

MAKO Needs Clinical Results, Hip Application to Capture More Share

Companies: ISRG, JNJ, LON:SN/SNN, MAKO, SYK, ZMH

October 11, 2011

Research Question:

How big is the market for robotic knee and hip surgery, and what makes MAKO Surgical's products better than competing products in the marketplace?

Summary of Findings

- The joint replacement market is steady but showing some signs of growth. Sources said 400,000 to 600,000 knee replacements and an equal number of hip replacements are performed each year in the United States. Partial-knee replacements comprise 10% to 25% of the market.
- Younger patients are demanding better-performing joint replacements. Older patients are showing a willingness to undergo joint replacement procedures as well.
- Surgeons and orthopedic medical professionals said adoption of [MAKO Surgical Corp.'s](#) (MAKO) [RIO](#) will be slowed by the robotic system's high cost and the lack of peer-reviewed clinical studies.
- The [MAKOplasty](#) partial-knee replacement procedure takes longer to perform than traditional surgery and has a lengthy learning curve. One source said the MAKOplasty adds 30 minutes minimum to the OR time and, thus, an additional \$1,800 to the procedure.
- Medical professionals are interested in the new [MAKOplasty Total Hip Arthroplasty](#) and look forward to the possibility of improved results for hip-replacement patients.
- Hospital administrators, surgical sales professionals and industry specialists were positive on the future of robotic surgeries, which they said offer better joint alignment, preservation of healthy bone, faster recovery, shorter hospital stays and better patient outcomes.
- [Biologic](#) joint replacement solutions are in the early stage of research and is considered the future of joint replacements.

	Joint Replacement Market Growing	MAKOplasty Adoption Will Grow
Medical Professionals	↑	→
Hospital Administrators	→	→
Medical Device Sales Professionals	↑	↑
Industry Specialists	→	↑

Silo Summaries

1) MEDICAL PROFESSIONALS

This silo comprises four surgeons (three with MAKOplasty experience), one nurse and one surgical technician each with MAKOplasty experience, and three medical professionals with no robotics experience. Sources said the number of joint replacement surgeries is steady or increasing slightly. The use of robotics is not growing, and sources questioned whether robotic-assisted orthopedic surgery offers any advantage. A robotics system is expensive, requires a long learning curve, and lengthens the procedure time. However, robotics supporters said the technology offers faster recovery, more precision and less exposure to infection. One source whose hospital has a MAKO RIO robot said usage has slowed for knee replacements because surgeons can perform the procedure faster by hand. However, the institution is looking forward to using the robot for hip replacements.

2) HOSPITAL ADMINISTRATORS

All four sources—two representing hospitals with MAKOplasty and two without—said use of robotic-assisted surgeries gives a facility a marketing advantage. The two sources with MAKOplasty reported reduced patient recovery time, spared healthy bone tissue, better joint alignment, and the advantage of having a MAKO Surgical technician in the OR. Two of the four said the joint replacement market is steady while one said the number of procedures is increasing.

3) MEDICAL DEVICE SALES PROFESSIONALS

All four sources reported an increase in the trend toward robotics, customized joints and minimally invasive procedures. Two also reported a trend toward increased use of partial-knee replacements. MAKO-like procedures can provide better precision and alignment of the joint, faster recovery and make mediocre surgeons better. One source said biologic solutions are being developed that, if successful, will devastate joint replacement companies.

4) INDUSTRY SPECIALISTS

Three of four sources said MAKO's market will continue to grow because its robot offers precision, accuracy and assistance to average or poor surgeons, but the remaining source said the system is nothing more than an expensive, unnecessary "toy" that often sits unused in OR closets. Two sources said the market for joint replacement is growing. MAKO has effectively marketed its system to patients and hospitals alike.

Background

In Blueshift Research's [June report](#) on Intuitive Surgical Inc.'s (ISRG) [da Vinci](#), one source said MAKO Surgical was the leading provider of robotic orthopedic surgery. MAKO markets both its Robotic-Arm Interactive Orthopedic (RIO) system (ASP \$825,000) and its [Restoris](#) implants for minimally invasive orthopedic partial-knee replacement procedures called Makoplasty. The RIO gives doctors the ability to pinpoint affected areas and selectively replace parts of the knee without touching healthy tissue. The procedure also offers more accurate alignment and placement of the new partial joint as well as shorter recovery times and less pain than a full-knee replacement. The company received Food and Drug Administration approval for its RIO robotic system in February 2010. Thus far, 86 RIO systems (84 in the United States and two in Europe) have been installed, and the number of MAKOpasty partial-knee replacements is steadily increasing. Currently, 65 studies and 46 abstracts on the MAKOpasty have been submitted for peer-review at five different conferences in an effort to build a strong base of clinical evidence supporting the procedure. Meanwhile, recent [publicity](#) surrounding problems with metal-on-metal joint devices has prompted the orthopedic community to return to using different material combinations.

As of Sept. 19, MAKO Surgical has been marketing the [MAKOpasty Total Hip Arthroplasty](#). Currently, nine centers are performing the total-hip procedure. Hip replacement surgery is considered a more mainstream procedure than partial-knee replacement. The worldwide market opportunity for hip replacement is estimated to be \$5 to \$6 billion.

CURRENT RESEARCH

Blueshift set out to determine whether MAKO Surgical will be able to maintain or grow its position in the orthopedic market and determine how expanded offerings will contribute to the company's success. Blueshift employed its pattern mining approach to establish and interview sources in six independent silos:

- 1) Medical professionals (9)
- 2) Hospital administrators (4)
- 3) Medical device sales professionals (4)
- 4) Industry specialists (4)
- 5) Patients (3)
- 6) Secondary sources (4)

Blueshift interviewed 24 primary sources and included four of the most relevant secondary sources focused on the orthopedic surgery and robotic surgery industries.

Silos

1) MEDICAL PROFESSIONALS

This silo comprises four surgeons (three with MAKOpasty experience), one nurse and one surgical technician each with MAKOpasty experience, and three medical professionals with no robotics experience. Sources said the number of joint replacement surgeries is steady or increasing slightly. The use of robotics is not growing, and sources questioned whether robotic-assisted orthopedic surgery offers any advantage. A robotics system is expensive, requires a long learning curve, and lengthens the procedure time. However, robotics supporters said the technology offers faster recovery, more precision and less exposure to infection. One source whose hospital has a MAKO RIO robot said usage has slowed for knee replacements because surgeons can perform the procedure faster by hand. However, the institution is looking forward to using the robot for hip replacements. Another source said only three of the institution's 35 surgeons use the robot; the remaining surgeons have been deterred by the learning curve.

➤ Orthopedic surgeon and founder of an orthopedic consulting service

This source is very familiar with evolving technologies, including the MAKOpasty technique. He could not estimate the total number of yearly procedures beyond a ballpark figure of several hundred thousand for knee and hip replacements each. Unicompartmental (partial) knee replacements comprise approximately 10% of the knee replacements, and usage is expected to remain steady. The robot-assisted MAKOpasty does not offer any significant benefits over traditional

surgical techniques. If a specific procedure needs a robot for optimal outcomes, the procedure itself has too many opportunities for failure and should be reviewed. The MAKOplasty requires longer OR time, adding approximately \$1,800 to each procedure. This source expects bundled procedures and reimbursement to comprise the majority of cases by 2014, at which point total cost will be the most significant factor. He said saving more of the patient's bone by using a robot-assisted procedure like MAKOplasty is more important if the surgeon expects the patient to need a future revision. Although the MAKOplasty may improve the recovery time slightly, implants from [ConforMIS Inc.](#) and [Materialise N.V.](#) offer similar results with less cost and shorter procedure time. Hospitals likely will use technologies like MAKOplasty as a marketing tool, but will see few substantive clinical benefits. He does feel the recent [metal on metal joint recalls](#) ultimately could affect the overall market.

