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SPECIAL FEATURE

Orthopedics Suppliers Brace for a Booming Market

As 78 million people approach age 60, suppliers to the orthopedic market face unprecedented demand and changing needs.

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Orthopedic device companies may be dependent on the natural limitations and weaknesses of the human body, but recent reports indicate that the orthopedics industry is anything but fragile. Driven by escalating demand, the orthopedics market is experiencing change in every facet of the market. As a massive demographic is ushered into its golden years, the need for strong and long-lasting orthopedic devices becomes increasingly urgent. Consequently, both OEMs and suppliers face enormous growth potential—provided they can keep up with the changing needs of the medical landscape and a new breed of lively senior citizens.

Market Forces

Research presented at the 2006 annual meeting of the American Academy of Orthopaedic Surgeons portended future prosperity for the orthopedics market. So much, in fact, the study forecasted that the number of procedures for first-time total knee replacement would skyrocket 673% in 2030, according to the engineering and consulting firm Exponent Inc. Similarly, the study predicted that the number of primary total hip replacements would climb to 175% in 2030.

The active lifestyles of aging baby boomers will generate demand for orthopedic implants required for such procedures as total knee replacement surgery.

Numerous factors could contribute to the meteoric growth that the market stands to experience. Among them is the nation's obesity epidemic, which is a driving force due to the excess-weight-related stress exerted on joints. Hospitals estimated that a whopping one-half to two-thirds of patients having joint-replacement surgery are overweight, according to an article published in the July 18 issue of the Boston Globe.

Advances in technology are fueling the industry and subsequently creating a need for the required tools and devices as well, according to Greg Riemer, vice president, business development, for Molded Rubber and Plastic Corp. (MRPC; Butler, WI; www.mrpcorp.com), a plastics molding company specializing in combining silicone and plastic materials with existing or new surgical instruments. He observes that orthopedic surgeons are performing procedures that they were incapable of doing in the past—such as laparascopic surgeries—that are easier to perform and result in quicker recovery

times for patients, as far as hip and knee replacements are concerned. As a result, new or adapted orthopedic devices and instruments suited for use in minimally invasive surgery are required.

While technological advancements and obesity are boosting orthopedics' share of the market, their roles as driving forces are eclipsed by another: the hordes of adults hovering at the brink of senior citizen–hood. Last year, the first wave of baby boomers celebrated its 60th birthday. Owing its moniker to the prosperous postwar period between 1946 and 1964 that witnessed rapid population growth, the baby boomer generation encompasses an estimated 78 million people. As this sizeable demographic continues into its twilight years, the demand for orthopedic implants and joint replacements will undoubtedly surge.

In addition to the sheer size of the aging population, its longevity is set to impact the industry as well. A national average life expectancy approaching 80 years dictates that orthopedics OEMs need to produce durable devices tailored to a demographic that will live longer than its predecessors. Orthopedics companies have already begun modifying devices to address the needs of people in their 80s and 90s, according to a 2005 report published by Technical Insights Inc.

The average profile of the elderly is changing, too. These able-bodied sexagenarians are spurring device development to accommodate their busy lifestyles, which now often include such pastimes as golf, tennis, and even working out. "These are people who are getting to be 65 and 70 years old and aren't content sitting on the couch any more," Riemer observes. "They want to retain an active lifestyle at an older age."

Material Selection

PEEK-Optima, shown here used for spine fusion cages, is replacing titanium in some orthopedic applications.

Legions of active baby boomers will soon turn to the orthopedics market to alleviate the natural wear and tear on their aging bodies. And to best serve these spirited seniors, orthopedic implants and devices will need to be more durable than they have been in the past. As device makers scurry to develop robust knee and hip implants that can withstand stress and bear the load of an active lifestyle, material selection will become increasingly important.

Concurrent with the swelling of the older population, the biomaterials industry is expected to balloon to nearly $10 billion by 2011, according to a report by MedMarket Dilligence. But while growing, the market is also changing. Polyethylene and various metals have long been the go-to materials for orthopedic implants. And while these materials maintain a stronghold on the market, they are losing their grip as time progresses and engineers begin to favor other materials and composites.

Titanium is increasingly replacing stainless steel because it is viewed as stronger, more biocompatible, lighter, and more corrosion resistant. However, some OEMs are turning to highly engineered thermoplastics to replace pricier metals in niche applications, according to Riemer of MRPC. Michael Callahan, president of Invibio Inc. (West Conshohocken, PA; www.invibio.com), a biomaterials company, has also witnessed this trend. Callahan points out that Invibio's PEEK-Optima is employed in several applications where titanium had previously been used. He attributes some of this shift to the increasing cost and decreasing availability of the metal resulting from demand for the material from the aerospace industry.

Other materials are poised for incorporation into orthopedic devices as well. Polymers will secure their presence in the orthopedics market, while ceramics will experience the most significant growth, a report by The Freedonia Group states. The report also foresees the rise of composites such as alumina-zirconia, owing to their more crack-resistant structures.

Material selection for orthopedic devices is application specific; however, there are various properties and factors that design engineers must take into account. In addition to biocompatibility, ideal materials for orthopedic applications should typically exhibit strength and load-bearing capabilities, as well as fatigue and corrosion resistance.

