# 7 Disruptive Trends in Orthopedics

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## Introduction

The Orthopedic Industry is changing faster than I can remember in the last 30 years. Disruptive changes are coming at us from many fronts:

- technology
- economics
- demographics
- politics
- compliance.

The Orthopedic manufacturers foreign to these trends will miss opportunities and will be left behind. The trends will even blindside some laggards. The opportunistic companies who recognize these trends will have to rethink their business models to succeed.

Warning: I'm not going to expand on the popular trends the market research companies drone on about year after year, like price pressures, reimbursement challenges, industry consolidation, younger joint patients, heavier patients' healthcare reform, or even Trump healthcare reform. I am also not going to give you statistics and projected market sizes. I will simply analyze and comment upon these 7 trends. You may not agree with me. That's okay. This is just my opinion.

Ok, let's get started.

## Trend #1 - The Smart Implant Revolution

Imagine this. On a dark, cold morning in February 2023, the Cleveland Clinic Orthopedic staff receives a worrying electronic note from one of their total hip patients, 64 year-old Samantha Ingram. This note, however, was not written by Samantha, but by Samantha's hip replacement. The note from her implant explains that a local Staph infection is brewing. It details the location of the infection and the bacteria level present. The office nurse contacts Samantha to bring her into the office, even though she insists she is fine. She arrives that afternoon. She receives oral medication and a minor procedure that locally treats the infection. Then, she is sent home with some new meds. Success. Samantha has avoided pain, an implant loosening complication, and a future hip-revision operation. The smart implant has done its job.

In the future, I believe most joint replacements, trauma nails/ plates, and spine devices will contain embedded sensors that allow the health care system to detect early problems, proactively treat these problems, and provide better care for the patient. These implant sensors will measure loads, temperature, motion, enzymes, bacteria levels, pH, particulates, etc.

Surprisingly, as we sit here in 2018, the technology exists for implantable sensors. Still, the top10 Ortho companies are not yet on board - Stryker, DePuy/Synthes, Zimmer/Biomet, S+N, Medtronic Spine, DJO Global, IART, NUVA, Globus Medical, Wright Medical. They have not yet invested in the R&D and regulatory processes for smart implants. As history tells us, this disruptive technology will come from small, risk-taking startups. Startups ask, "*If an implant could talk…what would a healthcare provider want to hear to treat the patient more efficiently?*" In other words, what is happening inside the body, near the device? And for what smart feature would a hospital pay a premium?



As we approach 2020, this trend will gain traction because of converging forces in four areas:

1. New technology capabilities in embedded sensing.

2. Orthopedic manufacturers (finally) starting to understand and consider using embedded chips.

3. The ongoing need for manufacturers to find product differentiation in order to prop up implant pricing.

4. A desire for the healthcare providers to deliver more cost effective care.

Now, let's get specific.

How will Orthopedics apply Smart Implants? When will these new applications emerge?

Applied Orthopedic smart technology will come in four major waves. Each wave will provide more sophisticated information than the last. The first wave is here, the second wave is being tested, and the third and fourth waves will arrive in the future.

These four waves are:

Wave #1 - **Smart Tools in the OR**: feedback or data given to surgeon real-time.

Wave #2 - **Smart Diagnostics on Demand**: accessed by Doctor or nurse at follow-up visits.

Wave #3 - **Smart Diagnostics by Exception**: sent by the implant to Doctor or nurse when an alert is triggered.

Wave #4 - **Treatment by Exception**: drug delivered by implant when an alert is triggered.

#### Wave #1 - Smart Tools in the OR

The first wave of smart implants focuses on smart tools in the operating room to improve surgery. The first chips have long arrived in Orthopedic surgery. Instruments with chips and RFID tags help surgeons make better decisions during surgery. Smart instruments and trials with embedded sensors will help surgeons position the implant and balance the load during surgery. The Intellijoint Hip is a good example of a disposable sensor measuring offset with trials. I consider smart tools as another level of surgical navigation, but these new tools with chips and RFID tags have several advantages over optical systems. This technology is cheap, portable, disposable and, most importantly, may help manufacturers earn another fee for each joint replacement surgery. Major orthopedic companies are working on these applications now. Companies like OrthoSensor will provide a smart knee trial to measure balance intraoperatively. Zimmer, Stryker and Biomet have already jumped to "partner" with OrthoSensor.

#### Wave #2 - Smart Diagnostics on Demand

The second smart implant wave focuses on smart diagnostics on demand. Diagnostic chips will help provide better care during regular patient follow-up visits. The first smart implants with embedded sensors will relay diagnostic data from inside the patient to a physician or health care worker post-surgery. Companies have dabbled with custom telemeterized chips in implants using radiofrequency transmission (RF) of data. So far, implants have included custom hip, knee, spine cages, and artificial discs. Most of these implants were large and bulky, with major design tradeoffs. Intellirod Spine has implanted wireless RFID sensor technology for monitoring spinal rod strains in Europe. But as of this writing in 2018, smart diagnostics are not commonplace in orthopedics.

Other opportunities with on-demand smart diagnostics include providing data in the doctor's office, such as implant positioning, load bearing data, range-of-motion (ROM) data, gait analysis, joint stability or potential for dislocation, bone ingrowth measurement, particle count around an implant (a link to osteolysis), temperature, pH, lactate, glucose levels and other local biochemistry.