- "I do not believe that robots, including the MAKO RIO, make a significant difference in procedure success and outcomes. If a surgical procedure requires the assistance of a robot, there are too many intrinsic opportunities for failure. The procedure needs to be refined and optimized or totally eliminated from the decision pool."
- "MAKO has made some money only because it is a nice marketing machine for the practice, hospital, group. But not all hospitals have a million-dollar budget for a piece of equipment they can market to the public."
- "A robot-assisted procedure like MAKOplasty merely saves a bit of patient anguish compared to a traditional revision operation."
- "The MAKOplasty procedure requires a longer OR time. With an additional 30 minutes compared to traditional surgery, the additional cost to the hospital, beyond the capital investment, is quite significant."
- "If a surgeon expects a patient will need a future revision, a greater amount of bone conservation is desirable. Customized implants like ConforMIS and Materialise, however, perform just as well and are less costly and quicker to perform."
- "Of the hundreds of thousands of primary knee replacements, only approximately 10% are eligible for a partial [unicompartmental] procedure. This figure will remain constant."
- "The joint replacement market is likely to see a spike in biological solutions, but on a case-by-case basis these are also very expensive solutions."
- "Bundled [knee and hip] replacements are projected to represent 66% of total reimbursements for these procedures by 2014 [currently at 16%]. At that point, cost reduction will be the most significant factor. Healthcare economics will be a huge force toward eliminating expensive gadgets that cannot reduce total procedure cost."

MAKO has made some money only because it is a nice marketing machine for the practice, hospital, group. But not all hospitals have a million-dollar budget for a piece of equipment they can market to the public.

*Orthopedic Surgeon & Founder
Orthopedic Consulting Service*

➤ Orthopedic surgeon and founder of two orthopedic device companies

Surgeons enjoy working with cutting-edge tools like the MAKO RIO robot, but other clinical options can produce the same results at less cost. This source reported some benefit in reduced recovery times and reduced exposure to infection, but he does not yet see a clear advantage to robotic-assisted orthopedic surgery. Robotic tools offer marketing advantages, but are unlikely to become the standard of care for knee or hip replacements. For now, not enough clinical evidence is available.

- "Every surgeon would like to try the newest tools/toys available, and some adopt them early. The early advantage does seem to be marketing because there is not a lot of clinical evidence available that can prove that one procedure is superior to another."
- "There are lots of unanswered questions about robot assisted orthopedic surgery. Is it cheaper? Will it become the standard of care? Is it faster?"
- "Right now there are other clinical options that can produce equal or superior result so it will be a while before many of the questions about the use of robotics for orthopedic procedures are answered."
- "Adoption of robotics, if at all, will take time and studies. The MAKO device is expensive, and hospitals and practices are not in a position to run out and get one simply to experiment with."

The early advantage does seem to be marketing because there is not a lot of clinical evidence available that can prove that one procedure is superior to another.

*Orthopedic Surgeon & Founder
Two Orthopedic Device Companies*

➤ **Orthopedic surgeon who has used the MAKOplasty procedure**

The number of joint replacements has remained largely the same each year. The MAKOplasty offers precision cutting, better alignment than other joint replacements and faster healing.

- “I was a pioneer in the MAKOplasty field. I was one of the first surgeons to do this procedure in 2008, and now I am very experienced.”
- “Our center does 500 to 600 joint replacements a year. Most of the replacements are total hips and total knees. We are always busy although I would say we do about the same number of surgeries each year. That is a lot of joint replacements.”
- “MAKOplasty offer more precise cutting and better alignment. The patients also heal faster.”
- “This is a very exciting period of development in orthopedics. There are many changes that benefit the patients.”

➤ **Orthopedic surgeon who uses MAKOplasty, and administrative assistant, state university department of orthopedics**

Demand for joint replacement is growing, but growth in robotic usage is not following suit because of the training required. Out of the department’s 35 surgeons, only three have used the MAKOplasty. Still, MAKOplasty patients have had faster recovery, less scarring, less pain, and shorter hospital stays. The surgeon source is considering doing partial-knee replacements on an outpatient basis.

Surgeon

- “There are a lot of people who need joint replacements. I’m not sure the market is growing much for robotics, however. It requires a lot of training.”
- “Patients are doing very well with the MAKOplasty. There is less scarring, shorter recovery, shorter hospital stay and minimum pain. Generally, a more rapid healing.”
- “Sometimes patients with partial-knee replacements need a total replacement years down the road. That happens sometimes; it depends on their rate of disease. Some degeneration progresses faster than others.”

There are a lot of people who need joint replacements. I’m not sure the market is growing much for robotics, however. It requires a lot of training.

*Orthopedic Surgeon
State University Department of
Orthopedics*

Administrative assistant

- “We have about 35 orthopedic docs, and only three of them use the MAKOplasty. [One doctor] has only been here for 10 months; yet he has done 15 cases. The other two doctors have each done one case. One doctor has had many more cases scheduled, but the poor guy, a lot of his cases haven’t cleared for one reason or another.”
- “We’ve had the MAKOplasty just four months. I didn’t know we were one of the few teaching hospitals to use one. I’m not sure why. Maybe it’s a money issue.”
- “Some [potential patients] ask for the MAKO.”
- “[One surgeon] wants to make the MAKOplasty [partial-knee] an outpatient surgery. [The patients] do extremely well and are only in surgery for less than two hours. I don’t know when that will happen.”
- “During surgery they use CT [\[computerized tomography\]](#) for accurate placement. The scan machine will go off if something isn’t quite right. It pushes the surgeon back to the right spot. It is an extra benefit to keep us in line. It’s just another thing to make sure the surgery is more precise.”

➤ **Orthopedic nurse educator who has used the MAKOplasty**

Joint replacements are on the rise, and robotics also may increase because of word of mouth. The MAKO name is becoming well-known, and patients ask for it. This source said manufacturers have taken care of problems occurring with metal-on-metal devices.

- “Knee and hip replacements are most definitely growing. Absolutely. I don’t know the percentage, but our cases have increased.”
- “Robotics is growing, too, especially after patients hear how well others are doing with the MAKOplasty. Patients talk to each other, and then they ask us about the MAKO. They also hear about MAKO in health education classes. It’s a new procedure, but word is getting out with internal referrals. Patients are pleased at how well they do, and that speaks loudly. It’s pretty new, so it will take some time.”
- “We are doing 78 total joints this month, and we have 17 to 20 knees scheduled with MAKOplasty. I’d say we use the MAKO on roughly one-quarter of our patients.”

- “We haven’t had any problems with the partial-knees yet. I don’t know if half of the totals [full-knee replacement] could use a partial, but I’d say at least a quarter since this reflects our surgery cases.”
- “We’ve probably done 200 MAKO cases, and we cannot wait until their hip replacement is approved.”
- “I haven’t had patients ask me about metal-on-metal problems. We haven’t had any concerns here. I think those devices come with a polyethylene cushion or high cross-fiber plastic between the parts.”

➤ **Surgical technician for orthopedic services, who has used MAKOplasty**

The market is not growing for robotic knee replacements. The learning curve is so long, and surgeons can do knee replacements more quickly without the robot. The source said the MAKO knee replacement may offer some better results, but interest is greater in the MAKOplasty total-hip replacement because it will take out some guesswork for the surgeon and allow a better fit and alignment.

