, especially women, are more likely to dislocate their hip joint because of the shallow concave shape, and thus more likely to wear out the cartilage covering both areas of contact. This can lead to scraped and deformed bones, resulting in limping, called claudication. In order to cure this condition, it is essential to undergo hip joint surgery.

One such surgery is "osteotomy," which is carried out at the initial stage when the cartilage is less deteriorated. Conventionally this was a fluoroscopy procedure, where a bone chisel gouged a deeper concave in the pelvis, reducing pressure and eliminating pain. However, our invention of the "Hip Joint Surgery Navigation" lowers the degree of difficulty and boosts the level of accuracy by projecting a three-dimensional image of the position and angle of the chisel on a monitor without using X-rays.

While an automotive car navigation system uses GPS (Global Positioning System), the Hip Joint Surgery Navigation uses an infrared ray sensor as a position sensor. We used to draw out a surgical plan by means of pre-surgery radiography, but at present CT scanning provides three-dimensional data, allowing us to identify a position and size more precisely. A combination of the image information along with the operation status of computer-assisted surgery allows surgeons to perform surgeries with one-millimeter, one-degree accuracy by sight, rather than by the sense of touch.

Setting an artificial hip joint in the optimal position

The Hip Joint Surgery Navigation is used in surgeries replacing a deformed hip joint with an artificial one because of rheumatoid arthritis other than hip osteoarthritis. By using computer measurements, the location where the tip of the bone chisel or drill reaches is projected in real time on a monitor, and the entire surgical process is recorded. This has allowed less-experienced surgeons to accurately set artificial hip joints in alignment with patients' bodies in the optimal position.

By being able to cut the bones while simultaneously checking the positioning of the surgical instrument, we can reduce the risk of surgical complications, such as blood vessel damage. Moreover, patient satisfaction is higher when there is minimal incision of the muscle, and the accurate positioning of artificial hip joints will help maintain a stable condition over a longer period of time. Additionally, there are drastically fewer restrictions on movement, so patients are able to enjoy moderate sports activities post-surgery.

Previously, artificial joint components needed to be replaced every 10 years due to wear and tear. Today, however, most of them show improved performance and enhanced durability, and are usable for more than 20 years.

** This is a summary of the lecture by Dr. Sugano, edited by the editorial desk.*

Nobuhiko Sugano
Professor, Department of Orthopedic Medical Engineering, Graduate School of Medicine, Osaka University

Dr. Sugano graduated from the Faculty of Medicine, Osaka University in 1985. After completing the doctoral course at the Graduate School of Medicine, Osaka University in 1994, he became a Research Assistant at the Department of Orthopedic Surgery, Faculty of Medicine, Osaka University. After assuming the position of Associate Professor in 2001 and then Assistant Professor at the Department of Organ Regulation Medicine (Orthopedics) at the same university, he was appointed to his current post in 2008.

Empowering Japanese Patients Through Innovation

Japan's Aging Challenge

Every country in the developed world is experiencing the "graying effect." But Japan is at the forefront of this global phenomenon of rising healthcare costs, a shortage of providers, and dramatic increases in the number of the elderly. No nation will feel the impact of this aging effect as much or as quickly as Japan.

Between now and 2050, Japan will witness a substantial drop in population as the number of people over 65 rises to 40 percent. That transformation will bring with it significant economic, cultural and clinical changes.

Although we have many issues at hand, Japan's healthcare system is fortunately one of the best in the world, in terms of the level and access to basic care. There is a lot to be proud of. However, the hospital-centered system that has worked well for earlier, younger generations of Japanese is already coming under great pressure to adapt to the demographic and financial realities of the 21st century. Today, the average Japanese sees a physician almost 14 times a year. That is three times the number of patient visits seen in most developed countries.

Japan also has twice as many hospitals and three times as many hospital beds than other developed nations, while the average length of a hospital stay in Japan is two to three times longer. Most of those other nations are also struggling to find ways to pay for their healthcare systems.

