Trends-in-Medicine

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by Lynne Peterson

SUMMARY

Falling reimbursement may cause a shortage of orthopedic surgeons doing joint replacement surgery at the same time that demand is increasing, and this could affect company growth predictions. ♦ Gender-specific hips and knees are both viewed as a marketing gimmick. ♦ Many orthopedic surgeons are dubious about hip resurfacing, many of those who perform it believe it should be restricted for ≤10% of hip patients – mostly younger men. Doctors are somewhat more optimistic about knee resurfacing. ♦ Stryker does not appear to have lost much if any market share due to its problems with Trident hip manufacturing or the government subpoena on its foreign trade practices, and its hip resurfacing system may take some share in that small market. ♦ Government investigations of the orthopedic industry – and surgeons themselves – are not over, but the investigations do not appear to be affecting brand loyalty, at least not yet. Likewise, the decrease in consulting agreements or the amounts paid to consultants does not appear to be affecting brand loyalty. ♦ Hospital pressure on implant prices and surgeon choice of devices is accelerating.

Trends-in-Medicine
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AMERICAN ACADEMY OF ORTHOPEDIC SURGEONS (AAOS)

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The meeting was rather mellow this year, with no real "hot topic." There were not a lot of new product introductions, and the number of exhibit booth lectures was significantly lower. Vendors appeared to be taking a very cautious marketing approach, given the current government oversight of the industry. A potential shortage of orthopedic surgeons for joint replacement surgery, debates on gender-specific implants, the outlook for hip and knee resurfacing, and discussions of ethical issues in the interaction between physicians and industry were perhaps the most interesting topics.

GROWTH OF THE JOINT REPLACEMENT MARKET – could hit a wall

Orthopedic surgeons and industry sources are predicting dramatic growth in both hip and knee arthroplasty over the next 25 years. The question is whether there will be enough trained orthopedic surgeons to meet the demand.

Between now and 2030, estimates are that total hip arthroplasty (THA) procedures will double, and total knee arthroplasty (TKA) will increase more than five-fold. One speaker estimated that the TKAs would double by 2016 and total hips would double by 2026. Zimmer signage noted that 540,000 TKAs were performed in 2007, and there is a potential for 3.2 million in 2030. The cost to the Centers for Medicare and Medicaid Services (CMS) for total joint arthroplasty (TJA) is expected to nearly triple between 2010 and 2030 to nearly $5 billion.

Why won't there be enough TJA surgeons? The key reason is reimbursement, and that has led to fewer doctors choosing to become hip and knee specialists. Dr. Daniel Berry of the Mayo Clinic, president of the American Association of Hip and Knee Surgeons (AAHKS), said, "The AAHKS is concerned about whether we are and will be training enough hip and knee specialists to meet the needs of American society over the coming decades."

Dr. William Healy of the Lahey Clinic said Medicare reimbursement is $1,336 for THA (CPT 27130) and $1,435 for TKA (CPT 27447). He pointed out that $1,400 also buys car service from Boston to Philadelphia, a Dolce & Gabbana hobo handbag, two Superbowl tickets, or three greens fees at Pebble Beach. He commented, "There are many reasons (there will be a shortage of TJA surgeons), but economic considerations are significant and prominent. Surgeon payment for TJA is too low…Furthermore, the trend in surgeon payment for TJA is decreasing …Since 1983, my THA payment has decreased 63%."

Dr. William Fehring of North Carolina charged that TJA is a "victim of its own success." He said, "Arguably the most successful operation in medical history has become a commodity…Reimbursement for THA has gone down 64% in

inflation-adjusted dollars from 1990-2005, and reimbursement for TKA has gone down 59% in the same time period…The council on graduate medical education projects a shortage of 12,000-15,000 orthopedic surgeons by 2020. Today, only 7% of AAOS members are joint replacement specialists. This percent is expected to *decrease* significantly in the face of increasing demand and declining reimbursement."

Several TJA experts pointed out that they already are maxed out in how many TJAs they can do or in operating room space/time which will keep their volume relatively flat over the next year. Other doctors said they will shift their mix from other procedures to hip/knee replacements as demand increases, but if reimbursement doesn't improve, they can't take up all the slack.

Other comments included:

- "We aren't sure when the growth slowdown will occur, but that is where we are headed."
- "There are people now who are being denied – like Medicare patients who had an infection…At tertiary centers we see an increasing burden from these patients because we accept all-comers, but that system will crumble as we get overwhelmed with patients that cost our hospitals money."
- "Over the next 5-10 years, the availability of surgeons may affect company sales growth."