In 2005, a patient received the first <u>wireless telemeterized total</u> <u>knee</u>. This modified J&J DePuy custom total knee contained a large embedded transducer in the tibial stem that relayed load information as the patient moved. In 2007, another patient received the first smart disc with telemetry capability.

Today, Consensus Orthopedics is providing on demand information with its <u>TracPatch</u> sensors stuck to the skin around the knee. TracPatch remotely monitors a patient's post-surgical activities by sending activity data to healthcare providers during the first six weeks of at home recovery. It provides range of motion (ROM), ambulation, exercise compliance and wound site temperature trends to healthcare providers.

Smart chips will eventually become the "black box" in every patient, and smartphones will likely help retrieve the information. Smart diagnosis chips may inform future human clinical trials and

animal trials to derive more meaningful data with fewer subjects.

#### Wave #3 - Smart Diagnostics by Exception

The third wave of smart implants will offer smart diagnostics by exception. In the 2020's, tiny diagnostic chips in total joint devices will sit silently for years until they detect a problem. The patient could be anywhere when the chip activates. The chip will send diagnostic data through an existing wireless infrastructure to the patient's hospital. These smart implants will only send wireless data when they detect issues, such as an early infection (based on the bio markers seen), osteolysis (the silent killer in joint replacements), and stress shielding that often leads to bone erosion, loosening, and revision surgery. The wireless data will add enormous value and efficiency to the health care system.

#### Wave #4 - Treatment by Exception

The fourth wave of smart implants will both diagnose and treat the patient, without surgical intervention, by the 2030's. These smart implants will detect a problem and "self-treat" the patient by delivering drug therapies or stimulation locally as needed. They may deliver antibiotics or growth factors long after surgery. Once again, these smart, on-board drug delivery vehicles will remain completely dormant until activated.

And finally, to illustrate this trend, I want to share some real examples of smart implant applications. I list these applications in chronological order from today's existing technology to future technology.

### **10 Examples of Smart Implant Applications**



#### 1) Performance, load bearing and ROM data collection

A good example is Theken Spine's first artificial disc with force monitoring sensors, called the <u>eDISC</u>. Another example is the <u>e-knee</u>, where researchers measure real-time forces inside the knee while the patient walks, climbs stairs and exercises.

#### 2) Remote Control Adjustment of Implants

The NuVasive / Ellipse Technologies' MAGEC and PRECICE implant systems enable both surgeons and patients to non-invasively adjust the implant's position <u>by remote control</u> using magnets.

#### 3) Local report of tissue condition

Ortho-Tag enables surgeons to gauge the pressure on an implant, the chemical balance and temperature of the tissue, and the presence of harmful organisms. Read here about more research on the <u>Smart Hip</u>, that can detect early bone ingrowth issues.

#### 4) Bone Ingrowth measurements or Spine Fusion detection

Researchers also investigated hip loosening, based on the use of <u>magnetic sensor oscillators</u>. However, today <u>Intellirod Spine's</u> <u>LOADPRO</u> monitors fusion with a strain gage measuring device attached to posterior fusion rods, which gives insight to the status of fusion.

#### 5) Implant ID and Patient ID data accessed by an RFID tag

The RFID tag is a good example, again from Ortho-Tag, that enables healthcare providers to track and ID total joints with the wave of a wand.

#### 6) Fracture Healing measurements

I know of at least one large trauma company that is already conducting feasibility work for this application.

#### 7) Infection detection

I am not aware of any work in this area.

#### 8) Early Joint Dislocation warning detection

Consensus Orthopedic's <u>TracPatch</u> sensors do this in the knee today and will do this in hips in the future.

## 9) Early osteolysis detection by particulate count measurement and reporting

I have not heard of any work in this area.

## 10) On demand local drug delivery (antibiotics, analgesics, growth factors) long after surgery

I have not heard of any work in this area.

## What is your company doing to prepare for the smart orthopedics world?

Is your team asking, "If an implant could talk...what would a healthcare provider want to hear in order to treat the patient more efficiently?

## Trend #2 - Mass Customization



Joint arthroplasty has become increasingly accurate and reproducible over the last 10 years with better planning and instrumentation. However, the total knee replacement and unicompartmental knee replacement procedures are still errorprone. The surgeon must possess a high level of technical skill and experience in making perfect bone cuts for stability, ligament balancing, rotational alignment and range-of-motion. The bone cuts in total knee procedures are a three dimensional puzzle. The surgeon has to rely on exposed boney landmarks during the case to position his instruments. As the incision gets smaller, positioning becomes harder.

Then, even if the surgeon makes perfect bone cuts, he only has access to a few pre-determined implant sizes for the entire population of patients—typically sizes 1 through 8 or so. Just as clothes in a retail store don't fit everyone perfectly, premanufactured implant sizes don't fit every patient. Millions of patients receive a joint replacement each year from one of the canned sizes "on the shelf." I have observed many joint replacement surgeries. When the surgeon starts fitting the trials, you often hear: "He looks like a 5 to me. Do you think he could take a 6?" Many people fit different size offerings; even the matched sizes don't have the proper medial-lateral anatomic ratios or anterior-posterior anatomic ratios for a given patient. Bones vary just like the rest of the person.

Mass Customization is the solution.

Today, mass customization technology is based on 3D imaging (CT or MRI), CAD (computer-aided-design) and CAM (computer-aided manufacturing) systems or 3D-printing. These systems produce personalized implants, or personalized fits of an implant for an individual patient. The result is a manufacturing run of "one."

