Trends-in-Medicine

April 2004
By Lynne Peterson

SUMMARY
Excitement is running high over artificial discs, which could take as much as 30% or more of the fusion market. ♦ BMP usage is increasing, but mostly on-label, not off-label because of cost and hospital resistance, which has increased. ♦ Minimally invasive surgery is a big deal, not just hype or a marketing gimmick. However, the procedures touted by Zimmer and Stryker are technically difficult, so experts expect – and hope – only the busiest doctors will do them. ♦ Ceramic-on-ceramic hip implants are gaining popularity, but breakage and cost are concerns. Many doctors believe metal-on-metal implants are better, but the safety of the metal ions they release is unknown. Highly cross-linked polyethylene hips are the least expensive, but there is no long-term data on them and wear is a concern. ♦ Several new kyphoplasty products have become available or are on the horizon, but none appears likely to unseat Kyphon as king of the hill. The spine market does not appear to be expanding, but more referrals may come from oncologists as marketing to those doctors is stepped up.

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AMERICAN ACADEMY OF ORTHOPEDIC SURGEONS (AAOS)

March 10-14, 2004
San Francisco

Hip and spine surgery dominated this meeting, with orthopedic surgeons very interested in artificial discs, bone morphogenic protein (BMP), minimally invasive hip and knee surgery, and new hip implant materials. More companies have entered the kyphoplasty arena, and doctors are increasingly convinced of the value of the procedure – but procedure volume was reported to be relatively flat.

MINIMALLY INVASIVE SURGERY (MIS)

According to the AAOS, about 300,000 patients get hip replacements. About 2,000 of these are expected to be replaced via some form of MIS surgery this year, and the number is expected to grow. Another 300,000 Americans get knee replacements each year, but only a few get MIS knee surgery. On average, joint replacement surgeons estimated that about 5% of procedures are being done with some form of minimally invasive surgery now, and this is expected to double over the next year, and in five years it could be the most common approach.

While there is a lot of hype from some of the companies, sources agreed that the trend is real. An expert said, "There is tremendous interest from surgeons and hospitals in this." Another expert said that at one AAOS session, about 1% of the nearly 2,000 surgeons in the audience indicated they currently use a two-incision technique, and 30%-40% said they have modified the length of their incision at least somewhat."

Some surgeons who don't do the new techniques avoid admitting that to patients for fear of losing them. One doctor commented, "I told my secretary that if patients ask if I do minimally invasive surgery, she is to say yes. Then, I tell patients that I use the smallest incision feasible – and that's the Webster's definition of minimally invasive."

However, every source sounded a warning that MIS – both for hips and for knees, but knees especially – is a technically difficult procedure that requires careful training. This is particularly a problem since it is estimated that 80% of total joint replacements (TJRs) are done by doctors who perform 20 or fewer cases a year. One expert said, "All of these operations are technically demanding and not necessarily for every orthopedic surgeon to do…You need to do at least 50 hips a year to be good at this." Another expert said, "Everyone is going to want to do TJR, so we need to make it safe, easy, and reproducible." A Georgia doctor said a 148-patient study at his clinic found no advantage to MIS – no reduction in hospital stay, operating time, opioid use, or pain.

Surgical Procedure	Advantages	Disadvantages	Average incision size	Ideal patient
Total Hip Arthroplasty (THA) • Mini incision • Berger procedure Total Knee Arthroplasty (TKA) • Bonutti procedure	Fast recovery Little blood loss Cosmesis X-rays not compromised Acceptable morbidity	Learning curve Some require special instrumentation	~3.5 inches	Thin

There are a variety of techniques for doing minimally invasive hip and knee surgery. Each has its proponents.

➢ **ZIMMER: Berger procedure for total hip arthroplasty (THA).** Zimmer, for example, has been aggressively pushing the MIS concept and has tried to trademark the term MIS for itself, suggesting that MIS hip surgery means a specific procedure – the two incision "Berger procedure" developed by Dr. Richard Berger of Rush-Presbyterian-St. Luke's Medical Center in Chicago. The advantages to this procedure are also some of the disadvantages: specialized instrumentation (available only from Zimmer) and visualization by fluoroscopy (which also exposes the doctor to more radiation). In addition, the learning curve is steeper for this than other THAs.