Experts agreed that unless the reimbursement problem is solved, industry projections for implant sales could hit a wall in just a few years, with growth slowing or even flattening. One expert suggested that surgeons will become more selective, putting off TJA procedures for diabetics, older patients, or obese patients who don't have serious functional disability, etc. Another expert said pain will become less of an indication for a procedure; functional ability will be the focus. A Midwest doctor said a two-tier system may develop: Patients waiting for an operation or paying more out-of-pocket in the U.S. or going outside the U.S. for the surgery. Another source offered this solution: Hospitals will hire foreign-trained surgeons, a scenario that could be good for hospitals (lower salaries and more procedures) and good for industry (more procedures). For example, he said the University of British Columbia, Canada, charges patients who want specific technology, "Maybe it will be more like elective plastic surgery. The industry may be able to sustain unit growth if people are willing to pay (more) for the procedure."

GENDER JOINTS – mostly hype

Gender-specific knees were considered a marketing gimmick last year, and that has not changed. Zimmer took some share – less perhaps than the company expected – with its Gender Solutions Knee, and Zimmer is readying a gender-specific hip as well. Other companies are also introducing their own gender-specific implants, but doctors were dubious that these would significantly expand the market.

Yet, direct-to-consumer advertising has been very effective. Patients frequently ask about the gender knee, but doctors who don't do it generally insisted they don't lose patients to other doctors who do use them. One doctor who uses mostly Biomet and J&J/DePuy knees also does gender knees but only when patients ask for them.

Gender-specific hips were also described as a marketing gimmick, and many doctors said that this is one product that most of them won't use, even with patient demand. However, they recognized that, as with gender knees, there will be some doctors who use it to market against other doctors or to draw patients to them or their hospital.

Comments on gender-specific implants included:

- *Tennessee:* "My knee patients aren't asking about gender-specific knees, but there is awareness."
- *Ohio:* "Gender knees are a joke. Patients ask about them, and I tell them what I do, and I don't lose patients, but more patients are asking for a particular implant."
- *Arizona #1:* "Gender knees are a gimmick. I haven't seen any documentation that they make a difference from a functional standpoint. Patients ask for them, though."
- *Arizona #2:* "They are a marketing gimmick, and they've caused me a lot of headaches. Patients see the ads, and the data are not there. I have to answer a lot of questions, but I'm not losing patients because I don't do them."
- *Oregon:* "Gender implants are a gimmick. The companies are just trying to find a way to make patella tracking a little better."
- *Michigan:* "They are not based on clinical data, so I don't do them."
- *Missouri:* "There is no need, and there are peer-reviewed articles that show that."
- *Minnesota:* "It's not a gimmick. I use the Zimmer Gender Knee, but it hasn't helped my practice. Women want it, and I'm practical, so I do it. I don't battle with patients; if they want it, okay. And there is a lot of patient demand, but I don't think patient demand will go up further with the other brands coming on the market; they are not a whole lot different."
- *Midwest:* "The literature tells us there is a size difference, not a gender difference."
- *Illinois:* "I use gender implants selectively because I'm concerned with the price. It is hard when patients ask for something very specific, but the advertising has gotten more patients into doctors' offices."

At an AAOS-sponsored press conference, experts debated the merits of both gender knees and gender hips. Interestingly, the pro arguments were made only by surgeons who were paid consultants to industry, while the con arguments came from both independent doctors and a paid consultant. Furthermore,

the con speakers offered studies to support their contention that gender-specific implants are not needed, but the pro speakers did not offer any study results to support the use of gender-specific implants.

Gender knees

➢ **Pro:** Dr. Scott Sporer of Rush University Medical Center, a paid consultant to Zimmer, argued that women's knees are distinctly different from that of men and that a large Swedish registry found women are slightly less satisfied with conventional knee implants than men. He also pointed out that an AAOS study found that men had statistically greater improvement ($p<0.05$) than women in Knee Society function (22.05 vs. 18.55) and total scores (70.16 vs. 65.53). He commented, "Do gender implants make a difference? I do believe we will be able to determine a difference. It won't be a major difference, but there will be differences in the small details…We need randomized prospective studies with an outcomes scale to measure the subtle differences."

➢ **Con:** Dr. Timothy Brox of Kaiser Permanente in Fresno, who has no ties to industry, presented a study which found no differences between the outcomes in men and women. He explained, "Last year, when I heard (at AAOS) that women were not doing as well as men (post TJR), I went home and did a conference call with colleagues. We decided the statement wasn't true, and we decided to put the statement to a test. We used the Kaiser Permanente Central Community Based Total Joint Registry, which has been in operation since 2001. This registry potentially enrolls all patients done by Kaiser orthopedic surgeons."

