

The Knee Market Begins to Bend for Start-Ups

(A#2006900113)

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Issue: *Start-Up*, May, 2006
Section: Feature Articles (Long Article)
Article Type: Corporate Strategy/R&D, Technology
Industry Segment: Supplies, Equipment and Devices; Supplies, Equipment and Devices/Implantable Devices
Subject/Market Dynamic: Orthopedic Implants
Market/ Customer: Physician Specialty/Orthopedics; Physician Specialty/Surgeon/Orthopedic Surgeon
Therapeutic Categories: Musculoskeletal & Connective Tissue Disorders; Musculoskeletal & Connective Tissue Disorders/Reconstructive
Companies: iBalance Medical Inc.; Johnson & Johnson; Johnson & Johnson/DePuy Inc.; MAKO Surgical Corp.; Stryker Corp.; Zimmer Holdings Inc.
Summary: The \$4.6 billion worldwide market for knee arthroplasty is technologically mature, but it is underpenetrated today and it's still growing at a robust 14% annual rate. Furthermore, changes in demographics and patient expectations have created a large, unmet clinical need: the 50-something year old with unbearable knee pain. Today, that is the focus of a great deal of technological innovation—most of it incremental—on the part of large companies that seek to increase the longevity of devices with wear-resistant materials, and technologies that improve device fit, or the precision of placement and the accuracy of alignment of implants. But recently, and somewhat surprisingly, venture-backed start-ups have also begun to enter joint reconstruction with their own technological solutions. Four new companies believe they've staked out spaces ranging from operating alongside multi-billion dollar companies without facing crushing competition from them, to taking a more head-on competitive posture, and in each case, to make a clinical difference.

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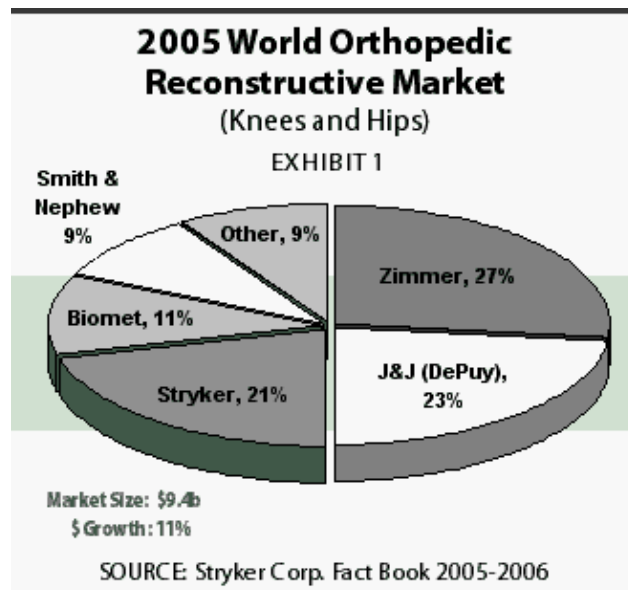
Start-ups innovate selectively in a mature market, aiming to complement—rather than compete with—giants in knee reconstruction.

By Mary Stuart

The spine industry has recently been enjoying a rapid pace of technological innovation and a frenzy of new company creation, but that's not the case in other segments of the orthopedics industry. In the device market for joint reconstruction of the knee, there has been a distinct lack of start-ups over the past 20 years. The knee implant market is technologically mature, offering devices that remain essentially unchanged from the 1974 design of total knee arthroplasty pioneer John Insall, MD. That's because current knee implants work well; they deliver a 95% satisfaction rate at 15 years.

According to Robin Young, a former Wall Street analyst and the editor and publisher of *Orthopedics This Week*, in light of such success rates, "Joint reconstruction is an industry that penalizes innovation and risk taking. A new procedure or a new approach only raises the possibility of a variable outcome." Young recalls that market leader **Zimmer Holdings Inc.**'s introduction of a novel two-incision hip was rocky. When word got out that complication rates were higher than average—in the hands of surgeons who weren't company trained, Zimmer would point out—surgeons stayed away from the new implants.

The hip and knee reconstruction markets reward consistency and reliability, and that's why five giant companies—Zimmer, **Johnson & Johnson's DePuy Inc.**, **Stryker Corp.**, **Biomet Inc.**, and **Smith & Nephew PLC**—dominate 90% of the \$9.4 billion market. (See *Exhibit 1*.) That's also why you don't see a wealth of venture-backed start-ups bent on disrupting the market with new technologies, as you do in other medical technology markets. Most orthopedic surgeons simply won't change techniques for products that offer uncertain or even incremental improvements over a standard with a 95% success rate.