Dr. Berger said his hospital has done about 250 Berger procedures to date, and since January 2003 100% of them have been done on an outpatient basis. However, Medicare does not pay for procedures done in the hospital if the patient stays less than 23 hours, so the Berger procedure is being reserved for younger (under age 65) patients or patients with private insurance. Dr. Berger said, "There have been no readmissions, no re-operations, no dislocations in these >200 patients…Patients have to climb the stairs, walk down a hallway, etc., before they can leave the hospital…We are placing them with fluoroscopy, and with that we are quite accurate…It turns out we get better results with this technique than with bigger incisions because of the use of fluoroscopy…You can do the same thing on the knee. We started that outpatient in the last six months, and 23 of the last 25 patients went home same day as well."

➢ **Modified posterolateral incision for THA.** This procedure uses a single, small incision and does not require specialized instrumentation. A user reported on a study of 634 patients with 4.4-year follow-up, "There was acceptable morbidity, uncompromised x-rays, and faster recovery (than traditional hip replacement surgery)…Typical patients take three to four weeks to go up and down stairs. With this, a patient may be able to do it in 24 hours."

Modified Posterolateral Incision Experience

Measurement	Incidence n=634
Average incisions	8.2 cm
Abduction	42.4
Dome gap	4.9%
Dislocation	1% (6 patients)
Femoral fracture	<1% (1 patient)
Neuropraxia	<1% (2 patients)
Hematoma	<1% (3 patients)
Wound infection	>1% (1 patient)

➢ **Mini THA – a single incision from the front for THA.** There is less of a learning curve with this than with the Berger procedure, but malapposition is a potential concern. A Georgia doctor said, "In our hands this approach is safe and consistent…However, we can't really find any objective evidence that this benefited these patients in any measurable way…and the subjective feeling of less blood loss could not be confirmed…We didn't see any difference in this, and both groups of patients (traditional, open surgery, and small incision surgery) did equally well."

Randomized, Prospective Study of Mini THA vs. Traditional THA

Measurement	Standard n=50	Mini n=52
BMI	28.7	26.1
Weight	86.5 kg	75.8 kg
Operating time	57.9 minutes	58.6 minutes
IV fluid intra-operatively	2410	2316
Received transfusion	20 patients	18 patients
First ambulation	1.1 days	1.06 days
Complications: DVT, CV, dislocations, urinary, wound problems, infections, fractures	15 events	19 events
Hospital stay	2.984 days	2.9 days
Results at 2 weeks		
No pain	10%	14%
Mild pain	80%	73%
Moderate pain	10%	13%
Results at 3 months		
No pain	94%	96%
No limp	68%	62%
Mild limp	32%	38%

➢ **STRYKER: Bonutti total knee arthroplasty (TKA).** This is an elegant procedure with a small incision, but it requires specialized instruments and has a very steep learning curve. Dr. Peter Bonutti, the developer and a consultant to Stryker, said, "With more than two years of follow-up in 21 knee patients, we've found this to be a good surgery, with

good pain relief…97% of patients had excellent functional results, and it is cosmetically more appealing (than traditional knee surgery)…and 100% of patients were independent in using the bathroom, getting out of bed, and walking by two weeks…Our MIS approach is at least equivalent if not superior to traditional knee replacement surgery…But this is a more difficult procedure…and we advise surgeons to approach it in an *evolutionary* manner…I think computer-assisted navigation is crucial."

Although Dr. Bonutti uses the Stryker Scorpio knee when he does this procedure, he said it can be done with other soft-tissue-friendly instruments. He said, "We are encouraging others to move to MIS, as a general technique, not to a specific program."