Based on the knee procedures in this registry from April 2001 through March 2006, Dr. Brox concluded, "We cannot advocate spending an approximately $1,000 differential upcharge per implant for 64% of our TKA surgeries…At this time, I and my colleagues do not recommend use of gender-specific implants."

Comparison Kaiser Joint Registry Results

Measurement	Men n=7,468	Women n=13,250
BMI	30.76	32.07
Diabetes	16.1%	13.8%
Rheumatoid arthritis	1.1%	2.6%
Post trauma	2.0%	1.0%
Deep infection rate	Nss gender difference	
Short-term revision rate	Nss gender difference	
Results at >9 months		
Pain score improvement post-op	5.05 points	5.41 points ($p<0.001$ but clinical significance unclear)
Range of motion improvement	Similar	
Patient satisfaction	Similar	

Gender hips

Pro: Dr. Andrew Glassman, an orthopedic surgeon in Columbus OH, who receives royalties and speaker fees from Zimmer and is a paid consultant to Zimmer, said, "We need greater recognition of the differences between male and female hips…I do believe, in some instances, gender-specific implant designs are useful. There is a mean population well served by currently available implants…but at the extremes for both male and female, I do think we are lacking…We don't have any scientific data to demonstrate gender-specific differences in the survivorship of total hip replacements, and there are no widely recognized differences in the clinical outcomes of total hip replacements in females vs. males. There are no clinical studies to support the use of gender-specific implants. But we do have indisputable scientific proof of significant differences in female vs. male anatomy…We also have a statistically higher incidence of dislocation, excessive leg lengthening, trochanteric bursitis in women as well as poorer clinical outcomes at one year…I think, in some instances, in my hands, it is due to the lack of appropriate implants."

Dr. Glassman suggested that gender-specific implants might be especially useful for surgeons who don't do a lot of hip implants. He said that one of the benefits of industry developing gender-specific implants is an increased emphasis on the anatomic differences between men and women, "In the U.S. the vast majority of hip replacements are done by people (surgeons) who do 25 hip replacements a year…and they do everything more or less in a recipe fashion. They are less comfortable doing extra manipulations…I would like to lobby for expanding the gender-specific concept not to just the implant, but I would like greater recognition of the anatomic differences between males and females. I think you have to educate doctors about that, and ask them, being aware of that, to pay more attention to the execution of their surgical plan and to the selection of the implant."

Con: Dr. Robert Bourne of the University of Western Ontario, a past president of the Hip Society – and a paid consultant to Smith & Nephew – presented the results of a retrospective look at 3,461 patients with 4,114 total hip replacements performed at his hospital, which found "little clinical need" for gender-specific hip implants. He said, "Survivorship, in our hands, seems similar and outcome change scores were similar. The contemporary implant systems are versatile enough to meet the needs of both genders…We did a similar study of knees…and it was very similar to the hip (results)… We didn't find any great difference in outcomes (between men and women)…And the Swedish registry just came out…and they could not find a big difference in knees. I think most of the systems are pretty versatile."

In Dr. Bourne's hip study, mean follow-up was 11 years, and all patients had at least two-years follow-up. Implants from all five of the top manufacturers were used, but Dr. Bourne looked at a subset of 1,735 patients who got Smith & Nephew hips, in the gender comparison. He reported similar revision

rates, and he said Kaplan-Meier survivorship was similar, with slightly higher survivorship for women vs. men, though that was not a statistically significant difference.

University of Western Ontario Hip Replacement Surgery Study

Measurement	Men	Women	p-value
Harris Hip total score	87.25	82.95	<0.001
Harris Hip pain score	40.06	59.47	<0.001
WOMAC total score	77.58	78.51	<0.001
WOMAC pain score	80.47	76.98	<0.001
SF-12 physical score	41.61	57.80	<0.001
SF-12 mental score	55.60	52.68	0.021
Revision rates	9.3%	8.3%	---
Short-term revision rate	---	---	Nss
Intra-operative calcar fractures	1.5%	1.5%	Nss
Other differences			
Cup size	59% 52-54 mm	77% 56-60 mm	---
High offset femoral stems	64%	48%	---

Customized knees

Customized knees generated no more enthusiasm than gender knees. They were described as either unnecessary or a gimmick, and doctors complained that they are too expensive. When they are used, doctors said it is very, very sparingly, but most surgeons said they do not use them at all and do not believe in them.