There are a large number of start-ups and technologies at the early end of the osteoarthritis cascade, the underlying disease responsible for progressive knee pain. Many orthopods hope that effective interventions at early stages of osteoarthritis will reduce the incidence and severity of knee joint degeneration, although these biological approaches are still years away from the market. There are dozens of small companies with tissue engineering approaches for cartilage repair, meniscus repair and replacement, and the repair of damaged anterior cruciate ligaments, soft tissues which guide and support the knee joint. (See *Exhibit 2*.) But when it

comes to replacing the knee joint itself, start-ups can't match the R&D dollars, the engineering and materials expertise, and the sheer marketing and distribution power of the large players. A case in point: this past March, in announcing the launch of its new *Gender Solutions* line of knee implants designed specifically for women, Zimmer disclosed that it would spend \$10 million just in marketing and advertising.

Technologies for Knee Repair	
EXHIBIT 2	
Disease Stage, Procedure	Selected Companies in Knee Repair Segments
Early Stage	
ACL Repair	Scandius BioMedical, Angiotech Pharmaceuticals, CrossCart, Pegasus Biologics, Tissue Regeneration
Cartilage Resurfacing (<i>not cell-based</i>)	Osteobiologics, ArthroSurface, BioSyntech, PolyNovo Biomaterials
Cartilage Regeneration (<i>cell or gene therapies</i>)	Genzyme, Histogenics, Ars Arthro, TiGenix, TissueGene, ChondroGene, Mesoblast, ISTO Technologies, Millenium (<i>sic</i>) Biologics
Meniscus Repair	Osiris Therapeutics, ReGen Biologics, Ars Arthro, Zimmer (with license from Revivicor), Histogenics
Intermediate Stage (bridge to total knee replacement)	
Tissue-sparing keyhole surgery	Mako Surgical
Unicompartmental (partial) arthroplasty	ConforMIS, Major manufacturers (<i>see Exhibit 1</i>)
High tibial osteotomy	iBalance, Arthrex
Late Stage	
Total knee replacement implants	Major manufacturers (<i>see Exhibit 1</i>)
Adjuncts to total knee replacement that improve accuracy of placement: cutting guides, computer-assisted surgical technologies and surgical navigation systems	OtisMed, Mazor Surgical Technologies, Medtronic Sofamor Danek, BrainLAB, Zimmer with license from MedTech SA
SOURCE: Windhover's Strategic Intelligence Systems	

At the same time, although the \$4.6 billion worldwide market for knee arthroplasty is technologically mature, it is underpenetrated today and it's still growing at a robust 14% annual rate. Data from the American Academy of Orthopedic Surgeons (AAOS) and industry sources indicate that more than 500,000 people in America (over one million worldwide) will have total knee replacement surgery in 2006. The market is expanding for several reasons, including an increase in osteoarthritis rates that simply comes with an aging population, growing numbers of sports injuries that kick-off degenerative processes in the knee joint, and rising rates of obesity, a disease that stresses knee biomechanics. Furthermore, patients' expectations of a high level of activity and a high quality of life, particularly in comparison with yesterday's elderly, will fuel the growth of orthopedic procedures going forward. Patrick Treacy, VP, marketing for **Stryker Orthopedics** says that when he began in sales in 1989, "I was taught that a total knee implant was intended to allow grandma to ambulate independently—to get up from the couch and walk to the kitchen free from pain. Today, people that used to run marathons before knee surgery want to continue to run marathons with our implants. We are being challenged by the patient community."

Today's prosthetic joints do have limitations, the biggest of which is a lack of durability beyond, at best, 20 years. Because devices are relatively short-lived, historically surgeons have advised patients under the age of 65 to hold off from total knee replacement, particularly because revision surgeries have low success rates. But now, changes in demographics and patient expectations have created a large, unmet clinical need: the 50-something year old with unbearable knee pain. Today, that is the focus of a great deal of technological

innovation—most of it incremental—on the part of large companies that seek to increase the longevity of devices with wear-resistant materials, and technologies that improve device fit, or the precision of placement and the accuracy of alignment of implants. Surgical navigation systems have a role to play here, as do some of the new gender-specific knee implants, which promise a better fit. (*See sidebar "Gender Specific Implants: Science or Marketing Ploy?"*)

But recently, and somewhat surprisingly, venture-backed start-ups have also begun to enter joint reconstruction with their own technological solutions. Four new companies believe they've staked out spaces ranging from operating alongside multi-billion dollar companies without facing crushing competition from them, to taking a more head-on competitive posture, and in each case, to make a clinical difference.