The Downside to MIS

Not every orthopedic surgeon believes MIS surgery is necessary. Critics pointed out that traditional TJRs are very successful operations. While they may make their incisions as small as feasible, they are not convinced that smaller is always better. A surgeon said, "What do patients want from MIS? No pain, no complications, longevity, rapid recovery, and a small incision. Cosmesis is #5, not #1." Dr. David Hungerford of Johns Hopkins cautioned, "There are a lot of reasons to be afraid, very afraid of MIS and TKR…We need enthusiasts, people who are the forerunners of events which will be commonplace, but we also need skeptics, or we will get led down paths we don't necessarily want to go down…Though these procedures have incredible interest and enthusiasm, I am concerned they may be performed to the detriment of our patients…We need to resist marketing and pressure from patients…Yesterday, patients asked us what they needed; today patients tell us what they want, and they do that because of hype they are reading in the press and in the newspapers…and I think that is an undesirable change…I think it (MIS) will be more compelling for the hip than for the knee…The knee is a much more technically demanding, sophisticated surgical procedure that doesn't tolerate the same degrees of alignment variances as a hip…For this to be a widespread procedure, you have to convince the skeptics that the thousands of orthopedic surgeons doing 20-40 procedures a year can get equivalent results without complications, and I don't think that transition will take place in two or three years."

The Industry View

A Medtronic official said MIS provides incremental value to his company:

- There is a premium on the product of about 20%.
- It helps get a sale that might have gone to another company.

HIP REPLACEMENT MATERIALS

There was no consensus among doctors interviewed as to which material is superior. A few sources mentioned that patients often come in asking for a particular material, but the doctors usually are able to convert the patients to what they prefer. A California doctor said, "Direct-to-consumer advertising is having an influence, but most of my patients are comfortable with what I recommend after I explain it."

Ceramic-on-ceramic could be the winner except it is expensive, and doctors are concerned about the possibly devastating results of a breakage. Several experts put the breakage rate at about 2%, though that may be going down with newer designs. A doctor commented, "This is very smooth and wears exceedingly little when everything is perfect…The wear is 100 times less than polyethylene, but it is brittle and can break when dropped…It is a catastrophe when they break…It is very hard to revise these joints and get rid of the ceramic debris…And now, there are reports in the literature about damage occurring to ceramics as a result of high contact stresses in flexion…New ceramics may be better, but they also may be worse."

Three companies currently have FDA-approved ceramic-on-ceramic hips: Wright Medical Technology, Stryker, and Encore Medical. Reportedly, CeramTech has a PMA for a ceramic-on-ceramic hip, and the belief is that it got the PMA from Wright Medical, though Wright won't confirm this. There is a possibility that some company could get the CeramTech PMA data and submit it, and that could put a competing ceramic-on-ceramic hip on the market quickly, but

Hip Replacement Materials

Material	Use	Advantages	Disadvantages	Patient Selection
Metal-on-metal	Hips	Little wear (<5 microns/year); Long experience; Good clinical results; Durable fixation	Highly elevated metal ions (chromium, cobalt, and titanium double) present a ***theoretical*** risk; Slightly elevated dislocation rate; Hypersensitivity reactions; More expensive than polyethylene	Younger men (≤60 years old); Younger women where child-bearing is not likely; **Not** indicated for patients with renal failure; Very active patients
Highly cross-linked polyethylene	Hips	Least expensive	No long-term wear experience	Women of child-bearing age; Older patients
Ceramic-on-ceramic	Hips	Low wear; Low bioreactivity	~2% breakage, which can be extremely difficult or impossible to revise; 37% of revisions fail within five years; Most expensive	Younger patients; Patients who can understand and accept the risk; Less active patients

the CeramTech PMA can't be re-licensed until November 2004. However, a new design would require a new PMA. Biomet reportedly has an IDE for a ceramic-on-ceramic hip, but Zimmer does not.

Doctors predicted use of ceramic-on-ceramic hips would increase, but most sources said their own use of each type is unlikely to change over the next year. A New York doctor who uses all three types of hips said, "I've done more ceramic-on-ceramic than metal-on-metal. My concern with metal is the ion toxicity. Ceramic have a breakage concern, but it is less with the new generation…I've been leaning to more ceramic and less metal…but it is hard to use ceramic when the hospital loses money on them." A Georgia surgeon said, "I do mostly highly cross-linked polyethylene. It is something we understand well, and it has wear characteristics very similar to other hard-on-hard implants."

