

Exoskeleton that helps paralyzed walk faces barrier in Japan

By **Yuri Kageyama**
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ATSUGI, Japan — Yuichi Imahata's nine-year-old daughter is thrilled her dad stands tall above her head. It's an experience that is new to her.

Imahata, 31, has been using a wheelchair to get around for seven years after a serious spinal-cord injury suffered in an accidental fall while working for a transport company. He completely lost sensation in both his legs and was told he would never walk again.

But he is now walking, at times with his little girl laughing beside him, because of a robotic exoskeleton called ReWalk.

The thrill is still limited to a rehabilitation center in Atsugi city, southwest of Tokyo, where ReWalk is available to a handful of Japanese paraplegics, skirting regulations, in the name of research.

It's already available in parts of Europe, and just received approval from the U.S. Food and Drug Administration for individual everyday use. But despite Japan's prowess in robotics, ReWalk advocates say its wider application in the country could be stymied by convoluted bureaucracy.

"It's a wonderful tool for people who sincerely want the joy of standing up," said Moriyasu Marutani of the Kanagawa Rehabilitation Center, who works with Imahata to use ReWalk.

"Safety is the biggest concern for winning its approval for medical use, as well as presenting data that work as scientific evidence of its health impact," he said. "Approval tends to take many years here, and so the hurdle is pretty high."

ReWalk, an invention of Israeli entrepreneur Amit Goffer, who was paralyzed in a 1997 accident, clasps on to the legs and waist, and is designed to create natural walking movements, including standing, sitting, and turning through upper-body motion sensors and special software. Medical experts say its use helps keep organs and bones healthy and also enhances mental wellbeing.

The product was one of the Israeli technologies highlighted with much fanfare as a symbol of flourishing commercial ties when Japanese Prime Minister Shinzo Abe met Israeli Prime Minister Benjamin Netanyahu during Abe's visit to the Middle East earlier this year.

Japanese robotics maker Yaskawa Electric Co. has been distributing ReWalk in Asia under a deal signed last year with ReWalk Robotics, based in Yokneam, Israel.

The effort is going far more smoothly in places such as China than Japan, said Yaskawa spokesman Ayumi Hayashida.

Hayashida believes ReWalk is being met by bureaucratic stonewalling that is typical of the frustrations Japanese businesses face in doing something new.

"We boast the No. 1 skill in robotics, but how we can actually use the skills is where we are behind the rest of the world," he said.

Under the Japanese system, there is a lengthy preliminary vetting process before a formal drug or medical device proposal can be filed. The Pharmaceuticals and Medical Devices Agency works with the health ministry to carry out consultations and nonclinical and clinical tests. Only after that can an application be submitted to be followed by a regulatory review and more testing.

The process has public safety in mind. Japanese drug approvals tend to take longer than the U.S. and Europe, but some feel the requirements are overly onerous and ill-suited to new technologies.

Hiroshi Yaginuma, a health ministry official overseeing the approval of medical devices, said ReWalk was not yet being considered for approval, and it was unclear whether it would meet the criteria for a treatment device. It is assessing the Hybrid Assisted Limb, or HAL, developed by Japan's Cyberdyne, in which a wearer's ability to walk is supported though it is not suitable for paraplegics.

Abe has promised a "robot revolution" including deregulation and research funding to double Japan's robot market size in manufacturing from 600 billion yen (\$5 billion) to 1.2 trillion yen (\$10 billion) per year, and boost it 20-fold in outside manufacturing, from 60 billion yen to 1.2 trillion yen by 2020.

Annual profits from robotics are already 340 billion yen (\$3 billion), or half the global market. That zooms to 90 percent for parts such as servo motors and force sensors.

Outside of manufacturing, however, regulatory barriers to practical and potentially life-changing robotics applications remain high.

"Technology is evolving and it spreads, finding new uses that weren't anticipated in the beginning," said Tomotaka Takahashi, creator of Kirobo, the boy-like humanoid that went on the International Space Station.



"It's truly pathetic when ridiculous regulations get set up, based on irrelevant and negative predictions," he said of the government approval system which he feels is out of touch with scientific innovation.

REGULATORY RED TAPE. Yuichi Imahata walks using a robotic exoskeleton called ReWalk at Kanagawa Rehabilitation Center in Atsugi, Japan. Imahata, 31, has used a wheelchair to get around for seven years after a serious spinal-cord injury suffered in an accidental fall while working for a transport company. He lost complete sensation in both his legs and was told he would never walk again. (AP Photo/Shuji Kajiyama)

Yaskawa, one of the top four robotics makers in the world in market share, built its reputation by supplying robotic arms and other automated machinery for automakers such as Toyota Motor Corp.

More recently, Tokyo-based Yaskawa has been expanding its lineup to robots that can co-exist with people, helping them get around and assisting in healthcare.

That area could boom in coming years because of Japan's aging population. There is also export potential because many other countries have growing ranks of old people as birth rates decline and longevity increases.

Yaskawa is hoping to fine-tune the \$71,600 ReWalk to make it lighter and smaller and hopefully cheaper. It currently requires upper body strength and is not the best design for the elderly. It also requires 40 hours of training.

Yet even in its current form, the device is freeing for wheelchair users, who can feel confined to a low eye-level.

"I've seen Americans using ReWalk on YouTube. They can reach things on shelves," said Imahata.

His wish is simple.

He dreams of wearing ReWalk to his daughter's school for the annual athletics event, standing in a crowd of parents, peering with anticipation over shoulders and heads, and catching a glimpse of his girl in action.

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