In the quest for better "fit" and better outcomes, patient-matched custom implants are finally coming of age. The personalized implant theory states that patients get a better fitting implant that results in better function, a longer lasting implant, and better bone stock preservation for better revision in the future.

The surgeons love the technology and drive the trend, and hospitals can use it as a marketing tool to "one up" the other hospitals across town. But, there are some downsides. The custom/personalization procedure costs more. The implant is more expensive and the patient must go through additional CT scans or MRIs. Because of the expense and complexity, the technology cannot transfer to emerging markets. Then, there are the long-term results. Some early total joint studies show improved outcomes in terms of better-aligned knees, but research requires the 15 year long-term outlook for proof of longterm results.

Let's break down the various technologies into categories. We believe there are five major categories of total joint customization. All technologies fall into one of these areas.

## The 5 Major Categories of Total Joint Customization Technologies

1. Pure Custom implants, based on MRIs or CT scans, are

used to manufacture custom implants. Most big Orthos offer custom implants, but they usually offer these for the more challenging anatomy cases or severe bone loss.

- Gender specific knees. Zimmer offered male and female versions in the late 2000's, but this trend faded as outcomes for the female design products did not improve. Zimmer markets the <u>Persona</u> knee today. This trend ran its course.
- 3. **Custom disposable instrumentation.** MRIs or CTs are used to create custom instruments, take the guess work out of generic cutting guides. This trend is the most common today lead by companies such as <u>Materialise</u>.
- 4. Custom bone prep with robotic-guided instrumentation. In surgery, a robot makes the perfect bone cuts based on MRI or Ct data. Stryker/Stanmore is the only company using robots so far.
- 5. **3D Printing of custom implants.** This trend is emerging rapidly as 3D printers (also known as additive manufacturing) can now produce implant materials in high-quality titanium, CoCr, ceramics and PEEK. These materials are technically feasible and the regulatory agencies have created pathways. In this area, dental labs and hearing aid manufacturers lead the way. The FDA is providing early guidance.

The big 5 Orthos largely lead the customization trend. Below, I list the manufacturers that offer customization, or personalization, and an overview of their products.

## 10 manufacturers that offer customization or personalization today

1. **ConforMIS** is an entire company based on custom/ personalized approach. ConforMIS uses: iUni-G2 with implants, iView patient-specific imaging data and iJig patient-specific instrumentation; the iTotal CR Knee Replacement, iDuo G2 next-generation bicompartmental knee resurfacing system; and the iTotal G2 Knee Replacement system.

- 2. **Biomet** markets Signature Personalized Patient Care System based on a 3D MRI to create external instrumentation without intramedullary reaming.
- J&J Synthes DePuy markets TruMatch Personalized Solutions based on software customized to specific anatomy and instrumented for specific patients. This enables the surgeons to implant the SIGMA total knee with less steps.
- 4. **MedActa** is a Swiss company that markets MyKnee instrumentation based on MRIs and x-rays for use with its GMK Total Knee System.
- 5. **Smith & Nephew** markets Visionaire Patient Matched instrumentation, based on MRIs and x-rays, to create custom instrumentation for the company's total knee implants: Genesis, Legion and Journey.
- 6. **Stanmore** is a UK company that markets the Savile Row unicompartmental knee based on CT scans. Stanmore builds a patient-specific implant and uses the same CT data to guide an intra-operative robot to make the bone cuts.
- 7. **Stryker** markets Triathlon Custom Fit Knee with ShapeMatch Technology based on MRI data to determine the best implant size. They create custom disposable instrument guides for each patient.
- 8. Wright markets Prophecy Pre-Operative Navigation Guides based on either MRIs or CT scans for custom instrumentation for the INBONE total ankle replacements.
- 9. MicroPort Orthopedics (formerly Wright Medical's hip/knee

business) markets the Prophecy Pre-Operative Navigation Guides called Evolution for custom instrumentation for the company's total knee systems.

10.**Zimmer** markets Patient Specific instruments based on MRIs to create disposable custom cutting guides for the company's total knee systems.

What is your company doing to compete in a customized procedure world?

## Trend #3 - Medical Tourism Reversal



This year, hundreds of thousands of Americans will travel outside the United States for health care. The rising cost of medical treatment in the U.S. sends Americans abroad in record numbers. Around 500,000 Americans leave the country each year for some sort of elective medical procedure, including Orthopedic procedures. Medical tourism originated in the 1990's with cosmetic procedures. Today, a large percentage of patients travel for common Orthopedic procedures—total hips, total knees, spine fusions, etc. There is no rule of thumb, but an OUS total joint procedure typically costs the patient 25% less than in the US.

This trend is driven by economics, demographics, globalization and technology, and cannot be ignored. The huge scale and logistics become as simple as calling your travel agent. If you don't believe it, just take a look at <u>HWBazaar</u> for an example. Choose a procedure, choose a country, and call to book your trip. One, two, three.

Want a state-of-the-art spine procedure not approved in the US.? Go to the Cayman Islands and have a US surgeons perform your surgery there - Spine.ky.

Past trends have now flipped. Historically, wealthy people in third world countries would travel to the major hospitals in developed countries. Now, people in developed countries travel to emerging-world countries for the cost benefits. You see, the internet has eliminated the friction in the system with international surgeon training and a more "global" patient.