SPINAL FUSION SURGERY

In the U.S., approximately 70% of ALIF patients get instrumentation, a Medtronic official estimated. He offered some other interesting insights:

- Asked why ALIF should be performed when posterior instrumentation is needed, he pointed out that TLIF is "a daunting procedure…PLIFs are especially popular with neurologists. They are a good procedure, but the down side vs. a TLIF is the need to retract the spinal cord, and the amount and duration of retraction is proportional to nerve injury."
- Asked why so much posterior instrumentation is being done in this era of BMP, he said, "If a patient needs decompression, most surgeons go posterior, and then put in posterior instrumentation. A TLIF destabilizes, so they need posterior instrumentation."
- "Anterior stand-alone cages were dead two years ago. With the new LTK cage and InFuse, stand-alone ALIF has revived."
- "Navigation systems have been most popular with younger surgeons at high volume spine centers."
- The SPORT trial, a randomized, NIH-funded study will compare discectomies, laminectomies, and fusions. This multi-year study was started about three years ago and is about half finished.

BONE MORPHOGENIC PROTEIN (BMP)

Use of BMP is increasing, but there is resistance from hospitals due to the cost, and doctors themselves are sensitive to the added expense of using BMP. Thus, few doctors said they are using BMP off-label. An expert said, "Growth of BMP in spine is very steep. More and more surgeons are using it all the time now that it has been out there a couple of years and the studies are coming in to demonstrate the efficacy…So, the adoption rate is very strong in spine surgery. In non-union and fracture, adoption is not as good…The approval of (Stryker's) OP-1 is a human device exemption, not full approval, so it is limited to 4,000 cases in the U.S. per year."

An expert discussed his view of the future of biologics:

- **The next step:** "…is to improve the delivery of InFuse (Medtronic, **BMP-2**) and OP-1 (Stryker, **BMP-7**), which is a powder and not particularly user friendly to the surgeon…Stryker is developing a new putty-type material which I think will be a lot more useful and will gain more interest by doctors because it will be easier to use…It will require another FDA approval process...and it probably will only be approved for spine (at first)…That may not prevent off-label use…but I've not seen a lot of off-label use with InFuse."
- **Beyond that:** "The next level will be injectable proteins. I know that Wyeth is working on a calcium/phosphate-based injectable…You could do that with MIS…That is about five or 10 years away…Stryker also is working on injectables, but Wyeth is a little ahead."
- **Longer term:** "In the next 10 years, the concerns with gene therapy will be resolved, and it will become safe and reliable...Now, it is only reasonable in life-threatening conditions, but in the future it will apply to non-life threatening treatments, and then you will begin to see its use in orthopedic surgery. You can get a lot more activity out of osteobiologicals if they can be delivered with gene therapy."

A Medtronic official discussed some of the issues related to BMP:

- He said an InFuse posterolateral trial is enrolled, testing a new compression-resistant carrier – a collagen sponge reinforced with hydroxyapatite.
- Asked how Medtronic intends to commercialize InFuse in trauma, he said, "In the U.S. we have a specialty sales organization. We hired a number of sales reps who will sell spine and trauma when it is approved in trauma – which we expect any day…Initially, we will target opinion leaders. There will be a slow roll-out, so we can assure the results are good."
- Multi-level BMP, he said, is "a long time away." He explained, "The FDA is increasingly comfortable with it, and we do have patients, but I'm not sure we want to do an $8 million study."
- Asked if a better delivery system could lower the dose of BMP needed, he said, "We are looking at different carriers, but the one we have is effective. We may change the dose (of InFuse) for different applications (e.g., scoliosis), but the trauma dose will be the same as the spine dose."
- The breakdown between cage+BMP and cage+allograft was estimated in the neighborhood of >20% vs. <80%. He said, "Allograft continues to do well. Some surgeons

are enamored with the new materials, but the jury is still out."