Comments on customized knee implants included:

- *California:* "A lot of patients ask about custom knees – even my wife asked – but it is probably just a marketing gimmick. There is no real scientific evidence, but it sounds great."
- *Ohio:* "Custom knees are not needed for most patients. The majority of joints can be treated with what's out there without customization."
- *Arizona #1:* "I can't say I believe in this, but only time will tell."
- *Arizona #2:* "Custom knees are more expensive. I'm not sure they are a gimmick, but unless it is a very tiny patient or a very large patient, there is no need for customization. I've never needed them yet, but I'm not against them. There is no patient demand."
- *Missouri:* "There is no patient demand, and most doctors don't respond to patient requests anyway…Doctors with poor results will be excluded by outcomes studies from Medicare in the future, and that will be a big factor (in the choice of procedures and devices) going forward."
- *Midwest:* "My use is very limited. The only time I may need it is in very complex revision cases. And it certainly is only for people with a lot of cash. There is no patient demand."

HIP AND KNEE RESURFACING – still controversial

Hip resurfacing

Hip resurfacing remains controversial and is growing very slowly among these doctors and their colleagues, and many surgeons have no plans even to start doing it. Those who are doing it, generally do it very selectively. Basically, doctors' concern is that resurfacing will come back to bite them (or, rather, their patients) in the future. Surgeons also pointed out that revisions are difficult and have worse results than first procedures, and many believe resurfacing will make revisions even more difficult, those experts who do a lot of resurfacing argue just the opposite – that resurfacing conserves bone and makes it easy to do a total hip replacement (THR) in the future. If there is any growth in hip resurfacing with the introduction of new products, it is likely to be small, incremental gains, not a sharp increase.

When hip resurfacing was introduced many years ago, the results proved unsatisfactory. Hip resurfacing was re-introduced in the U.S. in 2006 with Smith & Nephew's Birmingham hips, and all of the major vendors now have a hip resurfacing system on the European market. Currently, the only other hip resurfacing system with FDA approval is Stryker's Cormet, but the other major orthopedic companies all have devices that are approved in Europe, and these are expected to gain U.S. approval in 2008 or 2009.

Among the doctors interested in hip resurfacing, Stryker's Cormet is starting to get some attention. An expert said, "They have a very strong distribution network…Stryker has a very large, well-educated, and motivated sales force." However, federal monitors only recently approved the physician training program, so the launch is just really getting going.

How do these systems compare? They are all made of the same base metal – a cobalt chromium alloy. There are differences in the manufacturing of the articulating parts (the bearing surfaces). The main debated difference is the diametric clearance – which is the amount of size mismatch between the diameter of the inside of the cup and the diameter of the outside of the femoral shell. It has been suggested, but not proven, that a high diametrical clearance is associated with higher wear and to higher levels of metal ions in a patient's blood and urine. An expert said, "At this year's Orthopedic Research Society meeting, (researchers) from England reported on a clinical study comparing the whole blood and urine levels of cobalt chromium ions between a group of patients with the standard clearance Birmingham hip (Smith & Nephew) and a group of patients with a reduced (diametric) clearance Birmingham hip, a hip not commercially available yet. That study showed the reduced clearance hip had a lower level of whole blood ions…That confirms other studies that there is an advantage to lower clearance." Dr. Thomas Schmalzried of Harbor-UCLA Medical Center compared hip resurfacing systems this way: "It is not unlike the auto industry. Lexus, BMW, and Mercedes all make fine luxury cars, but there are trade-offs. If you want the safety of a

Comparison of Hip Resurfacing Systems

Measurement	Smith & Nephew	Stryker/Corin	J&J/DePuy	Wright Medical	Zimmer	Biomet
Hip resurfacing product	Birmingham	Cormet	ARS	Conserve Plus	Durom (Bonesave in U.K.)	ReCap Total
Metallurgy	Cobalt chromium	Cobalt chromium	Cobalt chromium	Cobalt chromium	Cobalt chromium	Cobalt chromium
Diametric clearance	Proprietary ratio to bearing (more than ARS)	N/A (>ARS and <Birmingham)	100 microns	N/A	N/A	150-300 microns
Acetabular fixation surface	Cobalt chromium beads cast into the component	Rough, non-porous	Rough, porous bead coating	Rough, porous beads	N/A	Rough, porous plasma spray
Sizing increments	4 mm	2 mm	2 mm	2 mm	2 mm	2 mm
Head size range	38-58 mm	44-56 mm	N/A	36-56 mm	38-60 mm	38-60 mm
FDA status	Approved 2006	Approved 2007	Approval expected in 2009	Approval expected in 2008-2009	Not approved	IDE study ongoing, plans to submit international data
C.E. Mark approval	1997	Approved	2003	N/A	Approved	2005

Mercedes, you can't have the handling of a BMW, but if you want the resale of a Lexus, you won't get the safety of a Mercedes."