### Case Study: Sue goes to Belgium?

Sue's real-life story illustrates today's reversed Medical Tourism patient. Sue Sorey, a Baton Rouge resident, is a typical patient who needed a total hip. She had advanced OA in her right hip that robbed her quality of life. Unfortunately, Sue did not have health insurance. Sue and her husband researched operation costs from all of the local hospitals. They received estimates from \$60,000 to \$100,000 out-of-pocket. They were devastated.

Then, they heard about Medical Tourism from a friend. A few weeks later, Sue Sorey's hip resurfacing surgery took place in Ghent, Belgium. The couple spent \$25,000 total, including the surgical procedure and 13 days of lodging and meals in Belgium. Sue said that she had immediate pain relief. Mission accomplished.

There are more benefits than the cost. The cost-saving opportunities initially drive patients to look outside the US, but they are commonly surprised by the other unexpected benefits they discover over the course of their medical tourism experience.

### **Patient Benefits from Medical Tourism**

1. A 75% cost savings on the procedure.

- 2. Experienced surgeons (many that are US-trained).
- 3. The same implant, instrument and imaging technology available in the US.
- 4. Personal care and attention that exceeds US standards.
- 5. Luxury accommodations.

### **Case Study: Wooridul Spine Hospital**

The <u>Wooridul Spine Hospital in South Korea</u> is a typical hospital catering to medical tourism. Wooridul offers perks seldom experienced in the US: a car, an English-speaking nurse to greet the patients, hospital rooms that look more like luxury hotel accommodations, great care, and proximity to tourist attractions and shopping during the rehab process. In 2008, Wooridul Spine Hospital brought in 1,000 foreign patients (1/3 US citizens) and millions in revenue.

How can U.S. hospitals compete? U.S. hospitals feel the pressure from medical tourism, in some cases offering to match foreign pricing to encourage patients to stay local.

The most popular destinations for orthopedic patients are India, Singapore, Mexico, Thailand, Columbia, Costa Rica, Belgium, and Turkey. But now, over 50 countries identify medical tourism as a national industry.

The Medical Tourism trend is driven by economics, demographics, globalization and technology. The trend's scale is huge; third party agents facilitate the trend's logistics. The babyboomer rise helps to throw fuel on this fire. 13,000 people a day hit their 60th birthday in the US. Many of these baby boomers are looking for high quality medical procedures at affordable prices. Telemedicine also enables medical tourism. As the technology barriers have broken down, patients and medical staff can exchange medical information and discuss pre-operative planning protocols and concerns before and after surgery. The tourism industry is also getting on board. Travel agencies, airlines and hotels realize that this is a business opportunity growing to their advantage. Medical tourism is not going away and has grown much since Thomas L. Friedman explained this trend in his book, <u>The World is Flat</u>.

Amazingly, an entire annual meeting dedicates itself to Medical Tourism: <u>The World Medical Tourism and Global Healthcare</u> <u>Congress</u>. The <u>Medical Tourism Association</u> also develops Certification Programs.

What is your company doing to tap into the Medical Tourism Reversal trend?

## Trend #4 - The 23-Hour Joint Replacement

Traditionally, orthopedic out-patient surgery was reserved for only the true "closed" procedures, like scopes. Usually, these are soft tissue procedures through a scope, such as rotator cuff repair, meniscus repair/removal, or even an ACL repair/ replacement. And sometimes, the surgeon will even perform bone shaving work through the cannula, such as a sub-acromial decompression. That's it.

Let's look at the hip, specifically. Total hip replacement surgery has always been considered an "in-patient" surgery. Each year, over 250,000 Americans receive a primary hip replacement. The typical hospital stay is 3 to 4 days with generous pain medicine. The facility often discharges the patient to a rehab hospital instead of his home.



Then, the hospital gives the customary limited weight bearing and bending, sitting and turning restrictions for 6 weeks to 12 weeks, to avoid dislocations and allow the bone to consolidate the implant.

But, the orthopedics industry bombards us with the terms "MIS," "mini-open" and "less-invasive." Manufacturers provide less invasive instrumentation each year and residency programs now offer full programs in MIS surgery. So, why can't bigger orthopedic MIS surgeries, through smaller incisions, be performed in an out-patient setting?

They can. The 23-hour hip is here. Surgery centers across the US are leading this trend. These early adopters push the boundaries and, surprisingly, are discovering unexpected positive outcomes. Patients are also having terrific results.

### Seven positive outcomes of the 23-hour hip

- 1. Smaller incisions
- 2. Lower pain scores
- 3. Earlier mobility
- 4. Lower deep-vein thrombosis incidences as a result of earlier mobility
- 5. Patients get to recover at home
- 6. Less blood loss—usually less than 100cc 7
- 7. Higher patient satisfaction

What does it take for a Surgery Center to do a 23-hour outpatient total joint stay versus a typical 3-4 in-patient day stay?

A successful "out-patient" total hip relies on three key areas:

- 1. Careful patient selection
- 2. Surgical expertise and technique
- 3. Judicious pain management

Remember, these total joint patients are not "sick." They just suffer from OA disease in the hip. Out-patient surgery uses the same technology, but different patient management. Just like an "in-patient" procedure, an "out-patient" surgery uses the same MIS surgical technique, the same MIS instruments, the same implant and the same basic OR suite and imaging tools. The differences include a more careful patient selection (typically younger and healthier), some extra training for the ASC / Surgery Center team, and a different anesthesia protocol for rapid recovery.