- “I don’t see the robotics market growing too much in knees. We’ve been doing MAKOplasty procedures for more than one year, and we’ve stopped doing as much. The number of surgeries dropped off tremendously lately. We just did our first one in a few months.”
- “Most surgeons have tried out the MAKOplasty, but they feel they can do the surgery faster with their own hands. We’ve done a total of 50 procedures, but not as many lately.”
- “There is definitely a learning curve to learning robotics. The first few cases take a lot longer as the surgeon and everyone are getting acquainted with the process.”
- “Sometimes at the beginning of a procedure, you aren’t sure if the surgery will be a partial-knee or a total. Sometimes it is hard to tell how much damage there is until you go in.”
- “I don’t notice much change between the MAKO and regular surgery. I guess some results are a bit better with the MAKO.”
- “There will be more excitement with the MAKO total-hip replacement, and we are waiting on that. The MAKO will allow the surgeon to fit the cusp more readily. Maybe the products aren’t any better, but you will get better alignment.”

I don’t see the robotics market growing too much in knees. We’ve been doing MAKOplasty procedures for more than one year, and we’ve stopped doing as much. The number of surgeries dropped off tremendously lately. We just did our first one in a few months.

*Surgical Technician
Orthopedic Services*

➤ **RN for an orthopedic clinic that does not use robotics, Wichita, KS**

Joint replacement surgery is on the rise but can be done well without robotics. A [Zimmer Holdings Inc. \(ZMH\)](#) representative guides the clinic’s surgeons during each joint replacement. Older patients who are active drive demand.

- “We do 30 to 40 total joint replacements every month. On average, say 35 a month, that’s 420 a year, for many years. That adds up.”
- “I think our volume is increasing a bit every year. Hard to say by how much, but our patients keep getting older and their joints are wearing out.”
- “I don’t hear anything special about the MAKO system or ConforMIS.”
- “We do total-knees and total hips. These patients have just worn their bones out, so we need to do total for all of them. I don’t think a partial would work for them.”
- “We don’t use robotics, no MAKOplasty, no navigation system. In the operating room, we have a physician’s assistant with the doctors, nursing staff, and a Zimmer rep. We use Zimmer products, and the rep gives us great feedback. I don’t see where a robotic would make things easier.”
- “The metal-on-metal has caused some issues on and off. Our docs only use metal and ceramic or plastic, with wall spacers. The ceramic has caused some squeaking problems in the past, however. This can be irritating to the patients, but it isn’t harmful.”

➤ **RN specializing in orthopedics/neurosurgery/spine, large medical center in Missouri**

The source’s hospital does not perform robot-assisted orthopedic procedures, and has accomplished a significant number of both hip and knee replacements. The best surgeons specialize in a single procedure, and each can accomplish 600 to 700 replacements per year. The specialized surgeons can complete a total-knee replacement in approximately 1 hour and 10 minutes. A mediocre surgeon may do the same procedure in 3.5 hours. The source said a facility with mediocre surgeons may opt for a technology like MAKOplasty to increase OR efficiency, but the hospital

would need to see very clear and quantifiable benefits to make such a large capital investment. He said he would opt for a more experienced surgeon, with an established team and track record, rather than gamble on one less week of recovery time with a robot-assisted procedure.

- “Our highly specialized surgeons perform either knee or hip replacements, not both. Each has a specific routine and approach. Some use a very traditional method, some utilize more advanced tools. In general, regardless of style preference, an expert can complete a total-knee replacement in an hour and 10 minutes. These surgeons accomplish 600 to 700 replacements in a year. A mediocre, or inexperienced, surgeon on the other hand may need 3.5 hours for the same procedure. This is where a system such as the MAKOplasty may be useful.”
- “Our medical center does not offer robot-assisted knee or hip replacement procedures. The benefit would have to be significant and quantifiable for us to consider the purchase.”
- “Patients do come here with an idea of what kind of procedure they want, so direct-to-patient marketing efforts are definitely effective. In our case, however, our level of expertise and successful track record assure patients that robots are not necessary.”
- “There is a real gray area between the added value of a robotic surgical system, like MAKOplasty, and the cost and training involved in implementing such a system. Other surgical robots have demonstrated that implementation requires a long learning curve, longer OR times, more staff and more complexity, with little gain in patient outcomes.”
- “If I had to decide, I would select the most experienced surgeon available—the one with a stable team, an established method, lowest rate of infection and highest rate of success. I would gladly trade a week of recovery time for the security of a known outcome.”
- “The learning curve for new procedures, particularly robotic methods, applies not only to the surgeon but to the entire surgical team.”

Patients do come here with an idea of what kind of procedure they want, so direct-to-patient marketing efforts are definitely effective. In our case, however, our level of expertise and successful track record assure patients that robots are not necessary.

RN, Large Medical Center in Missouri

► Physical therapist for a clinic in Vallejo, CA

More and more people are having joint replacements although not necessarily robotic surgeries. One or two of the clinic's doctors have tried a robot and found it slowed the procedure time. Hence, this source does not expect robotics to be widely adopted. Minimally invasive surgery, especially for knee replacements, is hardly ever done anymore because it does not seem to help in recovery or to shorten hospital stays. [Anterior hip replacements](#) will become more popular because patients do quite well following that procedure.

- “All hip and knee replacements at [our clinic] are done nonrobotically. I really don't know why they don't do robotics, but [the clinic] stays with the tried-and-true. And money is always an issue. Those robotics are expensive. And from what I've seen, robotics tend to slow some surgeons down. I've heard that robotic procedures may take longer. Awhile back one or two surgeons tried a robot, but it did slow them down. The other docs saw this, and they said forget it.”
- “We mostly do total knees, not partials. ... It is true that some partials need to be redone as totals—some of them fairly soon, others a few years down the line. We particularly see this with younger patients, kids with knee injuries. A partial will work for them for a while, but then they need a total. I'm not really sure why this happens. Maybe the replacements don't fit as well?”
- “We are just starting to see more anterior hip replacements, and those patients do better than patients with a posterior hip. I think the surgeons need to feel comfortable with the procedure, and it seems as if more surgeons are trying the anterior method. The anterior surgery heals faster, and patients have less movement restrictions. Sometimes these hips, if you move them at a short angle, will pop out, and the patients need to have the surgery redone. But this is less of a problem with an anterior procedure.”
- “We're also not seeing as much minimally invasive surgery. It kind of disappeared with the knee replacements. From my perspective, the minimally invasive didn't make much difference on a patient's recovery or length of hospital stay.”
- “I don't imagine that [the clinic] will be trying MAKOplasty anytime soon.”

2) HOSPITAL ADMINISTRATORS

All four sources—two representing hospitals with MAKOplasty and two without—said use of robotic-assisted surgeries gives a facility a marketing advantage. The two sources with MAKOplasty reported reduced patient recovery time, spared healthy bone tissue, better joint alignment, and the advantage of having a MAKO Surgical technician in the OR. Two of the four said the joint replacement market is steady while one said the number of procedures is increasing. One source said the MAKO system will see widespread adoption only when it can provide peer-reviewed clinical outcomes that establish credibility with the medical community.

➤ Manager of orthopedic unit that has a MAKO system, WA

Joint replacements are increasing. Patients do very well on the MAKOplasty; it is less invasive, and patients are in the hospital just 24 hours for partial-knee. The hindrance would be the robot's high learning curve. Have access to MAKOplasty gives hospitals an edge.