OtisMed Corp. is taking advantage of imaging, new planning software algorithms and automation technologies to rapidly perform custom manufacturing. It is creating patient-specific disposable cutting guides to spare bone by improving the accuracy of cutting, and thus also improving implant positioning and longevity.

Three other companies hope to bridge patients to the ultimate total knee replacement option with tissue-sparing intermediate procedures, along the model of minimally invasive procedures in other medical device segments—such as angioplasty and stenting in coronary artery disease as an alternative to coronary bypass surgery, or percutaneous heart valves as an interim option before open surgery for heart valve replacement.

iBalance Medical Inc. is offering devices to enable a predictable and reproducible high tibial osteotomy, a procedure that up until now has failed to gain widespread use because of its difficulty and complication rates. **ConforMIS Inc.** already has 510(k) approval for a line of custom-made implants that offer mini-repairs for single or multiple compartments of the knee, shortening healing times over total knee replacement and sparing bone, to ensure good outcomes on future treatment options.

Mako Surgical Corp. is perhaps the biggest risk-taker in the group of new companies; it will compete against major implant manufacturers with a vertically integrated system that incorporates human interactive robotics, computer-assisted guidance, new cutting tools, and novel implants that enable true keyhole surgery in the knee.

None of these companies are offering technologies that are disruptive or revolutionary, nor would such an approach find many backers in this conservative industry. All of the new companies are further hoping to minimize development risk by innovating in ways that fit into the 510(k) regulatory pathway, rather than the more clinically difficult PMA route. And most of them believe they'll best succeed by playing a role that is complementary, rather than competitive, to the entrenched players. Still, the market for knee repair is growing rapidly; in five years, there will be 60 million people in the US with osteoarthritis. Available knee implant technologies have only just scratched the surface, and new companies bet they can make their mark here as well.

Bridge to Total Knee Replacement

Vince Novak, president and CEO of iBalance, has spent his entire career in the orthopedics industry. Prior to founding iBalance, Novak was VP of marketing for Axya Medical Inc., a developer of products for arthroscopic shoulder repair, which followed a short stint at Innovasive Devices just before its sale to Johnson & Johnson. Novak was also VP of marketing at ReGen Biologics Inc., developer of a meniscus repair technology, after having come up through the sales ranks at Zimmer and Smith & Nephew. While at ReGen Biologics, Novak says he witnessed an osteotomy, a knee realignment procedure, being done in a patient who was also undergoing a knee regeneration procedure. He says he was astonished by the good results at the

hands of one particular surgeon.

The high tibial osteotomy is a decades-old procedure that is used to correct an angular deformity in a bone, such as a femur or a tibia. It generally requires making a large, open incision around the deformed site, and cutting out a wedge of bone, or opening the cut bone to form an open wedge void. The two divided bone pieces are realigned, and the angle between the two bone pieces is thus adjusted.

Throughout the years, Novak says, "Although I was frequently in the OR with many different orthopedics companies, I rarely saw this procedure being done." He was also aware, he says, that "many new companies were trying to regrow cartilage and the meniscus. I thought, 'How could you possibly do this without also doing a knee realignment?'"

Novak set out to discover why more osteotomies weren't being performed, and after speaking to many high-volume sports medicine surgeons, he discovered that the procedure was invasive, had a long learning curve, bore the risk of some severe complications, and the long-term outcomes weren't great. Success rates dropped off dramatically after five to seven years, Novak discovered. As total knee replacements improved over the years, reaching down from the 75-year-old patient to the 65-year-old, the procedure fell by the wayside.

It was work in tissue regeneration of the knee that revived interest in osteotomies. The clinical need is real, says Scott Rodeo, MD, associate professor of orthopedic surgery at the **Cornell University's, Weill Medical College** and co-chief of the Sports Medicine and Shoulder Service at New York's **Hospital for Special Surgery**. "Osteotomy is not going away. If you are going to resurface the knee with a cartilage implant, if there is malalignment of the knee, you have to correct that first. I do many osteotomies combined with these other things. There is potential there." However, Rodeo says that osteotomy is complex. "There are risks to the nerves and blood vessels around the knee. It can be difficult to achieve the exact alignment you want to achieve. Community orthopedists don't do many of these surgeries."