Furthermore, engineers should choose a material for their application with downstream processes in mind, such as sterilization methods and imaging, according to Callahan. "They [engineers] should also take into account the history of the material and the availability," Callahan advises. "We have seen instances where orthopedic companies have designed in certain materials and enrolled patients in very long-term and costly clinical trials only to find that the material was not available; it was taken away from the market. So, ensuring the long-term availability and supply of the material would be crucial."

Surgical instruments overmolded with silicone allow surgeons to have control during orthopedic procedures.

While availability and properties of materials should be considered when designing a product, design engineers must also be aware of a material's tendency to wear. Between today's active lifestyles and extended life expectancy, owners may outlast their implants—many of which have a lifespan of roughly 15 to 20 years.

Many materials have demonstrated wear over time. Components in joint replacements often rub against each other—especially in hip replacements—causing friction and particle debris. This friction can lead to inflammation of surrounding tissue, loosening of the implant due to micromotion or osteolysis, or failure of the implant. To rectify this problem, some patients need to undergo revision surgery, a procedure that is often more costly and difficult than the original surgery.

Because this dilemma is likely to become even more problematic as the baby boomers age, finding a solution is quickly emerging as a priority for the industry. “We’ve found that a lot of engineers are seeking alternatives and improvements,” Callahan says. “They’re trying to find a solution that increasingly helps the patients such that they don’t need to go into revision surgery, and the way of doing that is finding the best materials or the best combination of materials and how they interact.”

Product Testing

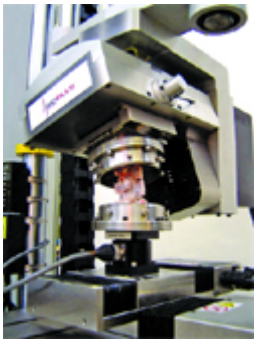
Since many orthopedic implants experience this problematic material wear, device testing is paramount. It is obviously imperative that implantable devices are biocompatible, but devices also need to be able to withstand a variety of tests to ensure their safety prior to implantation in an actual patient.

A device’s performance under fatigue and durability testing is critical. OEMs need to be certain that their products won’t easily break or buckle under strain and that they won’t wear quickly. These tests must be extremely comprehensive to ensure efficacy despite the baby boomers’ active lifestyles and prolonged lifespans. “Companies test to worst-case scenarios that evaluate what might happen if a patient is very active or if the surgeon did a poor job,” says Theresa Smith, senior applications engineer, Dynamic Systems, at Instron Corp. (Norwood, MA; www.instron.com), a supplier of testing equipment. “The idea is that if a device can hold up under these worst-case scenarios, it will hold up under more-typical usage.”

Realistic testing environments are of the utmost importance. In order to yield accurate results, devices must undergo testing that simulates the actual conditions in which they would function. Hip, knee, and spine components experience different kinds of stress and motion and thus need to be tested accordingly. Testing the wear on a total hip replacement over a number of cycles, the fatigue mechanisms of total knee replacements, and the wear resulting from cyclic loading on in-vertebral disc prostheses are all examples of implant-specific testing.

Common orthopedic device tests include impact, torsion, static, and dynamic. Impact tests mimic the event of a drop or impact to the device, while torsion tests apply a rotational motion. Static test systems establish yield, tensile, or compressive strengths, and dynamic test systems provide durability and service simulations. “For example, they [dynamic test systems] can be used to simulate a patient taking 10 million steps on a hip or knee implant,” Smith explains. “This is an FDA requirement to ensure that the implant will not fail soon after implantation. Dynamic systems can be run at high frequencies—the number of steps per second—so they can reduce the amount of time it takes to complete the test.”

Rising Challenges



The BioPuls six-axis spine testing system simulates spinal kinematics for the mechanical testing of spine implants.

A healthy and expanding market-place is bound to present a breadth of opportunities for orthopedics suppliers and OEMs. However, rapid growth and substantial demand often produce new challenges or amplify existing ones.

Testing for such developing markets as spine and tissue replacement, where standards are not yet firmly established because these areas of the human body are not completely understood, can be difficult, according to Smith. “Instron is very active in helping customers configure a system that will meet their needs, but this can be difficult when customers aren’t quite sure what their needs are,” she says.

Smith also suggests that design engineers obtain input directly from surgeons when designing a product. She points out that even if an implant or instrument seems ideal in theory, if surgeons are dissatisfied or do not feel comfortable, they won’t use the product.

As OEMs seek expedited processes to meet the growing demand, suppliers will inevitably begin to feel the pressure as well. “The [biggest challenge is] rapid turnaround, as well as trying to provide an economic solution for some products that, in some cases, are relatively low volume,” says Riemer of MRPC. “In our traditional OEM medical businesses, we generally try to go after larger-volume opportunities or applications, where the orthopedic industry tends to be hundreds or thousands of pieces. It’s a bit different as far as tooling up or making some of these lower-volume applications economical.”

But despite the demands of the industry—which will likely only intensify with time—suppliers recognize that it is an opportune time to cater capabilities to OEMs and the orthopedics market. “We knew that there was opportunity for silicone overmolding in the orthopedic market,” says Riemer, whose company overmolds silicone onto stainless steel instruments for a better gripping surface. “We wanted to pursue the market because we believe that there’s great growth potential within the current market, which the market’s already seen, and we’ve been led to believe that the growth will continue for the next several or many years.”

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