- "Joint replacements are definitely increasing."
- "We do total joint replacement of knee and hip and also MAKO partial-knee."
- "We've had the MAKO for about a month now. One doctor does 99% of all cases. Every once in a while, another doctor tries the robot. I think we do 16 to 20 MAKO partial-knees a month."
- "We've had a lot of success with the MAKO. The MAKOplasty offers a lot of advantages. The hospital stay is less than 24 hours. ... Overall, the procedure doesn't seem that invasive compared to the other replacements. They don't cut the tendon, which makes healing easier. It's a bit easier on the patients."
- "Learning the robot is definitely a niche area right now. We haven't had surgeons rushing to use the MAKO. There is definitely a long teaching process, an education leading up to how to use the robot. A tech person comes with the machine, to help us learn how to use it."
- "It takes a while to learn, and it is an expensive machine. This is not a good economy, and I think that has hit teaching hospitals particularly hard."
- "But it is a selling point for the hospital."
- "Outpatient? I can definitely see that. These patients are doing so well; they are more than ready to leave the next day."
- "I haven't heard about ConforMIS."

Learning the robot is definitely a niche area right now. We haven't had surgeons rushing to use the MAKO. There is definitely a long teaching process, an education leading up to how to use the robot. A tech person comes with the machine, to help us learn how to use it.

*Manager of Orthopedic Unit
Washington*

➤ Director of a joint replacement center that offers MAKOplasty, Texas

The volume of joint replacements has remained steady, with little dips related to the economy. The MAKOplasty has many positive qualities, including quick recovery for patients and sparing of healthy bone. A MAKO representative is present in every surgery and handles all the computer logistics.

- "You would think the market of joint replacements would increase, what with the baby boomers getting older. But I have to say we have a steady volume from year to year. Sometimes you even see a little dip in the number of procedures we do. I think it is directly related to the economy. People are delaying surgeries because they can't make the copayments. If you look at the overall patient volume, it is a bit of a decline."
- "MAKO allows for better alignment. It is a more precise, more efficient way of doing surgery. There are no discrepancies. There is more sparing of healthy bone. More structure, ligaments are preserved compared to conventional surgery."
- "MAKOplasty is minimally invasive, and the recovery is quicker for the patient. They are out of bed that same afternoon, walking the day of surgery."

You've heard of [Intuitive Surgical's] da Vinci, right? The MAKO is far easier. There is a company rep that stays in the operating room and does all the computer work, loading info, what have you. They do all the computer guess work.

*Director of Joint Replacement Center
Texas*

- “The MAKOplasty robot seems easier than regular robotics. You’ve heard of [Intuitive Surgical’s] da Vinci, right? The MAKO is far easier. There is a company rep that stays in the operating room and does all the computer work, loading info, what have you. They do all the computer guess work. Information from a CT scan of the joint is then put into the system. The computer keeps the surgeon from going too far and cutting into healthy tissue. The surgeon is guided all the way. We will have that rep for every surgery; that is my understanding. It is part of the deal.”
- “Some of our doctors aren’t interested in the MAKOplasty; they do not participate, and we don’t push them into it. That is OK.”
- “It is hard to find the right candidate for a partial-knee. Maybe only 10% to 15% of people qualify for the MAKO partial-knee. You need someone with mild to moderate bone degeneration, early to midstage arthritis. But it is basic human nature to live with the pain and keep going. All along, we’ve been told to hold off on a knee replacement for as long as we can. So many candidates we see have severe degeneration, bone to bone, and require a total-knee replacement.”
- “But with the partial-knee, patients can get a replacement and keep going and not worry about a total redo for some time. The partial-knee buys people time. I compare it to filling a cavity. That saves the tooth, and you won’t need a root canal for some time, maybe ever.”
- “As far as I know, MAKO does not have a total-knee yet. Partial-knees are really challenging. You would think they’d do that first, before getting the hip approved. But current total-knees seem to be doing OK, and we could really use a new hip method.”
- “The MAKO total hip was just approved in September. It is ready for market. Everyone here is very excited about it. The robot will be involved in planning and mapping the surgery. It will make hip replacements so much easier.”
- “I suppose you could say the MAKOplasty is a marketing tool for the hospital. ... We spent months and months of meetings deciding to get the MAKO. It took us nine months of feasibility studies to decide. ... However, I don’t believe that the MAKO is just a marketing tool. It is certainly a motivation factor, but if that was the only factor, the procedure would never fly. ... At the end day, we are looking at patient outcomes, and we want to be proud of those outcomes. I believe with the MAKO, we can be.”

The MAKO total hip was just approved in September. It is ready for market. Everyone here is very excited about it. The robot will be involved in planning and mapping the surgery. It will make hip replacements so much easier.

*Director of Joint Replacement Center
Texas*

➤ CFO of a Southwest physicians group

This source was unfamiliar with MAKO Surgical but quite familiar with robot-assisted technologies. Adoption of a new technology is driven by its total cost structure. Capital expenditure can be justified if clinical evidence shows that a partial replacement is as effective as a total replacement and that length of stay and rehabilitation can be reduced. The Medicare reimbursement ([DRG based](#)) does not change whether the procedure is done as an open surgery or a robot-assisted minimally invasive surgery [MIS]. For this source, a new technology’s most exciting aspect is its marketability. MAKO will need to provide compelling, peer-reviewed clinical evidence of the MAKOplasty’s superiority to gain long-term traction.

- “The total cost structure of a new technology/procedure is critical when evaluating adoption. Medicare will reimburse the same amount whether a procedure is accomplished by open surgery or through robotic assistance. So, in order to recuperate the capital investment, savings have to be realized elsewhere. Things like implant cost, reduced length-of-stay, lower infection rates and faster recoveries all play a role.”
- “Peer-reviewed, clinical outcomes will play an important role in establishing credibility among orthopedists and hospital administrators alike.”
- “The most exciting aspect of adopting a new technology, from a CEO perspective, is the marketing advantage it gives a facility. If I can substantiate claims of a faster procedure, retention of more of the patient’s own knee, and quicker recovery times, I have a distinctive competitive advantage.”
- “The Internet is a great resource; many patients come to the hospital

In order to recuperate the capital investment, savings have to be realized elsewhere. Things like implant cost, reduced length-of-stay, lower infection rates and faster recoveries all play a role.

CFO, Southwest Physicians Group

very well-informed. More and more even feel comfortable demanding a specific technology or procedure. In my experience, the facility that can offer more technologically advanced tools, like MAKOplasty, is seen as a higher-quality, cutting-edge option. This is a great advantage.”

- “The trend toward more robot-assisted procedures will only continue. The only caveat is whether the changes in healthcare regulation will affect a hospital’s ability to make such purchases.”

➤ Orthopedic surgical director for an Alaskan regional hospital

Joint replacement surgeries have been steady but stable, and are performed using noninvasive methods. The source was not familiar with MAKOplasty or ConforMIS. She said robotics is only appropriate for some surgeries. Total replacements have worked well for this hospital’s patients. Some patients with partial-knees eventually will need total repair.

- “Our joint replacements are done with noninvasive methods, not robotics. The patients have minimal cuts, and recovery is good.”
- “The hospital does robotic surgery for other operations such as prostate and gastric bypass. Robotics is good for the hard-to-reach places. We were the first in the state to have a robot [da Vinci]. It is better for some surgeries than others. We’re not considering the robot for joint replacements.”
- “I suppose the robotic gave us an edge, but we use it just for some surgeries.”
- “Last year, we did 460 total-knees and 226 total hips. We do a few partials. I think the numbers will be the same this year. People just keep coming in, but it’s a steady stream. I haven’t noticed any changes.”
- “Do many totals just need partial-knees? We mostly do totals, and the patients do well.”
- “It is probably true that some partial-knees need to be redone as totals.”
- “We don’t use MAKOplasty or ConforMIS. I don’t know anything about them.”