Reimbursement for BMP is an issue. Several sources said they are feeling "push back" from their hospitals, which is discouraging use because of the cost. A doctor said, "I think cost will continue to be an issue with the users of this material…It is very, very expensive, and when things are so expensive, people look much harder at the level of efficacy…It may be effective, but how effective is it? Is it worth $5,000? And if you combine it with DBM (demineralized bone matrix) and allograft, then it becomes even more expensive…That is the biggest impediment (to use)." A Medtronic official said, "Medicare is only 19% of spine business in the U.S., and commercial payers are good about reimbursing for InFuse." A Washington surgeon said, "I haven't used BMP yet, but I will start. My hospital is concerned about the cost, and I am concerned about the safety."

VERTEBRAL FRACTURE TREATMENTS

Competition is increasing in this space, though Kyphon remains king of the hill:

KYPHON'S KyphX Inflatable Bone Tamp is FDA-approved only as a conventional bone tamp in the reduction of fracture and/or creation of a void in cancellous bone in the spine, hand, tibia, and calcaneus. The company did not have approval to market it for kyphoplasty, even though that is exactly how doctors use it. However, on April 5, 2004, Kyphon announced that it has received 510(k) clearance from the FDA to market KyphX HV-R Bone Cement for the fixation of osteoporosis-related pathological fractures of the vertebral body during kyphoplasty.

Although the spine market does not appear to be growing, the company is starting to focus on oncology referrals, and that could expand the market for kyphoplasty. None of the Kyphon competitors have had much impact on the company yet – and none appear poised to do so, at least unless and until one of the major orthopedic companies becomes a competitor.

SYNTHES' hinged curette. Sources were not enthusiastic about this.

INTERPORE'S AOM. Interpore refers to its system as "osteoplasty" with AOM. What's not clear is how committed Biomet, which is purchasing Interpore, will be to this part of the business. Thus, it is too early to say whether Biomet can grow AOM sales.

MEDTRONIC. The company is poised to become a player in this area – and an official insisted it isn't via an acquisition. He said, "We have options. We had a vertebroplasty product (Parallax), and we will be introducting a new kyphoplasty system in the next six months. It will be a limited launch to good surgeons we can watch."

JOHNSON & JOHNSON. J&J reportedly has stopped work on its own in-house system "because of regulatory pathway issues." A source said, "We are reassessing the situation now, but we are not considering an acquisition."

JUPITER SURGICAL. This company, which has a larger cannula for vertebroplasty, did not have a booth at AAOS, but the company reportedly has a "couple dozen" users and is working to expand usage. An official said, "The issue is what you are putting in (the vertebral space). Thicker is better…We deliver the thickest substance with the safest and simplest method to relieve pain…We use a smaller quantity (of cement). We think that if we deliver less and keep it away from the cortical walls, then it can't leak through the cortical wall. So, we make a smaller pillar in the center and keep it centered…We are not a water balloon you are filling up…Kyphon has done a good marketing job on void creation, and the challenge is making it profitable for doctors and hospitals while giving patients what they need for pain release…It's all about the substance, not the procedure. Whoever comes out with a substitute for bone cement will do well."

ARTHROCARE/PARALLAX. There was no new information on this.

DISC-O-TECH MEDICAL TECHNOLOGIES. This Israeli company is the newest player. It recently got FDA approval for its B-Twin kyphoplasty system. Instead of a balloon to create a cavity, the user turns a knob on one end of the introducer and a hard plastic, irregularly-shaped spacer gradually expands to make a space. Then bone cement can be inserted through a tube inside the introducer and out through the implant. A Medtronic official commented, "We saw this and discussed it, but we haven't seen the data. We decided against this." Kyphon has filed a patent infringement lawsuit and is planning a second lawsuit against Disc-o-Tech.

SPINEOLOGY'S OptiMesh. This system – which the company is considering calling "optiplasty" – doesn't use either a balloon or cement. Instead, a cavity is created using a drill, then a polypropylene mesh bag is introduced through a cannula filled with a biologic granular bone-chip material (MTF). The CEO of Spineology, Douglas King, compared it to filling a sandbag with sand flowing through an hourglass. Once filled, the "sandbag" becomes a "solid" – that's granular mechanics. The CEO claimed the advantages are: elimination of cement and only one incision.