### A detailed look at one Surgery Center's Out-Patient Total Hip Process

### Pre-Op

Patients are enrolled in the clinical pathway program (including preoperative, intraoperative and postoperative care) with a cross-functional team—a surgical team with anesthesia, nursing, physical therapy, occupational therapy, and discharge planners. Patients attend a class taught by a nurse to walk them through expectations and potential complications. Then, they attend an additional physical therapy session. They are instructed in gait training with crutches to anticipate the next day's weight bearing as tolerated. Patients donate two units of blood.

### Surgery Day

On the morning of one surgery, 40 mg of Bextra—or 400 mg of Celebrex—and 10 mg of OxyContin were administered orally. The team usually uses an epidural anesthetic without narcotic additives, unless it technically cannot be inserted. Placing the epidural catheter failed in three cases, whereupon they administered general anesthesia. They avoided using both intravenous and epidural narcotics. They titrated Diprivan, a short-acting sedative, during the procedure. The patient received four mg of Zofran and 10 mg of Reglan intravenously during the case, to decrease nausea. Patients also stayed well-hydrated, to prevent postoperative hypotension and subsequent nausea. The team inserted a Foley catheter in all cases; we used a Foley in all patients to help monitor fluid status and eliminate urinary retention concerns. We administered Prophylactic intravenous antibiotics prior to the skin incision. One hundred forty-five of the 150 patients had an epidural anesthetic; three had general anesthesia (due to an inability to successfully enter the epidural space) and two had epidural anesthesia with a short period of

general anesthesia to relax the muscles and facilitate final hip reduction.

### Surgery

Intraoperatively, we titrated the epidural infusion and Propofol to achieve the minimum analgesia necessary for the procedure. We administered the adjunctive use of general anesthesia if the regional block did not provide adequate analgesia, or if the regional technique did not reduce the hip, or relax the patient, to perform the arthroplasty. The team used a cementless total hip in all cases. All 150 patients underwent a cementless, hemispherical, porous-coated acetabular reconstruction. This hemispheric component has a commercially pure titanium shell covered with a commercially pure titanium fiber-metal mesh with multiple holes to fixate the supplemental screws. We inserted the acetabular component with a 2-mm press-fit by implanting a component 2 mm larger than the last reamer we used to prepare the acetabulum. All cases used two supplemental screws. An UHMWPE cross-linked insert fastened into the shell. The inner diameter was 32 mm in all cases. All surgeries used a 32-mm head and all 150 patients had a full porous-coated stem. In cases with a modular head, we used one of five neck lengths. The team inserted these components using a minimally invasive technique that minimized prosthetic insertion damage to muscle and tendons. The patients had one of their own units of autologous blood transfused intraoperatively at the end of surgery, regardless of the surgical blood loss. The mean surgical time was 99 minutes (range, 66–141 minutes). The mean estimated blood loss was 266 cc (range, 100-1000 cc).

### Post-Op

In the recovery room, we administered a second dose of Zofran and transfused the patient's second unit of autologous blood. The patient was kept well-hydrated to prevent postoperative hypotension and nausea. The epidural (fentanyl 10  $\mu$ g/mL + 0.1% bupivacaine) continued in the recovery room at 6 cc, 1 cc every 15 minutes with a 40 cc for 4-hour lock out. Two hours after surgery, the Foley catheter was discontinued and 20 mg of OxyContin (10 mg of OxyContin for patients over 70 years of age or under 120 pounds) was given orally. Patients were allowed to take Norco 10/325 mg for breakthrough pain if needed. The epidural catheter was removed 4 hours postoperatively. The intravenous line was subsequently discontinued, but we maintained the intravenous catheter with a heparin lock prior to physical therapy. The patient underwent occupational and physical therapy 5 to 6 hours postoperatively. The patients were allowed weight bearing as tolerated and encouraged to rapidly advance to a cane or ambulate unassisted. We administered one additional dose of intravenous antibiotics following physical therapy. No additional antibiotics were given before discharge, or while patients were at home.

A clinical nurse was immediately available to address any problems, such as inadequate pain control, nausea, hypotension, dizziness, or over sedation. Breakthrough pain was first treated with hydrocodone 10/325 mg (5/325 for patients over 70 years of age or under 120 pounds); if this was insufficient, the patients could take IV morphine, up to 10 mg, and/or additional oral agents (Norco 10/325, OxyContin). Non-positional nausea was treated with 10 mg of Reglan and 4 mg of Zofran. Hypotension and positional dizziness were treated with an intravenous fluid bolus. Positional nausea, or orthostaticallyinduced nausea, was treated with an intravenous fluid bolus and 10 mg of Reglan. Oversedation was usually treated by allowing for the effects of the medication to subside. However, in severe cases, we utilized Narcan (naloxone hydrochloride).

Patients were discharged when they met strict criteria. As a hospital requirement, all patients must complete a formal physical therapy protocol. This protocol requires that patients can independently transfer out of bed to a standing position and transfer into bed from a standing position. Additionally, they must independently rise from a chair to a standing position and sit from a standing position. Patients must also be able to walk 100 feet and ascend and descend a full flight of stairs. The patient must exhibit stable vital signs, tolerate a regular diet, and have adequate pain control from oral analgesics. Only after all of these criteria are met is the final criteria invoked: "Does the patient feel comfortable going home?" When ready, the hospital discharged all patients directly home from the hospital and not to another care facility.

