

FDA approves new total wrist replacement device to treat painful arthritis

March 25 2020



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The US Food and Drug Administration (FDA) has approved a new total wrist replacement device for people seeking relief from painful arthritis. The design is the culmination of three decades of award-winning

research by Scott Wolfe, MD, a hand surgeon at Hospital for Special Surgery (HSS), and Joseph J. Crisco, III, Ph.D., director of the Bioengineering Laboratory at Brown University and Rhode Island Hospital.

The HSS Innovation Institute worked closely with Drs. Wolfe and Crisco to obtain a patent for their research and design ideas. The patent was then licensed to Extremity Medical, LLC, a privately funded medical device company in New Jersey.

"We believe the new wrist replacement, known as the KinematX Total Wrist Implant, has advantages over traditional implants," said Dr. Wolfe, chief emeritus of the Hand and Upper Extremity Service at HSS. "Our extensive research into how the wrist moves helped us design a replacement that more closely matches the anatomy and motion of a normal wrist. This should allow for more natural motion and increased durability compared to currently available implants."

"In our view, the KinematX will be a game changer in the field of wrist replacement surgery," said Doug Leach, managing director of Biomechanical Innovation at the HSS Innovation Institute. "Current wrist replacement devices are relatively dated. The new implant design leverages the clinical and bioengineering experience of Drs. Wolfe and Crisco, their seminal research, and modern-day engineering and design principals of total joint replacement in general."

Wrist arthritis is one of the most common and debilitating conditions treated by hand surgeons, affecting about five million people in the United States. A fusion of the wrist bones can alleviate pain, but patients are often limited in performing some activities. Wrist joint replacement surgery was proposed five decades ago as an option to relieve pain and restore function.

"Most people are familiar with total joint replacement in the knee or hip, which is much more common and highly successful," said Dr. Wolfe.

"Total wrist joint replacement has not enjoyed the same degree of success. Historically, some studies demonstrate failure rates of near 50% within 5 to 10 years, mainly due to loosening of implant components."

Dr. Wolfe and his longtime colleague, Dr. Crisco set out to design a better wrist replacement 30 years ago. The first step was to unravel the complexity of how individual bones move in a normal wrist and in one that has sustained an injury. Their research led to the design and validation of a noninvasive three-dimensional motion analysis system to measure wrist kinematics, which describes the wrist motions necessary for a wide range of activities. Armed with that information, they sat down at Dr. Wolfe's kitchen table and started sketching out their idea for a novel wrist replacement based on their research.

Over the years, Drs. Wolfe, Crisco and colleagues have received more than \$10 million in research grants from the National Institutes of Health to study the wrist. They have published hundreds of papers in peer-reviewed journals.

In 2017, they received the Kappa Delta Award from the American Academy of Orthopaedic Surgeons and the Orthopaedic Research Society, considered one of the highest honors for an orthopedic researcher.

The wrist is highly complex, made up of more than a dozen individual joints formed by eight small bones that collectively make up the wrist. It was previously believed that the wrist moved the hand in two different planes—up and down or side to side. The research by Drs. Wolfe and Crisco demonstrated that during many activities, such as throwing a ball, hammering a nail or pouring a glass of water, the wrist doesn't move in just one of these directions. It accomplishes the action by combining

movements in both planes.

"Traditional wrist replacements often constrain the wrist to move in one plane at a time, and this puts stress on surrounding joints," said Dr. Wolfe. "The increased loads on the implant-bone interface often lead to prosthesis loosening and mechanical failure. In addition, traditional implants often make it difficult or impossible to return to some activities, such as tennis or golf."

The KinematX is the only wrist replacement that is computer-designed to mimic the kinematics, or motion, of a human wrist—movements that are instrumental in throwing, hammering and other high-performance activities, according to Dr. Wolfe. The unique design should enable the implant to be more durable than traditional wrist replacements.

Surgery with the KinematX entails replacing the proximal carpal row bones of the wrist, which are those most severely affected by osteoarthritis. The device utilizes modular components in various sizes to replicate the complex anatomy of the wrist and allow the motion necessary for occupational, recreational and household activities.

The Innovation Institute at HSS played a key role in the development of the new [wrist](#) replacement. "Our goal is to work with talented HSS physicians, inventors and entrepreneurs to empower them to develop innovations in musculoskeletal health that could improve or even revolutionize patient care," Mr. Leach said.

Wrist [replacement](#) surgery with the KinematX will be performed on an outpatient basis. Dr. Wolfe says he already has a waiting list of individuals who are good candidates. A patient registry will be established at HSS and other leading medical centers across the country to track data on outcomes.

Extremity Medical, LLC will be responsible for the manufacture and distribution of the KinematX Total Wrist Implant, which is expected to be available before the end of the year.

Provided by Hospital for Special Surgery

Citation: FDA approves new total wrist replacement device to treat painful arthritis (2020, March 25) retrieved 4 May 2024 from <https://medicalxpress.com/news/2020-03-fda-total-wrist-device-painful.html>

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