Many of the solutions to the issues outlined here will come directly from innovations in technology, and will be especially critical in the areas of medical equipment, IT and information management. However, there is also a clear need for business and management innovations. Without properly trained professionals and an optimal system in place, it will not be possible to manage medical care going forwards.

Building a Bridge Between the Hospital and Home

Meeting the needs of an aging population could also mean adopting new technologies that can serve as a bridge between the hospital and the home. It is a path that will lead to a continuum of quality care, which should be our first priority. It can also enable long-term independent living for more seniors, and create a more cost-effective healthcare system for Japan.

Building a strong bridge between the hospital and home will not be easy. It will take a partnership between patients and providers, the private sector and the government, and between the innovators and the implementers.

It will also take a commitment to change, and that is not easily accomplished either. Most cultures are intrinsically conservative when it comes to change, especially among older people comfortable in their traditions and way of life.

As we are currently seeing in the U.S., changes in healthcare often generate strong emotions, in part because it is so personal. It is about how we choose to live and sometimes about how we decide to die.

It is about how we take care of our children, and more and more in the years to come. It is going to be about how we take care of our parents and our grandparents. It is about how we as societies determine the quality of life the oldest among us will enjoy.

Those seniors will have something to say on the matter as well. They are concerned about their health because they value their independence. Many fear becoming a burden on their

families. They have unique health needs, but they still have much to give to younger generations. And they want to contribute to their communities for as long as they are able. Whatever changes in healthcare occur, these universal attributes must be honored, respected, and leveraged for the overall good of society.

The 20th century paradigm of hospital-based care must be reformed to reflect economic and demographic realities. The healthcare systems of the future must focus more on prevention, screening, and early diagnosis, rather than on the last stages of the care cycle. New technical innovations in diagnostic procedures that are commonly performed in the hospital will need to be, and can be, performed in the home. This information will then be transferred to the caregiver regardless of their location, using new innovations that are actually readily available today. The issue is that such innovations are not being implemented, and so the benefits to the patient, families, caregivers and payers are not being realized.

Using hospitals to deliver routine care such as ongoing health monitoring may no longer be necessary, cost-effective or even preferable for patients. Innovative home health solutions are a better answer for patients, clinicians and the financial bottom line.

Hospital care will continue to be the setting for addressing serious clinical situations that require medical diagnosis and intervention that are not appropriate, safe or financially acceptable in the home. Let me be clear that hospitals will never go away, and that they are an integral part of our healthcare system. Therefore, innovations in the hospital are also required to assure that the continuity of care is provided in the home as well as intra-hospital.

Unfortunately, many of these new and or potential technologies are not covered by insurance. This is true here in Japan and in other countries like the U.S. Yesterday's healthcare regulatory framework has not caught up with today's remarkable technology.

Building a Healthcare Bridge to the Future

Home Healthcare is an evolving market which we believe will grow in new directions to meet significant demands caused by the increase in chronic diseases and an aging society. Philips is currently engaged in four main homecare markets: Sleep, Home Respiratory Care, Respiratory Drug Delivery, and Home Monitoring. By leveraging our expertise and experience, we intend to lead the evolution of healthcare through better awareness, diagnosis, treatment, monitoring and management of conditions for at-risk individuals.

Our focus on our customers and our commitment to work with them hand-in-hand to transform the home healthcare market to meet the needs of the future is critical to our ability to fulfill this vision and mission.

The list of new technologies is a long one, but I would like to highlight a unique Philips innovation that illustrates the benefits that home health technology can already provide.

The auto alert technology was developed based on years of fall detection experiences and movement detection algorithms to detect when an elderly person with the auto-detect pendant has fallen. The technology differentiates between someone sitting or lying down

for a rest versus falling and potentially being hurt. This is what is needed in an emergency situation.

For decades, Japan has been a pioneer in creating innovative technologies that have changed the world. Yoshiro Nakamatsu, the Thomas Edison of Japan, gave us the floppy disk and hundreds of other inventions. Another Japanese scientist invented the blue LED, which formed the basis for all high-capacity optical media. Japan was the first to create the original transistor radio, and has been keeping our kids entertained with interactive video games for more than two decades. And I can tell you many throughout the world are grateful for these wonderful innovations.