J&J/DePuy plans to introduce a new system internationally in 1Q09 with a separate stem that J&J officials said makes it easier for surgeons to do the procedure and to convert from conventional THR. The new system will also allow surgeons to choose the material. A J&J official said, "Right now, all the systems are metal-on-metal. Our device lets you choose the bearing you want – metal, polyethylene, or ceramic – because it is compatible with all the other bearings." Smith & Nephew also has a modular head in Europe, Synergy, that is available in poly, ceramic, or metal; it is not expected in the U.S. until perhaps 2009.

At an AAOS press conference on hip resurfacing, surgeons who do a lot of hip resurfacing (from 10% to more than 50% of their hip procedures) discussed this approach. They predicted that hip resurfacing procedures will grow as more companies get FDA-approved products on the market. They pointed out that it is best suited to large, healthy men and younger patients.

- Dr. Schmalzried, who gets royalties from a J&J/DePuy hip and a Stryker knee: "Hip resurfacing is rapidly increasing…Close to 30% of my procedures are women …It's like a 'two-for' (in women); you treat the arthritis and give something stronger than bone there…The benefit of resurfacing is that because nothing is put in the femoral canal…The conversion to a total hip replacement is not impacted…That may be the main benefit of hip resurfacing."
- Dr. Paul Breaulé of the University of Ottawa, a paid consultant to Wright Medical: "I will do women…for example, a woman under age 55 whose bone quality is excellent. When (a woman's) bone quality is poor, the cement can infiltrate and lead to premature fracture… About 25% of my hip resurfacing are women."
- Dr. Robert Trousdale of the Mayo Clinic, a paid consultant to J&J/DePuy and Wright Medical, pointed out that the downside to hip resurfacing is: femoral neck fractures, increased acetabular bone loss (with at least one design), and the physician learning curve. He warned against doing it in young females or in patients with kidney problems, poor mechanics, or metal hypersensitivity. He said, "In properly selected patients, one should be able to minimize the pitfall for resurfacing. Hip resurfacing provides reliable pain relief/function with the benefit of preserving femoral bone stock. I will consider it in young patients (<age 60), who are acceptable for a metal-on-metal bearing surface, have good femoral neck bone stock, and have enough femoral head to support an implant, and who have no major leg length, offset, or acetabular problems…I would do resurfacing in a woman who is heavier…A light, small woman is at higher risk for failure. I will do a woman, but 80% of the cases are men and 20% women in my practice."
- Dr. Paul Lachiewicz of the University of North Carolina at Chapel Hill, a paid consultant to Zimmer and Wright: "It is quite new in the U.S. It is a difficult operation and requires some training. The two companies (with approved U.S. products) are supposed to train surgeons, and they are doing a reasonably good job of that."

At another session, Dr. Martin Lavigne of the University of Montreal reported on a 210-patient, randomized trial which questioned some of the advertised advantages of hip resurfacing. All procedures were done by the same three surgeons with a posterior approach. They found resurfacing patients were significantly more likely to return to work and sports and had better step and hop test scores than THA patients, but functional scores and range of motion were no better with resurfacing than with THA. Dr. Lavigne said, "The difference (between resurfacing and THA) was not as much as we expected. I think we need to modify our message

University of Montreal Comparison of Hip Resurfacing and THA

Measurement	Uncemented 28 mm THA	Hip resurfacing
WOMAC score at 6 months	11	17
WOMAC score at 2 years	5	5
Hopping on affected leg at 6 months	78.9% easy/very easy 21.1% difficult/impossible	91.7% easy/very easy 8.3% difficult/impossible (p=0.023)
Step test (climbing stairs) at 6 months	76.3% easy/very easy 23.7% difficult/impossible	94.4% easy/very easy 5.6% difficult/impossible (p=0.015)
Returned to prior work	83%	96% (p=0.02)
Returned to sports activities at 1 year	7% high impact activities 28% moderate impact activities	15% high impact activities 28% moderate impact activities
Range of motion	Similar	
Patient satisfaction	Similar	
Complications	Similar	

to the patient…Both groups returned to a high level of activity. Hip resurfacing patients seem to be more active but not as much as expected."