3) MEDICAL DEVICE SALES PROFESSIONALS

All four sources reported an increase in the trend toward robotics, customized joints and minimally invasive procedures. Two also reported a trend toward increased use of partial-knee replacements. MAKO-like procedures can provide better precision and alignment of the joint, faster recovery and make mediocre surgeons better. Still, one source said robotics can slow a skilled surgeon, and require a long learning curve. MAKO’s direct-to-consumer marketing has been effective, and hospitals with robotics have a commercial advantage. One source said biologic solutions are being developed that, if successful, will devastate joint replacement companies.

➤ Medical device company’s territory consultant, with experience in robotic procedures, orthopedics specifically

This source said robotic procedures take longer and require a long learning curve. They offer more of a marketing advantage than an improvement in patient outcomes. Still, the MAKO RIO design appears sound and could offer better placement and alignment. The industry has shifted from a one-size-fits-all mentality for implants, so companies that provide highly customized implants, like MAKO and ConforMIS, could see additional market growth. The recalls involved other competitors, which also could benefit these two companies. Direct-to-patient marketing efforts play a significant role in generating demand. The economy is likely to push hospitals to trim other aspects of medical care rather than sacrifice a technology that gives them an advantage.

- “I don’t see that surgical robots in general offer any advantage to the surgeon. In fact, robots like da Vinci can often be detrimental to the surgical process as the procedure initially requires much more OR time and surgeons have a long learning curve. The MAKO RIO may offer advantages in implant alignment, but an exceptional surgeon is unlikely to find it beneficial.”
- “Hospitals will frequently purchase a robotic system for a competitive advantage rather than improved patient outcomes.”
- “The realization that standardized joint implants are not always an ideal fit is driving the trend toward highly customized implants. This trend will benefit companies like MAKO Surgical and ConforMIS. Competitive product recalls will also increase market share for these companies.”
- “Economic and healthcare reform pressure definitely force hospitals to cut costs and consolidate vendors. If a procedure like MAKOplasty is effectively bringing more business to the hospital, however, they will

Hospitals will frequently purchase a robotic system for a competitive advantage rather than improved patient outcomes.

*Territory Consultant
Medical Device Company*

find a way to budget for it.”

- “Effective direct-to-consumer marketing by medical device companies have created a population of patients who demand the latest and greatest technology. Patients view the facility that has the most advanced technologies, including surgical robots like MAKO’s RIO, as the best.”

➤ **Industry consultant, trained surgical assistant with a background in orthopedic surgical sales**

The total number of knee and hip procedures performed annually in the United States is growing because of an aging and increasingly overweight population. Robotic procedures like MAKOplasty are beneficial to patient outcomes because they are much less invasive. A less-invasive approach allows for quicker recovery, which is particularly important for patients with concomitant health concerns like obesity and cardiovascular disease.

- “There are a large percentage of knee replacement patients who are overweight and have other complicating conditions, including cardiovascular disease. Minimally invasive and robot-assisted procedures like MAKOplasty allow for a less aggressive surgical procedure. This helps patients heal faster and recover more quickly.”
- “Traditional total-knee replacement is extremely invasive. The less-invasive MAKOplasty procedure can potentially result in much faster recovery times.”
- “Safety and patient outcomes should always be the top priority. But I believe as long as the surgeon is skilled with the MAKOplasty robot, the robotically assisted procedure should be faster than more traditional, open surgery.”

➤ **Western regional sales manager for orthopedics and neurosurgery implants and instruments**

The number of total hip replacement procedures in the United States is approximately 400,000 each year, and is expected to increase threefold by 2030. Approximately 500,000 total-knee replacements are performed each year, and this number is expected to increase more than sixfold by 2030. Growth stems largely from an aging population. [Stryker Corp.](#) (SYK) and [Biomet Inc.](#) are the market leaders. Total-knee replacements had been preferred because of better outcomes and highly specialized surgeons who had developed a time-efficient workflow. However, the medical community has been warming to the idea of addressing the problem earlier because knee degeneration is progressive. The trend toward partial replacements is being driven by newer technologies like the MAKOplasty, which help streamline and perfect unicompartmental procedures. MAKO Surgical has successfully marketed the MAKOplasty. MAKOplasty can help a mediocre surgeon perform a better procedure. This source expects the market to see many more advances, including biologic solutions that could devastate mechanical joint replacement companies. Fewer physicians are opting to specialize in joint replacement because of reimbursement limitations, which will propel the development of new technologies that improve the outcomes of nonspecialists. An experienced MAKOplasty surgical team can perform the procedure in relatively comparable OR time. The source said joint replacement has yet to be perfected, as evidenced by the recalls.

- “The demand for knee and hip replacements is expected to grow exponentially. It has been estimated that by 2030, hip replacement procedures will triple to approximately 1.2 million per year. Knee replacements are expected to increase nearly six times in the same time frame, to 2.5 to 3.0 million cases per year in the U.S.”
- “While demand for knee and hip replacements increase, the pool of skilled orthopedic surgeons is decreasing. Many orthopods are opting not to specialize in joint replacements because of the limited reimbursement allowed by Medicare.”
- “There is a significant shift from default total-knee replacement to partial procedures. Because knee disease/damage is progressive, correcting the problem early allows the surgeon to maintain more of the natural knee. In addition to the ability to treat at earlier stages, patient awareness and improved technologies like MAKOplasty drive the trend toward a higher percentage of partial-knee replacements.”
- “MAKO Surgical has done a masterful job at marketing. They tell a great story. The truth is, though, establishing the long-term clinical benefits and advantages of a new orthopedic procedure takes many years.”
- “New technologies promise to make adequate surgeons more skilled and help streamline procedures. Currently, in the hands of an expert team, the MAKOplasty OR time is very similar to traditional surgery—perhaps an

While demand for knee and hip replacements increase, the pool of skilled orthopedic surgeons is decreasing. Many orthopods are opting not to specialize in joint replacements because of the limited reimbursement allowed by Medicare.

*Western Regional Sales Manager
Orthopedics Implants & Instruments*

additional 10 minutes per robot-assisted procedure. I believe as these technologies advance, the robotic procedures can reach a time-neutral or even more time-efficient procedure time.”

- “The future is biologics. If you can prevent joint degeneration, there will be no need for mechanical replacement.”
- “FDA recalls can potentially result in billion-dollar class action suits, which can destroy an organization. These recalls are a function of the inability to efficiently determine whether a specific material or technology is clinically superior. It takes years. Manufacturers also have a tendency to rush new products to market in order to remain competitive. So although the market has made a lot of advances, there is still a lot of ongoing research. Joint replacement has not been perfected.”

The future is biologics. If you can prevent joint degeneration, there will be no need for mechanical replacement.

*Western Regional Sales Manager
Orthopedics Implants & Instruments*

➤ **Consultant and sales business developer for an orthopedic device company; trained surgical PA**

Knee and hip replacements number 450,000 to 600,000 each in the United States. The MAKOplasty’s top benefits are the ability to perfect the placement/alignment for long-term success and the ability to customize the fit for the replacement joint. This source expects the industry to move toward performing more partial-knee replacements as a result of better techniques. A robot-assisted procedure cannot in itself improve surgical outcomes; the surgeon still needs the skills to execute the procedure and manipulate the robot. The source said surgeons’ compensation likely will not vary even if robotics are used; compensation is based on the complexity of the procedure and the Medicare-based DRG. Product recalls are “just a bump in the road” if the product quality and design are superior overall. Robotics’ adoption rate is affected by the economy. MAKOplasty should be marketed at a much lower price point.