Then, of course, there are robots. Nobody builds robots better than Japan. In Japan, there are robots that throw baseballs and play the violin and those that can even cook. There is even a robotic baby seal used in nursing homes where they provide a calming effect on patients. Recently, Japanese researchers unveiled a new hi-tech robotic wheelchair that looks like a motorcycle with a joystick.

It shouldn't be a surprise to anyone that Japan is a global technology leader. In 2006, Japan filed for more patents than any other country in the world – more than half a million, according to the World Intellectual Property Association.

The respect and care for the elderly in and of itself can be an innovation here in Japan if it is thought of broadly and used as a core in developing the future system for their support and care. It is also why I believe that Japan, as it faces the challenges of its own aging population, can also help find innovative solutions that will impact patient care and quality of life globally.

All of us have a stake in building a healthcare bridge to the future by empowering patients and clinicians with the technology of change. By educating family members to provide needed support, getting policy leaders to make the right decisions, and truly accepting and using innovation, we will have a better future.

Today's health technology gives us one piece of our 21st century healthcare puzzle. Future innovation will help put the last pieces in place for our parents, ourselves and our children.

Danny Risberg
Vice-Chairman, Chairman of Medical Equipment Committee, EBC
President & CEO, Philips Electronics Japan, Ltd, Philips Respironics Japan

Patient's Voice
Ostomy Patients and Stoma Appliance

By Mr. Michiaki Takaishi
President, Japan Ostomy Association, Inc.

Because of colorectal cancer, bladder cancer, or inflammatory bowel disease, ostomy patients discharge their body waste from the opening (stoma) created in the abdomen by

changing the discharge paths of stool and urine, and discard the released waste in a bag attached to the skin covering the opening.

Patients who have received ostomy surgeries around the world call each other "ostomates." These patients are recognized as physically disabled persons in Japan, and based on the number of physical disability certificates issued, the number of ostomates per 1,000 people is about 1.5 – in other words, about 200,000 people overall.

Because there are no sphincter muscles in the artificially created opening, patients are unable to consciously control the opening or closing of the stoma. Thus they are unable to live an ordinary life without stoma bags, where waste drains and accumulates. In other words, the quality of life (QOL) of ostomy patients depends on the quality of these appliances.

Ostomy surgeries seem to have been performed before modern medicine, but it was not until 30 to 40 years ago at most that high-quality stoma appliances like those used by ostomates today were developed and proliferated. Up until then, patients had managed with non-adhesive appliances such as diapers or containers secured with a belt. However, this led to leaked stool or urine, causing odor and rough skin. In 1952, it was discovered in the U.S. that karaya gum was effective as glue, so it has since become common practice to use a type of bag attached to the skin. Protective products using synthetic skin have also been developed since the 1980s, and lightweight, robust, and soft appliances that are gentle on the skin have since proliferated.

The Japan Ostomy Association, an organization of ostomy patients, has been around for 43 years – including a period as the predecessor voluntary organization – and the progress of stoma appliances in Japan overlaps with the history of the growth of our association. I believe this history reflects how the medical industry, manufacturers, and patient organizations have collaborated together to demand for better products.

I have lived with a stoma since 18 years ago when I had surgery, and now I am used to changing appliances each week. I still enjoy hobbies like playing musical instruments and mountain climbing as much as I did before the surgery, even while assuming the post of president. I am entirely indebted to the progress of stoma appliances that allow me to continue to enjoy this kind of lifestyle.

Japan Ostomy Association, Inc. http://www.joa-net.org/

Medical Journalist Viewpoint
Leveraging Companies' Craftsmanship

Mr. Katsuhiko Tagaya
Senior Staff Writer, *Asahi Shimbun*

"Originally, this was a machine tool manufacturer excelling at manufacturing lubricators for vessels. We entered the field of medical devices eight years ago. We have had difficulty

completing a project plan for business in this field," says Mr. Tsuneo Ohkusa, President and CEO of Yamashina Seiki Co., Ltd. in Ritto City, Shiga Prefecture, seemingly with a sense of accomplishment while talking about difficulties in entering a new field.