#### **Rapid recovery**

Following surgery, patients were moved to an overnight room where they received one-on-one nursing care. They could use recovery room nurses, but Dr. Caillouette prefers the added experience of intensive care nurses who may be better equipped to handle any possible complications.

Patients received 1,000 mg of acetaminophen every 6 hours and were treated with instant release oxycodone for breakthrough pain. "We try to avoid any intravenous narcotics after surgery, and that has worked out well," he said.

Patients received the same prophylactic care as in a hospital incentive spirometry, sequential compression devices, and deep vein thrombosis prophylaxis. Nurses monitored their vital signs (respiration, pulse oximetry, and electrocardiogram) through a system centrally located at the nursing desk, which allows the patients to rest comfortably with fewer interruptions.

When the anesthesia wore off, the patients were encouraged to sit up, dangle the legs, and eat a light, high fiber diet. About 5 hours after surgery, the patients began to ambulate with the help of a walker. Prior to the surgeon discharging the patients 23 hours post-op, the patients had to get into and out of bed on their own and climb stairs.

#### Home

Upon discharge, patients continued taking Bextra 20 mg daily, or Celebrex 200 mg for at least 2 weeks, and gradually decreased

their dose of OxyContin as needed; they took hydrocodone as needed for breakthrough pain. All patients received aspirin 325 mg twice a day through deep venous thrombosis prophylaxis for 3 weeks. Patients were encouraged to resume as many activities as they could tolerate. There were no hip precautions used throughout the recovery. These patients were allowed to drive when they had stopped all narcotic medications. The patients utilized home physical therapy until the patient could drive (typically within 1 week), at which time outpatient physical therapy began. They did not use visiting nursing care. Patients were evaluated clinically and radiographically in the office at 1 week, 2 weeks, 6 weeks, and 3 months postoperatively. The hospital assessed clinical outcomes using the Harris Hip Score, both preoperatively and at 6 weeks and 3 months postoperatively. A nurse clinician assessed the patient satisfaction at the 2-week office visit, by asking the question, "Would you be discharged home the same day and following the same clinical pathway again?" Continuous variables were compared using a paired student's T-test with a significance level of 0.05.

## 23-Hour Joint Replacement Trend illustrated in the News

The goal is a less than 24 hour hip stay, but one surgery center in Pennsylvania is pushing the limits with a <u>3-hour hip stay</u>. The AAOS study finds that one-day TJR has the same outcomes as admitted TJR. To learn more, here are <u>10 Surgery Centers that are performing outplacement joint replacements.</u>

What is your company doing to help Surgery Centers perform "out- patient" procedures?

## Trend #5 – Generic Implants, No Reps

Cheap orthopedic implants, coming to a neighborhood near you.

In the last few years, Generic Implant startups gained traction in the marketplace. The US market is saturated with high-priced implants that possess extra-expensive technology features. Their dirty little secret is that these features do not actually result in better clinical outcomes; surgeons just love to implant the latest feature technology. These devices are typically more complicated and less user friendly, and sometimes involve newer, less proven surgical techniques. "New" does not necessarily benefit the patient—think about all the new navigation equipment in ORs today.

A small visionary group of hospital leaders are reclaiming control of the Operation Room from the manufacturer's rep. These leaders are scattered in small towns and suburbs, taking back their OR with Generic Implants and demanding dramatic implant price reductions. They are willing to revamp their hospital and training processes to acquire these cheaper implants.

Enter: the new Generic Implant Manufacturer.

These startups are now making copies of legacy implants with proven biomaterials and designs. The patents have expired. The devices they copy have 10 or 20 years of proven clinical outcomes. The surgeons are already trained on the correct surgical techniques and understand the approaches. Generics offer implants without the sales rep support and, as a result, do not carry the overhead of the distribution sales force layer. The overhead can account for as much as 30-40% of a device price.

Generic startup companies are filling this need. By going directly to the hospital, generic startups can sell their devices for a

fraction of the price of "improved technology" implant systems with special features. Think suture anchors for \$30 instead of \$300. Think total hips or knees for \$1,200 instead of \$5,000.



Sounds too easy, doesn't it? What's the risk for these generic implant startups?

The bulk of the risk for the Generic implant startups resides entirely in the business model—marketing, distribution, and margins. By contrast, there is very little risk in the technology, the product, or even the regulatory path. Generic implant startups have tiny marketing budgets that usually start with a website. They all begin with a single hospital or surgery center where hospital profits incentivize an early adopter surgeon. The promise of low cost generic implants usually comes without any sales rep support.

The product is shipped "direct to hospital." The "absent rep" model means that nobody at the hospital can check instruments and implant inventory prior to the procedure, and there is no technical problem-solver in the OR with a laser pointer. For many hospital customers, the absent rep is a major psychological hurdle because they don't have the processes in place to manage all of the implants. Hospitals encounter a new logistical problem: startups ship the implants to the hospital and the hospital must somehow receive, check, process, sterilize and stage them at the right OR, at the right time, for the right procedure.

The big five Ortho manufacturers (Stryker, DePuy/Synthes, Zimmer/Biomet, Smith & Nephew, Medtronic Spine) control the market and will fight the generic implant trend because it

threatens their inflated pricing structures. They will fight it as long as they can. But, the Generic implant startups, like a pack of Chihuahuas, will bite into one small hospital at a time and will empower each hospital to take control of their pricing and their operating room.