- “The industry seems to be reversing the previous shift toward total-knee replacements, back to performing more partial replacements whenever viable. This shift toward partials is supported by positive ‘evidence-based’ outcomes. It simply does not make sense to destroy an entire knee if it is not necessary for an effective repair. I think the success of new procedures like MAKOplasty has played a significant role in this trend.”
- “I see the greatest advantage of the MAKOplasty robot is the ability to refine and perfect the alignment and placement of the implant. Correct positioning is vital to long-term success.”
- “Robot-assisted devices like MAKOplasty cannot improve patient outcomes in a vacuum. The surgeon still needs to have the skills to make the right incisions and effectively manipulate the robot.”
- “A highly skilled surgeon with a very competent OR team will likely be able to perform a traditional knee replacement just as quickly as one assisted by a robotic system like MAKOplasty.”
- “Hospitals certainly market new technologies and capabilities like MAKOplasty. They see these advances as a competitive advantage.”
- “Elective surgeries have definitely been affected by the economic downturn. Many patients that may need a joint replacement are delaying the procedure due to concerns over copayment and/or out-of-pocket expenses.”
- “I do not believe that surgeons will see a difference in their own compensation based on how the procedure is accomplished since they are paid by DRG code. The hospital may, however, bill differently between a more traditional and a robot-assisted procedure like MAKOplasty.”
- “If a technology is sound and the design and materials are of very high quality overall, I think a product recall can just be a bump in the road for a manufacturer.”

4) INDUSTRY SPECIALISTS

Three of four sources said MAKO’s market will continue to grow because its robot offers precision, accuracy and assistance to average or poor surgeons, but the remaining source said the system is nothing more than an expensive, unnecessary “toy” that often sits unused in OR closets. Two sources said the market for joint replacement is growing. MAKO has effectively marketed its system to patients and hospitals alike.

➤ **Trained surgical technician and a former surgery tech instructor at a nursing school**

This former MAKOplasty specialist believes the market for hip and knee replacements in the United States is in the range of 600,000 to 700,000 procedures each. Only 12% to 20% of those are viable candidates for the MAKOplasty partial replacement procedure, but the source still described the MAKO system as superior. No other competitor offers the

robotically assisted tracking and placement precision that assures the even wear and weight distribution needed for long-term success. The MAKO system was designed as a closed system (only MAKO implants can be used). He expects the robotics market to grow because of its more exacting process that results in more robust outcomes and greater longevity. Initial set-up time is longer for a MAKOplasty than for traditional knee replacement, but the robotic set-up is all performed by a MAKO Surgical employee. MAKO provides full performance support for every procedure accomplished (at no additional cost); the surgeon simply verifies the settings. The actual procedure time with MAKO is much more streamlined than traditional surgery. Regarding the recalls, this source said manufacturers often launch and actively market a system that likely should undergo further evaluation and refinement.

- “Increasing numbers of hip and knee replacements are performed every year, particularly in areas with high numbers of retirees. I would estimate between 1 to 2 million procedures annually, with the number of hip and knee procedures relatively evenly split.”
- “I would estimate only between 12% to 20% of total-knee replacement patients would be eligible for the MAKOplasty procedure.”
- “Utilization of robotic procedures like MAKOplasty are likely to increase overall and even be embraced in managed care environments. The extensive quality control checks and balances to establish and verify the correct implant dimensions and alignment tracking ensures optimal outcomes and long-term stability.”
- “The MAKOplasty procedure does require more set-up time compared to traditional knee replacement, but that set-up work is accomplished by a MAKO Surgical specialist. MAKO Surgical provides an expert technician, at no cost, for every procedure accomplished.”
- “Competitors like ConforMIS only offer a custom-fit implant; the surgical procedure is still nearly identical to traditional total-knee replacement. Their approach removes about twice the amount of bone compared to MAKOplasty. Moreover, MAKO is unique in its robotic offering, which serves to perfect the alignment tracking. Without precise placement, the knee is more likely to fail over time.”
- “MAKO Surgical and other manufacturers effectively market to both patients and hospitals. Patients see surgical advances as more reliable and less traumatic. The compelling story to a hospital is that they are able to nearly double the number of knees that can be accomplished, without adding staff. The MAKOplasty draws interest from patients. It helps maximize OR throughput and creates a much higher level of proficiency for average surgeons.”

The MAKOplasty procedure does require more set-up time compared to traditional knee replacement, but that set-up work is accomplished by a MAKO Surgical specialist. MAKO Surgical provides an expert technician, at no cost, for every procedure accomplished.

*Trained Surgical Technician
Nursing School*

➤ Former director of marketing for an orthopedic instruments and implants company

This source estimated the total worldwide market for knee and hip replacements at 2.5 million to 3 million procedures annually, with the United States representing approximately half of the total. She was unsure of what percentage of total-knee replacements would be viable candidates for a partial procedure like MAKOplasty. If knee damage is a result of wear and tear and is caught early, a partial replacement may be adequate. If the damage is a result of disease or misalignment, the patient almost will certainly require a total replacement. Although robotics may not improve the outcome quality of a superior surgeon, it will allow more surgeons who otherwise may not have the expertise to deliver optimal results. The market for capital-intensive surgical robotics in general appears to have slowed because of the economy, but she expects demand to grow over time. [Johnson & Johnson's \(JNJ\) DePuy, Smith & Nephew plc \(LON:SN/SNN\)](#), Zimmer, Biomet and Stryker the top orthopedic robot manufacturers. Although no company desires an FDA recall, most large companies are able to recover and regain their credibility in the market.

- “I would estimate the total global market for knee and hip replacements at 2.5 to 3.0 million procedures annually, approximately 50% of which occur in the United States. Hip and knee replacements are roughly on par with each other.”
- “Most knee damage initially occurs in the medial compartment, which if caught early, can be adequately corrected by a partial replacement like MAKOplasty. If the damage is the result of a chronic disease or skeletal misalignment, the likelihood that a total replacement will eventually be necessary is very high.”
- “The greatest advantage of robotic techniques like MAKOplasty is that they can help make a mediocre surgeon a much better one. I would expect these techniques would also need to reduce procedure time and increase efficiency in order to allow administrators to justify the purchase.”

- “Robotically assisted, minimally invasive procedure growth has been quite robust both as a result of direct marketing efforts to the consumer and the influence of surgeons trained on the technique. The economy has seemed to impact the number of new facilities acquiring these instrument systems recently. Unless the robot had already been budgeted, many facilities are simply not purchasing them right now.”
- “Manufacturer direct-to-patient marketing efforts, particularly the use of social media, can play a very large role in developing market pull from the patient level. Ultimately, however, if a patient has a surgeon they trust, that surgeon will typically be the most significant factor in deciding which direction to go-total or partial, traditional or robot-assisted.”
- “Product recalls are never desirable, but for most large companies a recall has negligible long-term results. Most, like [Johnson & Johnson](#), are able to recover and regain credibility quite effectively.”