In mid-June, a press conference was held in Osaka City on select cases for the Japanese government's "Kansai Innovation International Strategic Comprehensive Special Zone." Yamashina Seiki developed catheters in collaboration with Mr. Kiyokazu Nakajima, Assistant Professor (digestive organ surgery) at the Graduate School of Medicine, Osaka University. The catheters, which have a diameter of 2.5 millimeters and are equipped with irrigation and suction functions, as well as an electrosurgical knife, were highly evaluated.

Professor Nakajima's team consists of Fujifilm as an advisor, and four other small and medium enterprises in addition to Yamashina Seiki. The team hopes that this catheter product will become the global standard as the next-generation endoscope, along with a constant-pressure air-supplying system that inflates the stomach and intestines automatically for easier treatment.

Every company stepped into the field of medical devices out of a sense of crisis over Japan's manufacturing industry losing its edge. The issue facing all Japanese manufacturers, regardless of the company's size, is the same: What could be the main line of business for tomorrow?

Medical devices are positioned as a growing sector where many small and medium enterprises expect to take advantage of their own existing technologies. The wall is formidable for newcomers, however. Mr. Makoto Hosaka, who has been responsible for development since the beginning of the foray into this field, confesses, "This wouldn't have started without our encounter with Professor Nakajima."

There is little opportunity for newcomers to learn about clinical needs. A valuable source of information for Yamashina Seiki was the "Forum for Industrialization of Next Generation Medical Systems," held monthly for the last nine years by the Osaka Chamber of Commerce and Industry. Doctors make presentations on the technologies they require in front of employees from manufacturing companies, including big name firms. This fiscal year, more than 170 companies registered for the forum.

It has long been pointed out that the provisions of the Pharmaceutical Affairs Law are ill-suited in reviewing medical devices. In addition, the promotion of opportunities to link the clinical side with technologies, as well as the nurturing of service companies dealing with pharmaceutical application procedures and the production of prototypes, leads to the use of technologies by small and medium Japanese enterprises in medical care.

There is a precedent in the state of Minnesota in the U.S. Various companies engaged in the development of medical devices, universities, lawyers, and medical institutions have formed a medical device cluster. The Osaka Chamber of Commerce and Industry has been in partnership with the state of Minnesota since 2010, and the Chamber is considering sales of Professor Nakajima's endoscopes in the U.S. market by taking advantage of this channel.

As a result of the forum organized by the Osaka Chamber of Commerce and Industry, the number of cases making substantial progress in development has reached 123, including

Professor Nakajima's case. In addition to Minnesota, partnerships have also been made with Singapore and Germany. The day when the craftsmanship of small and medium enterprises can be leveraged for global medical care is not far off.

AMDD Awarded by the U.S. Commercial Service

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) received a Certificate of Appreciation from the U.S. Commercial Service on June 6, 2012.

This award is presented to companies and organizations promoting exports by U.S. enterprises to Japan in cooperation with the U.S. Commercial Service, as a part of World Trade Week.

(From left) Mr. John Peters, Minister-Counselor; Takashi Shimada, AMDD Chairman; Mr. John Roos, Ambassador

The AMDD was recognized for its activities to improve the regulatory environment related to medical devices and in vitro diagnostics, as well as related to insurance reimbursement prices in cooperation with U.S. Commercial Service. Mr. Shimada, Chairman of the AMDD, attended the award ceremony, and was presented with the certificate by U.S. Ambassador John Roos.