Experts estimated that currently only about 3%-4% of hip procedures in the U.S. are resurfacing. Sources predicted that hip resurfacing will remain a niche procedure in the U.S., and one pointed out that, after peaking higher, it has settled down to ~10% of procedures in Australia, where is has been done much longer.

Why is hip resurfacing so controversial among orthopedic surgeons? Dr. Schmalzried said, "The results of good, modern total hip replacement (THR) are really, really good, so for resurfacing to have a favorable risk:benefit ratio, you have to show you are getting something you don't get with THR…and that data are being gathered." Dr. Lachiewicz said, "There are still some people who had a bad experience with the last go around (in resurfacing)…and that has influenced the surgeon's perspective."

Many surgeons questioned about hip resurfacing had very negative things to say about it, but a few are doing it, and for those doctors instrumentation appears to be very important, and surgeons are giving the newer products a look. Comments included:

- *Ohio:* "Why change something that is working very well for something unproven. Patients need to be very carefully chosen for resurfacing."
- *Arizona #1:* "It is controversial. It is not a good idea in hips, and maybe it is a worse idea in knees. Eventually we will see gene therapy instead of total joint replacements."
- *Arizona #2:* "I have no plans to start hip resurfacing until I see clear data that it is at least as successful as hip replacements, but the evidence is not there yet for either hip or knee resurfacing."
- *Oregon:* "There is a place for it, but a small place. Patients do ask about it."
- *Michigan:* "A lot of the patient interest is advertising-driven. Patients do ask about it. Sometimes I lose a patient, but I still won't do it."
- *Missouri #1:* "I absolutely won't do that. It's a fad."
- *Missouri #2:* "I do resurfacing, but only on about 1% of patients, and that is not increasing because I select patients very carefully, and I don't push the edges of the indication. But as indications for older patients increase, it will increase with newer products beyond the ones in the current pipeline."
- *Minnesota:* "I use the Birmingham hip, and I would change only if the instruments were easier."
- *Illinois:* "The jury is still out on resurfacing. I want significant outcomes studies first, especially for a procedure with 95% good outcomes with conventional THR."
- *South Carolina:* "I do hip resurfacing in about 5% of patients. I get a fairly young patient population. Hip resurfacing is increasing because I'm seeing more patients who are candidates. Patients seek out who is doing it, and there are only about three surgeons in South Carolina doing it. I use the Birmingham system now, but I'm looking at others. Instrumentation is key…The Cormet instrumentation is better, more user-friendly. It caught my attention enough to consider a change."
- "Some doctors doing resurfacing are moving to something dubbed 'resurfacing lite' (a cap and a small stem), and they use that to market their practice."
- *California:* "I'm a believer in hip resurfacing, but I'm not doing it because I'm too old to start."

Patient demand

There is strong patient interest in hip resurfacing. Dr. Schmalzried said, "I had a woman contact me who had been surfing the internet…She was 60 with normal age-related bone loss – osteopenic or osteoporotic…She wanted resurfacing...I said it was not best for her…She argued that she wanted resurfacing and said we offered it on our website…When I wouldn't do it for her, she reported me to the Medical Board of California for fraud…There are surgeons who succumb to patient pressure, and some of those will fail, and that becomes a black eye (for the procedure)."

Knee resurfacing

Doctors are somewhat more optimistic about knee resurfacing (e.g., ConforMIS's iUni, which recently got a C.E. Mark) than hip resurfacing. A Missouri doctor said, "Knee resurfacing is

not as controversial because there are no inherent risks to the procedure itself." Another Midwest doctor said, "It is not something I do or find useful. The failure rate is incredible."

INDUSTRY RELATIONS WITH ORTHOPEDIC SURGEONS – chilly

Department of Justice (DOJ) fraud settlements appear to be having little impact on surgeon device selection. Every single doctor questioned insisted that the DOJ investigation and settlement is not impacting him/her, the hospital, or colleagues in terms of brand loyalty, which they insisted is based more on what was used in their training, sales reps, and service from the vendor. None of the doctors questioned admitted to getting consulting fees, though some said their colleagues did. All insisted that the new regulations won't affect brand loyalty.

Four of the six orthopedic companies – Biomet, Smith & Nephew, J&J/DePuy, and Zimmer – reached a settlement with DOJ and signed deferred prosecution agreements (DPAs) that ended the government investigations into whether their financial relationships and consulting agreements with orthopedic surgeons violated federal anti-kickback laws and the False Claims Act by inducing the doctors to use a particular joint replacement device. Under the settlement, the companies agreed to pay a total of $311 million, and all these companies agreed to operate under corporate integrity agreements (CIAs), with 18 months of oversight by a federal monitor appointed by the DOJ.