➤ Vice president of engineering for an orthopedic device company

The market for knee and hip replacements is growing each year and is expected to reach 3 million replacements in 15 years. The metal-on-metal device is obsolete, and the industry is returning to the traditional metal/ceramic/plastic combination. One-third of patients receiving total-knee replacements really only need partial replacements. With a customized implant, robotics are not necessary. The implant saves the surgeon time and guess work and provides an easier recovery for the patient. Also, hospitals do not need to buy expensive robotics to perform knee replacements.

- “[The joint replacement market] is growing. It increases each year, especially in younger, active people. It’s not just a market for older patients. It nearly hit 600,000 last year, and I’m not sure what it will be this year. But it will be higher. The market may reach 3 million replacements in 15 years. You do the math.”
- “Patients receiving totals but only needing partials? I don’t think it is as high as 50%. Maybe a third though.”
- “MAKO is really the only game in town for robotic joint replacements. There’s also [Curexo Technology Corp.’s] [Robodoc](#) robotic device for total-knee, but MAKO is the game.”
- “The robotic joint replacement market is relatively small, around 2%. Most of these surgeries are performed without robotics. It depends on what the surgeon has been trained on and how skilled he is. It takes awhile to learn robotics. A surgeon skilled in standard surgery can do the surgeries quickly, in 1.5 hours.”
- “The metal-on-metal devices caused big problems in the hip. Metals rub against each other, and minute particles may break off around the area. Sometimes devices are made of several types of metal that might not be compatible. The metal-on-metal device is virtually dead now. We are back to a traditional combination of metal, ceramic and plastic. The ConforMIS implant is metal on plastic. It is quite stable. They will last 20 years, just like the others.”
- “The ConforMIS device is an alternative to robotic surgery. The implant requires the same level of invasiveness as standard surgery, but there is no guess work for the surgeon. The implant is just like the patient’s knee. Everything has been done ahead of time, and the device slips in easily. There is no time out to program the robot, which takes around 20 minutes to set up. There is no need to buy a million-dollar device. In that sense, hospitals will save a lot of money using the ConforMIS.”

➤ Former orthopedic nurse and current administrator for a Web forum on joint replacement

The robotics market is not growing. The robot is simply an expensive toy, and a number of units go unused. The ConforMIS system is basically unnecessary; standard implants are suffice. A high number of partial-knee replacements need to be redone as a total replacement within six to 12 months.

- “I very much doubt if robotic orthopedic surgery will continue to grow. The initial outlay is prohibitive, and I’ve heard that many hospitals have stopped using the kit anyway, with the devices standing unused in a cupboard in the operating room.”
- “The set-up costs [of the robot] are prohibitive though some firms might seek to expiate this by offering the kit on a long-term loan basis. The real money is made in the sale of the consumables such as the implants and drill bits.”
- “A lot more time is spent setting up the robot, as is the case with most of these toys.”
- “The advantage of robotic orthopedic surgery is that the area of preparation is predefined. The disadvantages of robotic surgery is that this area is often inconsistent with the needs of individual knees. It is sometimes necessary for the surgeon to disable the robot so he can do the job properly, which means removing

A lot more time is spent setting up the robot, as is the case with most of these toys.

*Former Orthopedic Nurse &
Joint Replacement Web Forum Admin*

[osteophytes](#) or other damage that hasn't come within the area of the robot's work. The robot won't let the surgeon go to that place, so he has to switch the robot off and 'freehand' it."

- "I'm somewhat familiar with ConforMIS. I'm not convinced that such surgery is totally necessary as the standard knee implants have served for an awful long time with a great degree of success."
- "The conversion rate of partial [knee replacements] to total [knee replacements] is frighteningly high. Some need to be redone as early as six to 12 months."
- "I couldn't possibly say if the metal-on-metal failures are impacting the products."

5) PATIENTS

None of these three sources underwent a MAKOplasty or knew anything about the procedure. All three said they trusted their doctors and went with their recommendations. They also said they would follow their doctors' advice again if additional procedures were required.

➤ Total-knee replacement patient, Milwaukee

This 82-year-old female source experienced total replacement on each of her knees approximately 10 years apart, the first 16 years ago. With both procedures she had minimal discomfort and a very fast recovery. The second procedure was accomplished with a noticeably smaller incision but was not robotically assisted. She said a broken ankle that needed surgical repair this past summer was much more unpleasant and required a significantly longer recovery. She is aware of robotically assisted procedures but said she would not have been inclined to select that option unless her surgeon convinced her of the benefits over the traditional surgery.

- "I had one total-knee replacement 16 years ago and the other six years ago. I would not have had the second done if the first hadn't gone so well. In both cases, I was fully recovered and mobile in little more than a month. The only difference to me was the first left me with a 12-inch scar and the second a 4-inch scar."
- "Both traditional total-knee replacements went extremely well. I tell anyone who needs the procedure to go ahead and get it done. I personally wouldn't have considered a robot-assisted option unless my surgeon could convince me it was a much better way to go."

I personally wouldn't have considered a robot-assisted option unless my surgeon could convince me it was a much better way to go.

Total-knee Replacement Patient

➤ Patient with total-knee replacement, Cupertino, CA

Robotic surgery was never discussed by this 55-year-old patient's doctor, but she said together they opted for a replacement that offered a wide range of motion. The surgery went well, and she will undergo the same procedure for her other knee in a year or two.

- "I don't think I had robotics. It never came up, and I never asked. I trusted my doctor because he really has a high reputation."
- "I don't know the name of the device. Was I supposed to? But I do know that we chose the one that could have the most flexibility. Maybe it was a MAKO; that sounds familiar. The doctor did talk to me about the different ranges, and because I'm active, I asked for one that had the most range of motion."
- "I had a total left knee replacement in 2009. I was bone-on-bone for a long time, so total was my only option."
- "The recovery took a long time. I did physical therapy for two to three times a week for several months. I thought it was slow, but a few months later I was riding my bike 50 miles. Everyone said it was great. It seemed like I had good function."
- "I do have some scar tissue. I can bend my knee back and almost touch my butt, but not quite. I haven't needed any special treatment for it. You can just feel the pull inside sometimes."
- "In another year or two, after I'm fully healed, I need to have the right knee done. And I'd do the same all over again. It seems like everything went well without robotics."
- "I haven't heard any stories about the metal-on-metal. I think I'd go with what my doctor recommended and not get too excited about the rumors I heard."

➤ **Patient with two total-knee replacements and one total-hip replacement, Los Altos, CA**

This 76-year-old source's surgeon does not perform robotic-assisted procedures. The doctor did talk to her about the metal-to-metal problem, and she would follow his advice on what device to use. Her recovery period was longer with the knee replacements than with the total-hip procedure.

- "My surgeon does not do robotics, but he came recommended by a friend. I've certainly had a few replacements by him, and if I ever need a second hip, I'd have him do the surgery. I trust him enough."
- "I think physicians do the type of surgery they can do best. Doesn't it take awhile to learn robotics? These guys are doctors, not engineers."
- "My doctor did talk to me about the metal-on-metal thing. We even discussed the manufacturer although I can't remember now. My hip replacement is a metal-to-ceramic. I just listen to my doctor."
- "I had an anterior hip [procedure]. I heard this was easier on the patient. I think they go through less muscle, maybe just pull the muscle apart, rather than cut it. It's much easier to recover from hips than knees. I only needed physical therapy for a month after my hip surgery."
- "So far, my other hip is fine. But yes, I would do another anterior surgery if I had to have another replacement."

Secondary Sources

Our review of secondary sources found discussion of the MAKOplasty Total Hip Arthroplasty system and a New Jersey hospital's recent addition of a MAKO robotic system. On a patient's forum, community members voiced their dissatisfaction with their MAKOplasty knee recovery time. Our final source, a health blog, highlighted the present and future state of robotic procedures in orthopedic surgery. Cost and clinical outcomes will dictate the future.

