

Demand for Implants Still Going Strong

Non-fusion technologies, ceramics, orthobiologics expected to drive growth.

Michael Barbella

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The human body is an extraordinary machine. With trillions of cells, tens of thousands of miles of blood vessels, hundreds of muscles and an intricate genetic code that controls the functioning of all its parts, the body is a complex organic machine designed to constantly renew itself and run for decades with little maintenance. Few, if any, man-made machines are built as well as the human body.

Our bodies, however, are not infallible. While subject to normal wear and tear, they can break down or fail due to disease, neglect, overuse or aging. These breakdowns require a fix that is far superior to the body's remarkable self-repair mechanisms.



Over the last century, scientists and engineers have worked diligently to find ways to fix medical problems that have become too overwhelming for the body. Much of the effort has focused on the development of artificial body parts that rival the original.

Whether it's the knee, hip, eyes, ears, heart, kidney, brain or breast, advancements in technology, raw materials and medicine have made it possible for doctors to use artificial replacement parts almost anywhere on the human body. Once the subject of science fiction novels, artificial body parts are now a common and popular alternative to those suffering from defective joints, blocked arteries, poor vision or hearing loss.

The need for artificial body parts—particularly joints such as hips and knees—has been rising over the last several decades as people live longer and lead more active lives. Aging baby boomers are increasingly driving the need for joint implants as they strive to age gracefully and retain the mobility they have enjoyed for most of their lives. from defective joints, blocked arteries, poor vision or hearing loss.



These spinal screws are manufactured by Omni Components Corp., a Hudson, N.H.-based firm that makes components for the medical device and other industries. Photos courtesy of Omni Components Corp.

“The [joint] implant market is going to continue to grow,” said Steven Hughes, sales manager for Ortho-pedic and Medical Devices at C5 Medical Werks, a ceramic implant manufacturer based in Grand Junction, Colo. “People are going to need these replacements. You have an aging population that wants to remain active and younger patients that don’t want to lose their mobility at such an early age. It’s definitely going to be a growth industry.”

Market research supports Hughes’ assertion. The global joint reconstruction market, valued at \$12.2 billion last year, is expected to grow by more than 9 percent annually to reach \$17.4 billion by 2012, according to a December 2008 report from Global Markets Direct, a worldwide business intelligence firm. Key growth segments within the joint reconstruction sector include gender-specific knee implants and hip and knee resurfacing product lines, the report stated.

Forces Currently Shaping the Implant Market

As the demand for joint replacements has escalated, the market has come to a crossroads. Surging demand has driven orthopedic companies to look beyond the time-tested, conventional methods of fixing aging joints and develop implants that use new materials and surgical techniques.

One of the newer materials that has gained popularity in the joint replacement market in recent years is ceramics. This substance has enabled companies such as C5 Medical Werks to meet a longstanding industry challenge of developing bearing surfaces that can withstand the higher demands of younger, more active patients. The development of those bearing surfaces has been a challenge in itself, thanks to the anatomy of the hip.

The human hip joint is composed of a ball and socket. The head of the thigh bone (femur) moves inside the cup-shaped hollow socket of the pelvis. A total hip replacement consists of a stem that fits into the head of the thigh bone and provides stability, a ball (to replace the head of the thigh bone) and a cup to replace the damaged hip socket.

The earliest hip replacements (in the late 19th and early 20th centuries) used a variety of materials, including muscle, celluloid, silver plates, rubber struts, magnesium, zinc, glass, decalcified bones and wax. Since those early days, though, doctors have significantly whittled down the list of materials that can be used to make an effective implant. Most hip implants performed over the last four decades have used metals such as titanium, cobalt-chromium and nitinol, or a combination of metal and plastic to replace the ball and cup.

These materials, however, lead to wear over time. Joint replacement components—particularly those found in the hip—rub against each other, causing friction and particle debris. The friction can lead to the inflammation of surrounding tissue, loosening of the implant, or in extreme cases, failure of the implant. As a result, some implant patients undergo revision surgery, a procedure that can be more costly and difficult than the original procedure.

Revision surgeries could become more commonplace over the next few decades as the post-World War II generation enters its golden years and seeks to retain its active lifestyle. Longer life expectancy of these busy senior citizens has forced orthopedic companies to modify

implantable devices using materials that are more durable than traditional models.

Ceramic implants have proven to be more durable than their metal and plastic counterparts. They produce less friction and can last up to 200 times longer than traditional hip replacements, laboratory tests have shown. These implants also minimize trauma and recovery time for patients, making them ideal for younger baby boomers and amateur athletes (of all ages) with sports injuries.

“Ceramic implants can be more expensive than implants made of metals or polymers, but they offer the benefit of an increased lifetime,” Hughes noted. “Younger patients that need [hip] implants want ceramics because they know they can delay or avoid altogether [revision] surgery to replace worn components.”