Spineology has had a CE Mark for more than a year. King claimed the adoption rate is high in Germany, Switzerland, Italy, and Greece, but he declined to specify how many European sties are using OptiMesh. He said, "We are someone limited by supply. We are waiting for our next

delivery…There are a limited number of instrument sets…But I'd say we do about 40 procedures a month in all four countries...Larger sizes are selling best so far." Asked when manufacturing volume is likely to improve, he said, "We are working on it, but it won't really improve until we get the next round of financing, and that is what I'm working on now…We hope to have money in place by June (2004)."

In the U.S., OptiMesh received FDA approval in November 2003 for treatment of vertebral body defects with bone graft materials. However, the company did not have a booth at AAOS, and the first U.S. post-approval case was not done until March 11, 2004. Spineology does not expect to launch OptiMesh in the U.S. until summer 2004 because of a lack of inventory. The company currently has only one sales person and is signing up distributors. The CEO said, "Distributors are working on a good faith basis with us now in Florida, Georgia, Maryland, Southern California, Michigan, Ohio, and soon in Phoenix…We think this will attract orthopedic surgeons and neurosurgeons who, in the past, have not participated in this segment."

Reimbursement issues are not yet resolved, but King is optimistic. OptiMesh costs about $3,800 for one level without the bone chips, which retail for about $500 per level. He said, "I think there is potential for this to be higher than for kyphoplasty, partly because of what we do in preparation of the vertebral body and putting allograft bone into the site."

ARTIFICIAL DISCS

At AAOS last year, interest in artificial discs was not very high, and they were considered too far away – if they succeeded at all. This year, they were a hot topic, and doctors are eagerly awaiting the introduction of the first artificial disc, probably later this year. Doctors were talking to sales reps and leaving their business cards at the J&J and Synthes booths, anxious to make sure the reps knew how interested they are. The uptake is likely to be very quick and very broad. Some doctors already have a waiting list of patients who want the surgery, and patient demand is expected to be strong.

Some of the issues that may affect widespread use of artificial discs include:

- How much motion they really give. A speaker said, "It may be that improper motion is worse than no motion."
- Calcification around the devices.
- Explantation.
- Recurrent stenosis and myelopathy.
- Lack of long-term data.
- Biomechanical limitations, such as edge loading, optimal biomaterials, and design.
- Surgeon training. While most spine surgeons interviewed are interested in using artificial discs, experts warned that not everyone will be able to do them. A California expert said, "10%-20% of surgeons can do this. The average doctor will have a hard time with it."
- Need for perfect placement.

Sources estimated that artificial discs will quickly replace a significant percentage of fusions. One expert said, "Artificial discs may account for 20%-40% of procedures for busy doctors. Artificial discs will be more than 10% of fusion procedures, probably in the 20%-30% range." Another source said, "Artificial discs will penetrate the lumbar fusion market in the range of 5%-40%, so I'd assume about 10% – and that's what it is in Europe, 10%." A surgeon with extensive experience with Synthes' ProDisc said, "I did about 600 fusions a year, and now I do about 150. 80% of lumbar fusions converted to artificial discs. Now, about 30% of my fusions are ProDisc. I use it for Pars defect, frank instability, ≥Grade 2 spondylolisthesis and severe facet degeneration… Artificial discs will not only cannibalize the fusion market, they also will expand the market because a lot of patients refuse fusion surgery."

Patients may drive use of artificial discs. Doctors said patients already are asking for them, and several doctors said they have waiting lists. One expert said, "Patients will shop for a specific disc."

Artificial Discs in Development

Company	Nucleus	Total lumbar disc	Partial lumbar disc	Total cervical disc
Biomet	---	Regain	Regain	Rescue
CerviTech	---	---	---	PC
CryoLife	BioDisc	---	---	---
Disc Augmentation Technologies	Thermo-polymer	---	---	---
Interpore	---	---	---	MINT Titanium/ ceramic disc
Johnson & Johnson/Link	---	SB Charité	---	---
Medtronic/Spinal Dynamics	---	Maverick	---	Bryan and Prestige
Raymedica/ Medtronic	---	---	PDN-Solo and Solo-Excel	---
SpineCore	---	FlexiCore	---	CerviCore
SpineWave	Injectable disc nucleus	---	---	---
Stryker	Aquarella	---	---	---
Synthes/Surgical Dynamics	---	ProDisc	---	ProDisc
Zimmer	---	---	Spiral	---