Stryker Orthopedics, which was also being investigated, voluntarily cooperated with the U.S. Attorney's office in New Jersey, which was heading the investigation, and, therefore, was allowed to sign a Non-Prosecution Agreement (NPA) with the DOJ. This requires Stryker to implement the same reforms imposed on the other four companies under the DPAs, including 18 months of federal monitoring and a CIA. Wright Medical is the only major joint vendor ***not*** involved in the DOJ investigations and settlements.

However, the bad legal news is not over in the orthopedic area. Watch for more bad news for:

- **Private orthopedic companies.** Howard Young, a partner in the law firm of Sonnenshein, Nath, and Rosenthal and a nationally-recognized healthcare fraud and abuse expert, said, "It is mischaracterization to say we are beyond the settlement stage and are entering a quiet period (in orthopedics). There are a number of ongoing investigations. Whistleblower lawsuits are filed under seal, so there is not a lot in the public domain, especially among companies not in the public domain…I think there is a lot more to come…There is still a bit of an unsettled feeling across the industry."
- **Surgeons.** Although the "vast majority" of surgeons have no financial relationships – were not receiving either consulting fees or royalties from industry, there are a few doctors who may be investigated and charged individually. One orthopedic surgeon interviewed said he didn't ever have any consulting relationships with industry, but he knew of a colleague who used to get consulting and now reportedly "was bringing home large sums of cash." However, none of the other 30 doctors questioned at the meeting reported any similar irregularities. Rather, several insisted that they have distanced themselves from industry more than is required. Doctors also said they are more suspicious of unusual approaches or schemes suggested by companies or their sales reps, applying the "sniff test" to them – if there is even a whiff of anything not right, they are steering clear.
- **Repeat offenders.** Just because a company has worked out a deal with the Office of the Inspector General (OIG) or the Department of Justice and entered into a corporate integrity agreement (CIA) – like the four orthopedic companies – doesn't mean that they are now "good guys." The government has numerous examples of companies getting caught in illegal behavior more than once and even having more than one CIA. Lewis Morris, Deputy Inspector General and Chief Counsel in OIG, under the Department of Health and Human Services (HHS), commented, "You wonder if the strategy of giving companies a second chance to reform themselves is a prudent one… There are a number of companies we currently have under investigations (*Note: He did **not** say these were orthopedic companies*) who are two- and three-time losers… From a strategic standpoint…we have been thinking of how to raise the bar higher, do something with more 'starch' than a CIA (short of barring them from participating in the Medicare program altogether)…You will see that strategy manifest in the next couple of months…There are a couple of companies planning to plead to misdemeanors…We think a company taking criminal charges is in a different place than merely entering into a million dollar False Claims Act…So, we are thinking of how to handle that…I hope none of the recent CIAs (in orthopedics) will show up again, but companies are comprised of individuals. Can I say with absolute certainty that no one will mess up? No, with absolute certainty, someone ***will*** mess up again."

What's legal and what isn't in orthopedics is not totally clear yet. Dr. Berry of the Mayo Clinic noted, "There are a lot more companies, more surgeons, more doctors involved in the process of working on devices and trying to make them good things for patients…but with that, there are a lot of gray zones…And we are going through an era where the gray zones are starting to be parsed."

Young said other companies in the orthopedic industry are taking the DPAs very seriously, "The level of activity of companies not subject to the agreement is astounding. They have read them (the DPAs) and understand that they are the government's latest thinking in terms of good, sound compliance and business conduct. There is a lot of change going on in the industry, even among companies not part of the

agreement…I can't name specific companies…but if you talk to compliance officers, many would raise their hands and say, 'Yes, we are very active in enhancing compliance controls.'"

The AAOS is trying to educate its members. Dr. Jim Beaty, an orthopedic surgeon in Memphis TN and the 2007-2008 president of the AAOS, said, "We are doing everything we can from an academy perspective. We are providing information to members…Every member got a letter from me on the importance and seriousness of this issue…We are doing everything we can to educate our 30,000 members of the seriousness of this."

How do these fraud investigations get started? Morris explained, "Within the Department of Justice, there are two driving forces: (1) 94 U.S. attorneys, and (2) main Justice… Some investigations are driven by main Justice – where there is a more centrally-coordinated response, but investigations also can be developed out in the field."