Novak accordingly founded iBalance, with \$8.24 million raised from angels and venture firms Sutter Hill Ventures and Skyline Venture Partners, to try to correct these deficiencies of the osteotomy. With an instrument-guided technique and an implant, known as the *Axial Knee Realignment System*, Novak says iBalance has created a safety envelope around the tibia to protect soft tissue and neurovascular structures. "Our technique sets the surgeon up so he or she makes a very reproducible osteotomy cut from patient to patient. We have developed instrumentation that guides surgeons so they can address the proper issues of knee realignment, the biomechanical axis, controlling the tibial slope, and making sure that the tibia is maintained in an anatomical alignment." Because those variables aren't controlled for in conventional procedures, says Novak, long-term outcomes are compromised.

Novak foresees two large markets for his company's technology. With a seven- to ten-year life (which remains to be proven) it could bridge the patient in his or her 50s to a total knee implant. The procedure could also improve the success rates of regenerative procedures in the younger osteoarthritic patient, the 35 to 40 year olds who will undergo cartilage or meniscal repair procedures. Healing of soft tissues in the knee requires normal loading and stressing, and the knee realignment procedure can help provide that environment. Finally, Novak points out, the osteotomy doesn't have a record of successful long-term outcomes, in part because its invasiveness and risks restrict its use to patients whose disease is really severe. A predictable and safe version of the osteotomy could reach upstream to patients with less joint degeneration, so that smaller corrections could serve.

It is still very early for iBalance; the company has validated its technology in cadaver studies, and it is in the process of transferring to a pilot run from which it will be performing verification testing to submit to the FDA in the fall. iBalance intends to follow a 510(k) pathway as have other osteotomy companies in the past (for example, **Synthes-Stratec**, **Biomet** and **Arthrex GMBH**). The company plans to limit its launch to a few

sites and surgeons to drive good outcomes data, and with a patient registry, to collect data before a general launch.

iBalance may partner with distributors to get its devices into the hands of surgeons. "We don't have a lot of competition in this market," says Novak. "A lot of distributors that sell total joints don't now have an osteotomy system."

A Fitting Approach to Knee Surgery

The knee is a complex joint; it's not a simple hinge just designed for flexing, it has six degrees of freedom, and it permits rotational, rolling, and gliding motions. Like any joint, the precision of alignment and positioning of joints have an impact on the mechanics of wear and tear, and on the longevity of knee implants. Thus, although it doesn't sound very exciting, a lot of technologies are being brought to bear on improving the accuracy of device placement. That's the goal of OtisMed Corp., which was formed by a group of entrepreneurs who had already studied such problems from within the surgical robotics industry.

OtisMed's CEO Charlie Chi, PhD, was formerly at Integrated Surgical Systems, a now defunct developer of a computer-assisted orthopedic surgery for hip and knee joint replacements. Such systems have never been able to penetrate more than 5% of the US market, Chi points out, for several reasons. They are expensive, costing multi-hundreds of thousands of dollars; they add additional steps to surgeries; and they're not accurate enough because they use imprecise landmarks for positioning. In starting this new company, Chi and his partners still considered the need for prosthetic alignment accuracy in total knee arthroplasty, but this time they came up with the idea of developing a patient-customized, disposable instrument to help surgeons accurately determine the right implant size and positioning before the procedure, and to accurately cut the proximal tibia and distal femur. OtisMed has developed a mechanical registration device that it hopes will help surgeons consistently place the prosthesis in the right position.

Chi says, "Like making a customized mouth guard for somebody's teeth, we can make a cutting guide that fits over a particular patient's knee." The company brings to the challenge an understanding of how the knee works, from its founders' years in the surgical robotics business, and software algorithms that automate the planning and manufacturing process. Finally, it brings to knee surgery the ability to manufacture with 99.9% reliability high-volume customized medical devices, a capability seen elsewhere in the medical device industry at orthodontics company **Align Technology Inc.** (See "*Align: Selling Innovation to Late Adopters*," IN VIVO, February 2004 [A#2004800032].)

OtisMed makes its cutting guides from a preoperative MRI scan of the patient's knee, an imaging procedure routinely conducted before knee surgeries. The imaging center uploads images to OtisMed's server. OtisMed reconstructs the knee in a three-dimensional model, and places the requested manufacturer's prosthesis in the position that is anatomically correct for that particular patient. From there, the company creates a template, which Chi describes as a "six degrees of freedom alignment jig." Chi says, "That whole process takes just a few minutes because it is all run by software and machines. It is all automated. We have a finished good, we package it, and ship it off to the sales rep or the distributor, and they walk into the OR with the cutting guide and the proper implant sizes." Chi says a complete set can be created every 10 to 15 minutes.