If market projections are correct, companies that manufacture hip and knee implants geared toward younger patients will have a solid customer base for the next 20 years. More than 50 percent of the demand for total hip replacement is expected to come from patients younger than 65 by 2011, according to research from the American Academy of Orthopaedic Surgeons (AAOS). Patients younger than 65 also will comprise more than 50 percent of the candidate population for total knee replacement that same year, the research concluded.

By 2016, more than half of primary knee replacement patients will be younger than 65. Demand for the procedure is expected to grow the fastest among patients in the 45-54 age range, AAOS data has showed.

Coinciding with this demand for joint replacements will be a shortage of available surgeons to perform these procedures. Two studies presented at AAOS' annual meeting earlier this year concluded that there may not be enough orthopedic surgeons in the future to provide joint replacements to all patients that need them. In 2016 for example, 46 percent of needed hip replacements and 72 percent of needed knee replacements will not be performed due to a surgeon shortage, stated a study co-authored by Dr. Thomas K. Fehring, an orthopedic surgeon at OrthoCarolina Hip and Knee Center in Charlotte, N.C.

Fehring's study estimated that 400 hip and knee specialists will enter the work force between 2008 and 2016, while 1,584 generalists with a hip or knee focus will be qualified to perform surgeries then. At the same time, 963 specialists and 3,568 generalists will retire, leaving a work force of 5,038 in 2016, a shortfall of 34 percent.

“A lot of the brain trust and tribal knowledge held by the people who are retiring has to be replaced,” said Rick Holka, president of Hudson, N.H.-based Omni Components Corp., a manufacturer of precision engineered components for the orthopedic medical, commercial high-tech and aerospace industries. “This is an issue facing every industry today, including surgeons, precision machining and every type of manufacturing endeavor in this country.”

A New Class of Materials

In light of the surging demand for joint replacement procedures, orthopedic companies must improve implant reliability and durability, industry experts said. Advances in technology and materials in the past five years have enabled manufacturing firms to produce long-lasting implants that resist corrosion and are flexibly stronger than their predecessors.

Two types of materials that have improved the quality of ceramic implants are alumina and zirconia-toughened alumina. A white or nearly colorless crystalline substance known for its hardness and strength, alumina is resistant to high temperatures and causes little or no reaction in environments with biomaterials.

Zirconia-toughened alumina (ZTA) is becoming more widely used in ceramic implants because it is stronger than alumina, has similar high wear resistance, has a high temperature stability and offers the same excellent biocompatibility as alumina. In addition, ZTA has a much higher fracture toughness and provides high flexural strength for components that might encounter high loads of tensile stresses during use.

The development of zirconia-toughened alumina has been a key material advancement in the ceramic implant sector because it greatly reduces the chance of ceramic fracture. This is a particularly important attribute as orthopedic firms look to manufacture new artificial femoral head designs that better match those found in the hip.

“There’s a trend now toward larger diameter femoral components, which are anatomically more similar in size to the femoral head in the body,” C5’s Hughes noted. “The typical femoral head implanted 10 years ago was 28 millimeters, but now these femoral components have a much larger diameter head. When you use a femoral head that is similar to the one that is inside your body, there is less of a chance of that femoral head to become dislocated. And it gives the patient a more stable joint, which is truly beneficial.”

Other types of ceramic materials that can give patients a more stable joint are Dura-Z and CeraPure YTZP. CoorsTek Inc., a technical ceramics manufacturer based in Golden, Colo., has developed both substances.

Dura-Z is a type of zirconia that is partially stabilized with magnesium. Like ZTA, Dura-Z is flexibly strong, but represents a significant performance gain over other materials such as iron and steel. It is the most fatigue-resistant standard zirconia available, according to the company.

CeraPure YTZP (yttria-stabilized tetragonal zirconia polycrystals) provides excellent chemical resistance in chemically corrosive environments, and its flexural strength is nearly double that of traditional ZTA, data from CoorsTek indicates. The substance is stabilized with yttria.

Though ceramic implants and components are used more in Europe and Japan than in the United States, analysts still expect product sales to skyrocket over the next three years as a greater number of patients choose ceramic joint replacements and researchers find more applications for the material. One estimate from Aarti Shetty, a medical device industry analyst for business research firm Frost & Sullivan, predicts ceramic product sales to grow at a compound annual growth rate of 10 percent between 2008 and 2012. (Editor’s note: For more insight into the joint reconstruction market, turn to ODT’s Q&A with Shetty).

The evolution in implant materials has not been limited to ceramics, though. Metals have undergone a similar progression in recent years, leading to substances with higher strength, improved fatigue resistance and enhanced wear resistance.