The most active assistant U.S. attorneys' offices have been Boston, eastern Pennsylvania, and New Jersey, which has been particularly active in medical device fraud investigations. In addition, Morris said a prosecutor in Missouri has built an expertise in quality of care, predicting, "You are likely to see a lot of things from there (in the future)." But companies don't have to be headquartered in any of those jurisdictions to fall under their scrutiny. Morris explained, "For most of the major healthcare providers in the U.S. you can establish venue anywhere in the country…You just need an envelope crossing their jurisdiction, more or less."

Other assistant U.S. attorneys (AUSAs) also are getting more active in healthcare fraud investigations. Young explained, "One reason I think we are seeing many of the whistleblower cases popping up in other (state) districts is the sheer volume of cases in the historically prominent AUSA offices is that there are so many cases that many will take years to resolve because there are not enough investigators…So, whistleblower attorneys and whistleblowers are looking at whether they want to wait or go to a less active AUSA office."

The Department of Justice is not the only federal agency that can initiate or participate in healthcare fraud investigations. The FBI, FTC, IRS, etc., also investigate. In addition, state attorneys general also conduct investigations. Morris said, "More and more states are getting into this action…States that are putting out Medicaid money now have a strong financial interest in getting into the fray."

There is even a training center, National Advocacy Center in South Carolina, where experts in healthcare fraud share their expertise with other investigators. Morris said, "We and others go down there and train our colleagues. We have model indictments and model complaints…We spend a fair amount of time sharing information to maximize enforcement resources."

BRAND LOYALTY AND PRICING

Orthopedic surgeons remain incredibly loyal customers. None of the surgeons questioned has recently changed vendors, and few plan to change vendors – unless forced to do so by a hospital contract. A doctor who is planning to change said, "I'm a Zimmer customer, but I'm thinking of changing to Encore Medical because the Encore rep is much better than the Zimmer rep…It is a pain to change, and I don't do it lightly."

Stryker's recent problems with the Trident hip replacement, for example, have not caused any doctor questioned to change vendors, though a few complained that it was a real headache for them in terms of patients. One user said, "A very small percent of the Trident user base was affected. Trident was manufactured in more than one plant." A Louisiana user said, "Just because one product of a company had a problem, I won't change." A competitor said, "It (the Trident problem) hasn't had much impact. We've only picked up a couple of customers as a result." A Michigan user said, "A patient brought in an article about it and asked which hip he had, and then five patients called. But I did a lot of research and talked to the sales reps. Before, other companies had recalls, so it was like a 'catch-up' for Stryker. We didn't throw them out with the bath water." A California user said, "I've been following patients as usual, nothing special, and I've been keeping patients informed, but that's all. I was pleased with Stryker's response, and I didn't change vendors."

Hospitals are getting more aggressive in trying to influence the choice of implants used. This is a trend that has been going on for a few years, and it is accelerating, but surgeons insisted it is not being driven or encouraged by the DOJ settlements. Hospitals want to establish a preferred vendor or vendors and get volume discounts. In one case, a Midwest surgeon said he was forced to move to a different vendor even though the implant he used was cheaper than what the hospital negotiated. In another case, a surgeon was able to forestall a hospital contract by proving to the hospital that the implant he prefers is less expensive.

Comments included:

- *California:* "It sounds like DOJ went overboard because of a few doctors and companies…There has been no change in (brand) loyalty at our hospital."
- *Tennessee:* "There is pressure from hospitals on doctors. The knee I like is more expensive, and that's their biggest complaint, but I won't change."
- *Ohio:* "Our hospital only lets us use certain implants. They decided which I can use, and I had to change. The hospital says it gets volume discounts – but what I was using before I changed was cheaper."
- "A hospital 30 miles away has restricted orthopedic surgeons to one company because of a contract, but I can still use my choice."

- *Arizona:* "Our hospital was pushing on price before the Justice Department investigations, which won't change things for most doctors. The choice of a particular vendor is mostly a service issue. I think all the products are comparable, but I prefer J&J/DePuy because of their service."
- *Michigan:* "There are quirks to each that keep you using them….Hospital pressure has increased to choose two or even one vendor…The DOJ investigations have affected the companies more than surgeons. Brand loyalty is not about what you get from the company; it's about your training."
- *Missouri:* "Hospitals are all increasing the pressure on our choices, but that is not related to the DOJ."
- *Minnesota:* "Hospital pressure is increasing, and there are more volume contracts. They are not asking us to do bad stuff, and you have to support their effort to control cost. It's all volume-related…But patient demand can dictate implant change."
- *Illinois:* "I have a loyalty. I want familiarity with a device, and if you jump around, you lose that familiarity."

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