Chi believes that his company's cutting guide will help surgeons cut down on OR time because "We can eliminate all of the alignment steps typically required to place these devices in the correct position." Precision positioning should also translate into better patient outcomes—less pain, quicker recoveries, and better long-term results. Chi notes that his company enhances, rather than competes with, implant manufacturers, and OtisMed can work with the implants of any manufacturer. With more than 500,000 knee replacement surgeries in the US each year and a market growing at double-digit rates, Chi believes his company has an enormous opportunity.

Getting to Patients Sooner

In many medical specialties, minimally invasive procedures have been able to bridge the gap for patients either too young to receive implants that are required to last for a lifetime but don't, or for those who don't want to suffer the lengthy recovery times of invasive surgeries. But so far, currently available minimally invasive technologies haven't really done this for the knee. They're still invasive, and they still largely don't provide, on a consistent and reliable basis, enough benefit to justify the risks and recovery times of surgeries.

As an interim alternative before end-stage total knee arthroplasty, major manufacturers have developed unicompartmental knee replacement devices. These replace only damaged portions of the knee, most often the medial compartment, which accounts for 90% of the unicompartmental replacement surgeries because that's the portion of the knee joint that bears the most weight. Although these less invasive surgeries do spare bone and tissue, they're not minimally invasive in the usual sense of the concept. They perhaps reduce a 7- to 12-inch incision down to 4 to 6 inches, but implants are still large, and procedures still cause a fair amount of damage beneath the surface. Furthermore, because of the difficulty in positioning devices accurately through a small incision, instead of a hoped-for durability of ten to fifteen years, devices often fail anywhere from six months to five years.

The founders of Mako Surgical set out to enable the first truly minimally invasive knee replacement surgery. The result is *Makoplasty*, which will ultimately offer a keyhole surgery that will allow the patient a shorter hospital stay, a quicker recovery, and preservation of much of the tissue that is destroyed in current procedures, according to Maurice Ferré, MD, CEO of Mako Surgical.

Mako (which stands for Modular Arthroscopic Keyhole Orthopedics) combines expertise in surgical navigation systems—the background of Ferré, who founded Visualization Technology Inc., remaining with General Electric Co. after the acquisition of his start-up by the imaging giant—and in robotics, one of the core competencies of Mako predecessor z-cat Inc., an early developer of computer-assisted surgery technology.

Chief technology officer Rony Abovitz, an engineer who co-founded z-cat, explains that his company partnered with Biomet on orthopedic applications of software and surgical navigational systems, but z-cat retained the rights to use the technology in conjunction with robotics, a combination that became the basis for the *Makoplasty* solution. To date, Mako has raised \$25 million in venture funding, including a \$20 million August 2005 Series B round from a group of investors that includes MDS Capital, The Exxel Group, Aperture Venture Partners, MediTech Advisors, Ivy Capital Partners, and Sycamore Ventures. [W#200530315]

Ferré says that his experience at VTI taught him the importance of a vertical approach, of solving particular clinical problems with a complete solution. Thus *Makoplasty* will combine visualization with novel instrumentation for minimally invasive cutting, and implants that can be delivered through a keyhole. "Conventional procedures cause tissue damage on the way to access sites, but our technology will deliver resurfacing components to the disease site in a very targeted way."

The company's first *Makoplasty* product line will target early-stage disease in a minimally invasive way with a high-precision device that will correlate to better outcomes, says Abovitz, in particular, a unicompartmental (unicompartmental) implant.

Mako has developed a variation on the Repicci technique for unicompartmental implant placement for its first product release. Abovitz explains that surgeon John Repicci, MD, has perfected a tissue-sparing technique, which has worked best in his hands. Abovitz says that Repicci, who was once a dentist, has the hands of a sculptor, in the artistic sense. Using a tiny burring instrument borrowed from dentistry, Repicci is able to precisely sculpt bone through a minimal incision and sends most of his patients home the same day with

excellent results. But other physicians don't have the same artistic touch, says Abovitz, so it was his company's goal to recreate Repicci's success rates with the help of its technology.

Mako's *Haptic Guidance System* has a similar burring instrument, proprietary haptic robotics, and surgical navigation software that together guide surgeons to make bone-sparing cuts within a circumscribed area of bone predetermined by pre-surgical planning. The surgeon holds an instrument like he would hold a pen, and the robot also holds it. Within the boundaries, the robot feels weightless; the surgeon cuts freely. But when the instrument hits the virtual boundaries, the robot provides the sensation of a wall, so that the surgeon doesn't cut outside the lines. "We can be incredibly precise and accurate with the robot," says Abovitz, "and that will allow us to make smaller implants that are still biomechanically compatible."