➤ **October issue of *Orthopedic Design and Technology***

MAKO's RIO has been expanded to include hip replacement procedures. Approved by the FDA in February 2010 for partial-knee replacement, the robotic system now can be used for total-hip replacement. Nearly 300,000 hip replacements are performed yearly in the United States and represents a significant new market for MAKO. Worldwide, the hip replacement market is valued at \$5 to \$6 billion.

http://odtmag.com/news/2011/10/07/MAKO_Surgical_Rolls_Out_Robotic_System_for_Hip_Replacement

- "MAKO Surgical Corp. is now offering its RIO Robotic Arm Interactive Orthopedic System for use in total hip replacement procedures. MAKOplasty—which is what the company dubs its arthroplasty procedures—for the hip is the newest application for MAKO's RIO system and builds on five years of experience with the company's partial-knee resurfacing procedure for patients with early to mid-stage osteoarthritis."
- "Nearly 300,000 primary hip replacement surgeries are performed annually in the United States using conventional techniques, according to the American Academy of Orthopaedic Surgeons."

➤ **Sept. 5 NJ.com article**

Kennedy University Hospital has become the first hospital in southern New Jersey to perform partial-knee replacement with the MAKO system. Dr. Jess Lonner stated that 600,000 total-knee replacements are performed in the United States each year, and he thinks 50% to 75% of the patients are candidates for partial-knee replacements. Younger patients are becoming more common, and they are demanding procedures that allow them to remain active.

http://www.nj.com/gloucester/voices/index.ssf/2011/09/carly_q_romalino_kennedy.html

- "Kennedy is among 70 hospitals in the country that offer the knee replacement option to patients with degenerative arthritis of the knee. In the tri-state area, only Pennsylvania's Bryn Mawr Hospital in the Philadelphia suburbs performs the procedure."
- "Although surgeons have had the capability to perform partial replacements for decades, doctors rarely used the technique. 'The technique was very difficult,' said Lonner of the pre-robotic assistance era. 'It's hard to do well and accurately every single time, that's why most orthopedic surgeons did not perform partial-knee replacement. ... It's easier to do technically and total-knees are more accommodating of subtle errors in alignment.'"
- "More than 600,000 total-knee replacements are performed in the country every year. Lonner believes about 50 to 75 percent of those patients could be candidates for partial-knee replacements. More than 65,000 partial-knee surgeries are performed nationwide every year, he said."

- “Our patients coming in for knee replacements are getting younger and younger. Our fastest growing replacement groups are 55 and younger,” said Lonner, who has noticed that many of his patients are still working-age folks that don’t want to be out of work for an extended period of time. ‘They want knees that are more young and active.’”

➤ **Aug. 8 posting on Bonesmart.com’s knee replacement recovery forum**

Some recent MAKOplasty patients reported disappointment with the length of their recovery period and their physical therapists’ lack of knowledge about the procedure.

http://bonesmart.org/public_forum/makoplasty-pkr-7-weeks-t12489.html

- “I had my MAKOplasty on June 21 2011 and I have to say that it is taking much longer that I expected to recover. The swelling is a constant problem and so is the pain. Mt ROM is about 95. Two weeks ago at PT my tech was pushing on my leg to get the ROM larger and he tore some tissue inside my knee, so I had bleeding inside and the swelling was as large as ever. Now I am afraid to go back to PT and I am doing my own exercise. I am not sure if I would recommend this for anyone. I was told it would not take this long to heal. I can see this going on for probably 8 to 10 months. Also PT techs have no clue about this procedure here in the U.S. Bad move for me. Still on pain killers when I need them.”
- “I had my Mako on June 14th and had a total a year ago. I expected the Mako to go much easier but it did not. Thank goodness for this site where I learned that I had bone cut and that it was just like the total-knee and that I shouldn’t expect to be running around right away.”

➤ **June 20 posting on the Breaking Story health blog**

The present and the future of robotics in orthopedics are discussed in six points. Currently, robots are used in few orthopedic procedures, and strong clinical-based evidence of superior results is lacking. The high expense also has restricted adoption. Marketing to both hospitals and patients has sold systems.

<http://thebreakingstory.com/health/robotics-in-orthopedic-surgery-6-points-on-the-present-and-future/5002.html>

- **“1. What robotic and computer-assisted technology is capable of now?** Currently, there are only a few orthopedic procedures, such as partial-knee and hip replacements that have robotic or computer-assisted technology to help facilitate the surgeries.”
- **“2. Applying evidence-based research to robotic technology.** Strong, evidence-based studies showing that robotic technology produces better outcomes are lacking, and many orthopedic surgeons are unsure of spending the extra time and money to train on the systems.”
- **“3. Marketing the technology.** While the technology doesn’t have hard clinical evidence to support its use, device companies have been able to sell their systems to hospitals across the country. Much of the success of these sales can be attributed to marketing by the company, but the sustained use of the technology could be a sign that hospitals and surgeons are seeing good results.”
- **“4. Patient demand for robotic surgery.** In some communities, patients are driving the trend toward robotic- and computer-assisted procedures by demanding them from their physicians.”
- **“5. Dealing with the technology expense.** Purchasing the equipment and software for performing robotic or computer-assisted surgery places a great burden on the hospital or healthcare provider. Some surgeons are partnering with hospitals that purchase the equipment, but even taking the time out of daily practice to train and become proficient on the technology can be difficult, despite the potential benefits of using the systems.”
- **“6. Will robotic technology still be around in 10 years?** With increased pressure to reduce the cost of healthcare and emphasis on evidence-based medicine, robotic technology must prove its efficacy to continue its increased use. The systems will need to come down in price, which will happen if more products come into the market.”

Next Steps

Blueshift will monitor the adoption of the MAKOplasty for both partial-knee replacements and total-hip replacements. We will try to determine if the new anterior hip replacement procedure will in any way inhibit the adoption of the MAKOplasty hip replacement procedure. We will review clinical studies currently underway on the MAKOplasty procedure to determine if data supports improved patient performance. We also will look at which biologic solutions are available for joint replacement and

their commercialization timelines. Finally, we will contact additional teaching hospitals to gauge their familiarity with and adoption of the RIO Robot and MAKOplasty procedure.

Additional research by Renee Euchner and Pam Conboy

The Author(s) of this research report certify that all of the views expressed in the report accurately reflect their personal views about any and all of the subject securities and that no part of the Author(s) compensation was, is or will be, directly or indirectly, related to the specific recommendations or views in this report. The Author does not own securities in any of the aforementioned companies.

OTA Financial Group LP has a membership interest in Blueshift Research LLC. OTA LLC, an SEC registered broker dealer subsidiary of OTA Financial Group LP, has both market making and proprietary trading operations on several exchanges and alternative trading systems. The affiliated companies of the OTA Financial Group LP, including OTA LLC, its principals, employees or clients may have an interest in the securities discussed herein, in securities of other issuers in other industries, may provide bids and offers of the subject companies and may act as principal in connection with such transactions. Craig Gordon, the founder of Blueshift, has an investment in OTA Financial Group LP.

© 2011 Blueshift Research LLC. All rights reserved. This transmission was produced for the exclusive use of Blueshift Research LLC, and may not be reproduced or relied upon, in whole or in part, without Blueshift's written consent. The information herein is not intended to be a complete analysis of every material fact in respect to any company or industry discussed. Blueshift Research is a trademarks owned by Blueshift Research LLC.