This trend will not stop. As of this writing, there are at least 23 generic implant companies, but a new one pops up every quarter. I list below some generic companies and the product areas that deliver these solutions to Hospitals and Surgery Centers in the US.

### List of 23 Leaders in Generics Implants

- 1. Orthimo (Total Joints) http://www.orthimo.com/
- 2. Ortho Direct USA (Sports Med, Joints, Spine) <u>http://</u> www.orthodirectusa.com/
- 3. RoG Sports Medicine (Sports Med) http://www.buyrog.com/
- 4. Siora Surgicals Pvt. Ltd. (Trauma) <u>http://www.siiora.com/</u>
- 5. ImplantPartners brand under MicroPort fka Wright Medical (Hip, Knee) <u>http://www.implantpartners.com/</u>
- 6. Syncera brand under Smith and Nephew (Hip, Knee) <u>http://</u> syncera.com/us/
- 7. United Orthopedic Corporation USA (Hip, Knee) <u>http://</u> www.uocusa.com/
- 8. Villoy Implants (Hip) http://villoy.com/

- 9. Responsive Orthopedics (Knee) [ACQUIRED] [acquired by Medtronic]
- 10.**OrthoSolutions (Extremities)** <u>http://</u> <u>www.orthosolutions.com/</u>
- 11.Intralign (Joints) http://www.intralign.com/
- 12.Intuitive Spine LLC (Spine) http://www.intuitivespine.com/
- 13. SpineDirect LLC (Spine) http://www.spinedirectonline.com/
- 14.Emerge Medical (Trauma) [ACQUIRED] <u>http://</u> www.emergemedical.com/news.html
- 15.Convenant Orthopedics (Joints, Trauma) <u>http://</u> www.covenantortho.com/
- 16. The Orthopaedic Implant Company (Trauma, Spine) <u>http://</u> www.orthoimplantcompany.com/
- 17.NovoSource (Total Knees) [FOR SALE]
- 18.Empower Spine (Spine) http://www.empower-ortho.com/
- 19. Parcus Medical (Sports) http://parcusmedical.com/
- 20.Back2Basics Spine (Spine) <u>http://</u> www.back2basicsspine.com/
- 21.Eisertech (Spine) http://www.eisertech.com
- 22.Prodigy Orthopedics (very early) <u>http://</u> prodigyorthopedics.net
- 23. The Progressive Orthopedics Company (Knees, Hips) http://progressiveorthopaedics.com/

### **Generics in the news**

A detailed case report of how one Hospital successfully controlled implant costs

Beating High Orthopedic Implant Costs: How to Save Money With Generics

The Taiwanese are coming

What is your company doing to compete for the generic implant business?

## Trend #6 - Think BRIC

The big five Orthopedic device companies (Stryker, J&J/DePuy/ Synthes, Zimmer/Biomet, Smith & Nephew and Medtronic Spine) have found themselves in the center of a perfect storm of converging economic, regulatory, and reimbursement trend uncertainty within the US market. Just as Thomas Friedman predicted in his best seller, <u>The World is Flat</u>, the flattened world has finally reached Orthopedics.

The flattening world is a massive trend. Recently, the big orthopedic players have given up on the US and EU markets for sustained profits. They are running to greener pastures. Let's look at the facts. Expensive technologies saturate the US market. The US market also has the highest density of sales reps, increasing price pressures, changing, unpredictable regulatory bureaucracy, and liability with no predictable ceiling (J&J's legal exposure on Metal-on-Metal will be north of \$2B).

In order to deliver earnings and dividends to their shareholders, the big Orthos have no choice but to ignore the largest markets in the world—America and Europe. This shift has resulted



in the big Orthos moving their resources, inventories, training, clinical studies and R&D efforts from outside US and European markets to the big emerging markets. See: BRIC.

The big four emerging orthopedic markets are the BRIC

countries, **Brazil**, **Russia**, **India** and **China**. These four countries represent 41% of the world population and grow their economies faster than the US GDP. They represent the largest medical markets in the world outside the US, Europe and Japan. They all have emerging middle classes that demand higher-quality medical. In India alone, analysts predict the middle class will grow from 50 million people to 580 million people between 2010 and 2025.

Let's look at why the big Orthos are seeking greener pastures outside the US/EU markets.

### 9 Reasons to Think BRIC

1. US Regulatory hurdles.

The FDA has become unpredictable, unreliable, and antitechnology. This is well-documented from the countless manufacturers who first moved their clinical studies outside the US. See Trend #2.

2. R&D Investment.

US investment in new technologies has simply become too steep. For Class III devices, companies today must invest 8-10 years and \$95M before seeing significant revenue.

3. Growth Rates.

Revenue growth has slowed to 5% or less for the big five Orthos (Stryker, J&J/DePuy/Synthes, Zimmer/Biomet, Smith & Nephew, Medtronic Spine). The double digit revenue growth days are over.

4. Distribution Establishment.

The Big 6 Orthos have already fully penetrated new first world markets with sales and distribution organizations. They now have feet on the street in the BRICs.

5. Price Pressures.

Well-documented price points are dropping in the US.

6. Reimbursement Challenges.

Reimbursement is becoming more challenging in the US.

7. Surgical Training.

The BRICs train orthopedists at a faster rate than the US. The total number of US trained Orthopedists has become stagnant.