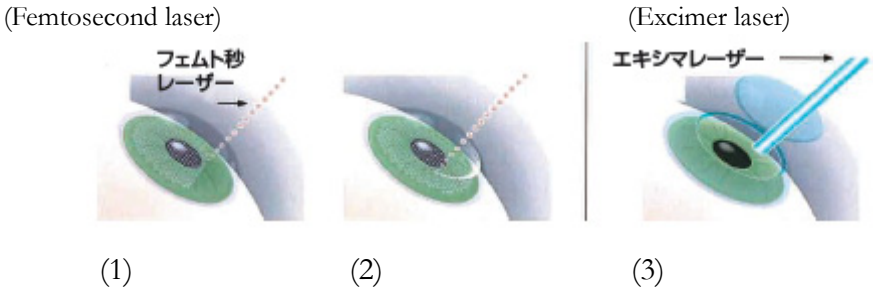
First observed in 1933, World Trade Week has since expanded its scope to include many activities in recognition of the importance of international trade to the U.S. economy. President Obama delivered a statement on May 21, emphasizing its importance.

The Value of Medical Technology
(Ophthalmic Materials)
iLASIK: Refractive Surgery Approved by NASA

LASIK (laser in situ keratomileusis) is a surgery to correct the refractive errors of myopia and astigmatism using a laser. The number of LASIK surgeries in Japan is estimated to be about 200,000 a year (surveyed by AMO).

Generally, the LASIK procedure includes creating a flap using an ophthalmic keratome (blade), ablating the corneal stroma underneath with an excimer laser, and repositioning the flap.

iLASIK is a technology combining certain testing equipment with laser equipment, and allowing custom-made vision correction. The wavefront technology is used to measure deformation of the corneal surface different for each patient, create a flap using a computer-controlled femtosecond laser instead of a keratome (*see Figure 1 and 2 below*), and irradiate (ablate) the corneal stroma with an excimer laser according to individual deformation of the corneal surface (*see Figure 3*).



(1) Irradiate the cornea with a femtosecond laser to form an ablated surface.
(2) Ablate the periphery of the flap in the same way.
(3) Lift the flap and expose the corneal stroma to perform the excima laser irradiation. Reposition the flap to complete the LASIK surgery.

LASIK was approved for the employment requirements of fighter pilots by the U.S. Department of Defense in 2006, and for the recruitment standards for astronauts by NASA in 2007 and by JAXA in 2008. The author received an iLASIK surgery at the end of 2007 following the NASA announcement, and while my pre-surgery vision was 0.08, it went up as high as 1.0 afterwards. Since then, I have been enjoying my life without glasses or contact lenses. Although iLASIK is an extremely accurate and safe surgery, I advise you not to be swayed by lower prices, but rather to receive surgery from a reliable ophthalmologist.

(By Kodama Junko, AMO Japan K.K.)

AMDD participates in "Children's Day for Visiting Kasumigaseki"

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) joined the exhibition booth named "'Devices' and 'Machines' to Fight Diseases" on "Children's Day for Visiting Kasumigaseki," held on August 8–9, 2012.

"Children's Day for Visiting Kasumigaseki" has been held as part of "Children's Day for Visiting," organized by the Ministry of Education, Culture, Sports and Technology since 1996. It is designed to provide children with an opportunity to visit ministries and agencies including the Ministry of Health, Labour and Welfare, and to help them deepen their understanding toward administrative work.

Organizations that participated in "'Devices' and 'Machines' To Fight Diseases" in addition to AMDD were the Medical Equipment Committee of European Business Council, Japan Electronics and Information Technology Industries Association, Japan Medical-Optical Equipment Industrial Association, Japan Federation of Medical Devices Associations, Japan Medical Devices Manufacturers Association, Japan Medical Imaging and Radiological Systems Industries Association, Japan Ophthalmic Instruments Association, and Japan Contact Lens Association.

The booth had hands-on exhibits of various devices and machines, such as equipment that displays the inside of an abdomen using a camera during surgical procedures, a simulation of blood sampling, a device to remove a stone formed inside the body, and equipment to assist a weak heart. Many children were able to learn more about the medical world through these medical devices.

Value of Medical Technology

Our mission is to make more people understand the unlimited potential of advanced medical technology and its contribution to the reformation of the Japanese medical care system

Note: All opinions in this newsletter are the personal opinions of the authors, and do not necessarily represent the opinions and activities of AMDD.