Following is information on specific artificial discs:

BIOMET

Biomet has three artificial disc in development, Regain, which uses a pyrocarbon implant material. This material is not new; it's been used in about three million cardiac valve prostheses with 15 million patient years. It is chemically inert, biocompatible, has seven times the strength of cortical bone, and has extremely high wear resistance. Several trials are planned:

- Lumbar Regain starts in June 2004. Biomet is waiting for FDA approval to start this randomized trial. A one-year, randomized, multicenter European trial on the safety and efficacy of Regain will be run simultaneously with the U.S. trial.
- Cervical Regain starts December 2004.
- Cervical Rescue starts in June 2005. An investigator said, "Many of the current devices are difficult to place, are bone unfriendly, and leave no revision options…This is designed for ease of administration and for bailout, if they need a revision."
- Lumbar Rescue starts in December 2005.

JOHNSON & JOHNSON'S SB Charité

This will most certainly be the first artificial disc on the market. The company has submitted a PMA and was granted expedited review. An FDA advisory panel is expected, but no date has yet been set. (The Orthopedic Devices panel has meetings tentatively scheduled for June 3-4 and August 12-13, 2004, but the agendas for those dates have not been announced.) A J&J official said:

- Training will require at least five cases, "It is relatively straightforward but highly precise."
- Procedure time is about 60-90 minutes.
- Revisions are most common post-fusion where the disc was left in to act as a spacer.
- The disc can be retrieved, but it is touchy and potentially dangerous to do this. The core also can be replaced.
- European sales are satisfactory – now that the company has transitioned to its own sales force, but European doctors still want to see data.
- The key selling points are expected to be: (a) experience with the bearing surface materials, (b) 15-years experience with an essentially unchanged device, and (c) confidence in the design.

MEDTRONIC

- **Prestige**. Durability tests found no failures, a wear rate of 0.27 per million cycles, no inflammatory effect, and no debris at distant sites. The pivotal trial is expected to finish enrollment in December 2004, with two-year follow-up from the last patient. A Medtronic official said equivalency to fusion should be enough for FDA approval, and then the company will seek to show an advantage over fusion. It is expected to be on the market in 2006. The advantages cited for Prestige over ProDisc or SB Charité are: long (10 year) clinical history in Europe, stainless steel composition, and good biomechanics.
- **Bryan:** Durability tests found no failures, no cracking or obvious fraying, a yellow color change, no evidence of oxidative processes going on, and 18% wear after 39 million cycles. The mean size of particulate debris was 3.2 microns with an elliptical shape, which is considered a positive.

Medtronic has at least three disc trials underway. All have two-year follow-up. **A Medtronic official indicated that enrollment in the Maverick trial ended in March 2004, and enrollment in the Bryan and Prestige trials should be complete in summer 2004.** Another official said, "There is a chance – if there is enough statistical significance – that we could do an early submission…There is an interesting horse race underway between disc replacements and fusion, where the results are getting better and better."

SYNTHES' ProDisc. Two two-year trials are fully enrolled and ongoing. An official indicated the company has the option to submit on 22-month data, which would mean late 2004.

- A one-level study that finished enrollment in December 2002.
- A two-level study that began in October 2001 and completed enrollment in May 2003.

An official said:

- Procedure time is about 90 minutes.
- Extensive training will be offered when ProDisc is rolled out, and a course will be required before surgeons can use this product.
- So far, European sales have been "very good."
- The disc can be revised.

A surgeon who has extensive experience with ProDisc compared ProDisc to J&J's Charité. He cited these advantages to ProDisc:

- Easier insertion.
- More constrained. Charité is unconstrained, and ProDisc is semi-constrained. He said, "Charité may be the only unconstrained disc ever; the others coming are all constrained."
- It will be approved for two levels, while Charité will have approval for only one level.

MISCELLANEOUS

There was no new information at the meeting on what plans Boston Scientific and Guidant have for the spine space.

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