The U.S. Department of Energy laboratory in Ames, Iowa, is developing a cheaper and better way to make titanium alloy powder for artificial joints. The research team, according to

published reports, has developed and patented a special pouring tube that can withstand molten titanium. The team also has come up with the atomization technology for turning molten metal into titanium powder. This development is significant because it could lead to the development of titanium implants, which would be corrosion-resistant for a patient's entire lifetime and less costly than stainless steel joints.

K2M, a spinal device development firm in Leesburg, Va., has developed cobalt-chromium rods that can be used in complex spinal pathologies and procedures. The rods, introduced to the market last year, feature flexural rigidity properties comparable to 5.5 mm diameter stainless steel and 6.35 mm titanium alloy, according to a news release issued by the company. The cobalt-chromium material, the release stated, is more MRI compatible than stainless steel.

The Spine: Conquering the Final (Implant) Frontier

The spine can be an intimidating body part for orthopedic surgeons. It packs a lot into its 45 centimeters (43 cm in women): more than 100 joints, 220 specialized ligaments, more than 120 individual muscles, 34 vertebrae, 31 pairs of spinal nerves and 23 intervertebral discs. As if that wasn't enough, the spine also houses and protects the spinal cord—the main conduit for information connecting the brain and peripheral nervous system.

The spinal implant market has experienced explosive growth over the last decade as doctors and researchers develop alternatives to spinal fixation procedures. That growth is expected to continue through 2012, as orthopedic firms develop innovative new products and generate “favorable clinical trial data for spinal non-fusion product lines,” according to a report from Global Markets Direct. The report predicts a 10 percent annual growth rate between 2008 and 2012, prompting the market to swell from \$551 million in 2008 to \$792 million in 2012.

Despite this projected growth and the increasing popularity of non-fusion procedures, industry experts told Orthopedic Design & Technology that spinal implant technology has lagged behind advancements to other parts of the body. Part of the reason for this technological gap, experts said, is the daunting nature of the spine and the high risk associated with spinal implant procedures.

“In my view, in orthopedics, the spine has been one of the last, perhaps most challenging frontiers that has been addressed by technology,” Omni's Holka noted. “[The spine] can be an area of intimidation. Spinal procedures can be very invasive processes. To implant rods and connectors in a patient's spine you have to work around discs, nerves and muscles. It's a considerably high-risk procedure. From what I understand both surgeons and patients have been afraid to do certain work on the spine for fear of making things worse. As an industry, we are overcoming that fear.”

Future Growth Factors

Despite the risks associated with spinal implant procedures, the spine is expected to play a central role in the future growth of implant manufacturing. While breakdowns of the hip and knee are usually associated with an aging population, back problems are not limited to the elderly (or Hollywood stunt person).

Industry statistics show that more than 250,000 Americans have a spinal cord injury. Fifty-six percent of these injuries occur between the ages of 16 and 30, and the most common causes include motor vehicle accidents, falls, violence, and sports-related injuries, the data indicates.

Small bone extremities also will play a part in the future growth of implant manufacturing, industry experts said, as will continued demand for minimally invasive procedures. Innovations in minimally invasive technologies have enabled patients to choose alternative orthopedic procedures rather than the traditional, more complex and painful surgeries.

“The hip and knee implant markets are already witnessing this trend with the resurfacing option becoming increasingly popular with patients who want a more conservative alternative to total joint replacement,” the Global Markets report stated. “This bone-conserving approach results in a better range of motion and less risk of dislocation than traditional total replacement. Increasing awareness among patient groups and orthopedic surgeons’ greater familiarity with minimally invasive procedure techniques is likely to positively impact the growth dynamics of the orthopedic devices sector in the next five years.”

Orthobiologics is another area that will drive future growth, as manufacturers look for ways to differentiate themselves from their competitors. According to the Global Markets report, orthobiologics is the fastest-growing segment of the implant market, with more than 100 products at different stages of clinical development. The report predicts the orthobiologics sector, valued at \$5.4 billion in 2008, to grow 9.3 percent annually to reach \$7.5 billion in 2012. Increased use of bone morphogenic proteins and autologous growth factors in orthopedic and spine surgeries is expected to drive segment growth over the next five years.

Demand for orthopedic implants has grown astronomically over the last several decades as an aging but lively generation searches for ways to remain active. Other factors have contributed to the surge in demand, including skyrocketing rates of obesity, and a greater understanding among patients about the technology behind implant procedures. With demand expected to increase steadily for the next 20 years, companies that manufacture orthopedic implants can expect to have a solid customer base for the foreseeable future. With this golden opportunity though, comes a responsibility—to both the patient and the industry. Omni Components’ Holka summed up the future responsibilities of orthopedic companies rather simply: “The mission is to work toward providing people a much better quality of life by making sure the implant corrects what needs to be corrected. A part of that work is to continually improve the expected life of an implant, make it better, smaller, and less obvious to the patient when it is implanted.”