In the coming month, the company of 42 current employees will begin clinical evaluations as part of its design validation of *Makoplasty*, for implantation of its unicondylar implant, and plans to pay close attention to a small group of surgeons over the next 12 to 15 months as it perfects its technology and surgical techniques. Ultimately, the company plans to develop a breadth of implants across the full spectrum of disease, from early to late stage, with the input of its surgeon and scientific advisors, including Scott Banks, PhD, a noted researcher from the **University of Florida**, and an expert on the kinematics of the knee, as well as Dana Mears, MD, a pioneer in the new minimally invasive orthopedic procedures.

For the knee arthroplasty industry, today's goal is to capture the patient earlier. That's what's behind the approaches of ConforMIS, Mako Surgical, iBalance, and the major implant manufacturers. Ferré sees a day, not too far from now, when Mako's solution will enable surgeons to say to patients, "You'll walk out the same day. We don't guarantee that this is your last surgery, but we will give you 10 to 15 years of painless knees, where you have preserved your total knee option. When this starts to degenerate, you will always be a candidate for a total knee," he says.

That's what more and more surgeons want, too. The Hospital for Special Surgery's Scott Rodeo says, "I would like to have an implant that I could put in that would be fairly easy to do; on which the patient could run, jump, and play basketball, even if it would fail in seven years. As long as it's easy to do and doesn't have a long rehab, that's OK. You could put high loads on it, and it would be relatively easy to convert it when it fails. It doesn't exist today, but I think it's possible."

A new group of start-ups is ready to prove him right, and if they do, they'll be rewarded with a large market.

Gender Specific Implants: Science or Marketing Ploy?

Several of the major implant manufacturers, Zimmer and Stryker in particular, have been fond of poking fun at themselves recently, from public forums such as the annual meeting of the American Academy of Orthopedic Surgeons (AAOS) in March 2006, for only just noticing that the anatomy of women is different from that of men.

This is just the implant manufacturers' way of drawing attention to the fact that they have recently introduced new implants in what they hope will be a hot new growth segment in an otherwise mature market. Stryker recently introduced its *Triathlon* knee, the first knee implant for women, it says, and at AAOS, Zimmer unveiled its plans for *Gender Solutions*, its product line designed specifically for women.

Women currently represent 60% of the patient population for knee reconstruction today, and even with that majority of the market, there remains a large untapped female patient population, companies believe. First of all, women suffer from osteoarthritis at three times the rates of men, according to a recent study in the *New England Journal of Medicine*, and the prevalence of obesity, which puts stress on the knees, is much higher in women than in men.

Now Zimmer, on the verge of launching its *Gender Solutions* product line with a \$10 million marketing budget while it awaits 510(k) approval, wants to differentiate its devices with the message that its implants for women have been designed based on science, not size. Zimmer's chairman Ray Elliott has been vocal recently about his opinion that Stryker's *Triathlon* product line, which is for both women and men, became a gender-specific product line only after Zimmer announced its *Gender Solutions* strategy, and he points out that Stryker's claims are, for the most part, largely based on smaller device sizes for the smaller knees of women. Zimmer wants to make it known that it developed *Gender Solutions* with an exclusive license to data from D. Mohamed R. Mahfouz, PhD, co-director for the Center for Musculoskeletal Research and an assistant professor at the **University of Tennessee**. Mahfouz analyzed five years worth of data and more than 800 femurs and patellae, and on 22 out of 23 measures, he detected statistical differences between the knees of women and men, characteristics such as "the narrower width of female femurs, reduced anterior condyle height and a tendency toward a more lateral patellar track," according to Mahfouz.

Now Biomet and Johnson & Johnson are positioning products for the new market. The major manufacturers in joint reconstruction appear to be using the gender-specific campaigns to grow their device markets in two ways: first, to capture market share from competitors, and also to grow the overall market by bringing in patients from an underpenetrated women's health market, and second, judging by the advertising campaigns, to attract new kinds of younger patients of both sexes into the market, without making revolutionary changes in implant designs.

So far, the strategy appears to be working. Stryker just reported that it had implanted 30,000 *Triathlon* devices in women. For the last two quarters, says Patrick Treacy, Stryker is the fastest growing knee company because of the positive reception to *Triathlon*.