8. New Punitive Taxation.

Additionally—as if there's not enough wind in the device companies' faces—the Feds have installed a gross sales tax of 2.3% on device sales within the US. There are other financial challenges outside the US, but at least they don't take 2.3% right off the top.

9. Technology Leverage.

The move to BRIC markets does not require new innovation. Companies can leverage the technology they already developed, manufacture more technology and sell into new markets. The exporting cost is far less than the cost of new research and development.

### The Four Challenges of going BRIC

- 1. The price points of existing US products will not fly in BRIC, so the US has to develop more cost-effective implant systems.
- 2. Big Orthos need more medical training, even though many are trained in the US.
- 3. Orthos need more sales distribution, even though the big five Orthos have a foothold in the BRIC markets. These massive growing markets simply need more representation.
- 4. It is difficult to repatriate the profits.

### The BRIC Trend illustrated in the News

Medtronic announced they are growing to 2,000 employees in China. Smith + Nephew announced they will reorganize to strategically focus on BRIC; they are pumping more R&D money into BRIC products. Smith and Nephew makes an emerging markets move into Brazil.

China recently became the #2 Orthopedic market in the world. Stryker recently bought a Chinese device maker for \$765M. China received 6 Drivers for their expanding market. Zimmer made an acquisition into China.

What is your company doing to compete in a BRIC world?

## Trend #7 - The Innovation Migration

Why do Peyton, Kobe, A-Rod and Tiger have to go to Europe for stem cell treatments? Peyton got a stem cell injection in his neck in Germany because the US does not have the best treatment available. Stem cell injections are just one example of a cutting edge technology not available in the US. Thanks to a mix of politics, bureaucratic foot-dragging and scientific caution at the FDA, the US prevents orthopedists from culturing stem cells, let alone culturing them into stages as advanced as their foreign counterparts.

The US has lead innovation in Orthopedics as far back as I can remember. US innovation leadership has improved millions of lives worldwide. Americans have always been the first to access new advancements. Now, this is no longer the case.

There is now a technology drain in the US. Innovative orthopedic clinical studies rarely start in the US because of the FDA's ongoing assault on novel and innovative devices. The CE-marking process of manufacturer self-registration is much more predictable, a more reasonable and shorter process. The CE marking is the manufacturer declaring that the product meets the requirements of the applicable EC directives. Third party notified bodies audit the declaration over a central regulatory body. This takes much less time than navigating through the FDA's whims. Through the CE mark, Europe is now the first market to gain clinical experience with a new technology. European patients get the new stuff first.

Let's look more closely at the FDA problem.

The FDA's review times are becoming longer and longer. This is well-documented. Research groups such as Boston Consulting concluded that today's FDA doesn't keep pace with US orthopedic technology innovations. Recent debacles, like the Metal-on-Metal hip recalls, spooked the FDA into even more conservative bureaucracies.



But perhaps the biggest issue of all is the lack of predictable review cycles. Under this administration, the FDA has become very unpredictable. Innovators find that clearance is uncertain, often vague, and FDA guidance changes throughout the process. Often, the FDA contact changes during the regulatory process. If the FDA could tell the manufacturer that the process would take five years, then the manufacturer could plan accordingly. The FDA cannot even do this.

The FDA appears to be driven by politics, not science.

Orthopedic IDE/PMA devices are now on a drug timeline from start to clearance. The average PMA clearance takes 8-10 years and \$100M in funding. Most small innovators don't have the financial stamina for this marathon; VCs and other funding vehicles don't have the risk tolerance for these durations. Furthermore, the FDA has required more devices to take the PMA route over the last two decades.

Part of the FDA irrational conservatism comes from an increase in recalls over the last few years. But, when analyzing these, the FDA found that 96% of the recalls involve little or no risk to patients. Only 131 recalls from 2005 to 2009 were considered "high risk." Also very telling is that the 510(k) process cleared 87% of these "high risk" recalls. The FDA cleared almost 20,000 devices from 2005 to 2009. It's not so much that the 510(k) process is broken. The FDA instead let some devices through the 510(k) process that should have gone through the clinical scrutiny of the PMA process. Looking toward the future, the 510(k) pathway for many new devices will require clinical data.

Startups with Class III devices (PMA) under development are bailing out to Europe where the regulatory pathway is reasonable and predictable. Unfortunately, US patients will receive stifled innovation as a result. All the new technology clinical testing has moved to Europe. This will contribute to the Medical Tourism trend.

Is orthopedic innovation in danger of never coming back to the US? Yes, unless the US takes steps to reduce barriers and open up processes. The FDA must streamline product-testing and control processes. The FDA could potentially approve medical devices for safety, and then the market could determine efficacy, at least to a greater extent than at present. Europe practices this method.

On top of all this, the US government has thrown a 2.3% gross tax on Orthopedic companies for US revenues. Most companies are small and unprofitable, but have to send 2.3% to the feds while losing money each year. This gives patients another incentive to go abroad.

What is your company doing to weather the US innovation hurdles?

## The Future

In closing, these 7 disruptive trends above are already here. But much more change is coming at us in the future. Let me touch on a few.

The blockchain will revolutionize digital transactions with money and electronic health records forever. Startups and healthcare providers are just starting to experiment with the blockchain. Al will bring instant diagnoses into the home and 3rd world countries with devices such as the <u>XPrize Tricorder</u>. And <u>Amazon</u>, Google and perhaps <u>Apple</u> will disrupt healthcare in ways that we cannot see yet.

Be careful out there!

