

Orthopedics This Week

week in review

4 Best Orthopedic Hospital in U.S.? ♦ How does a 15 bed physician-owned hospital in fly-over country beat out every other ranked hospital in the United States—all 3,414 of them—to be number one in patient satisfaction? You might be surprised.

8 ACOs and the Creative Destruction of Healthcare ♦ Could the next few years be a period of “creative destruction,” as this fragmented fee-for-service system morphs into a more coordinated system of care? The answer is yes and the reason is A-C-O. Who will control ACOs—physicians or hospitals? That is the most important question of all.

12 Recon Revenue Growth Rates Drop ♦ The large joint reconstruction market has slowed further, taking revenues on the trajectory of a roller coaster. Read on to find out how both procedure volumes and pricing are taking revenues for a ride.

16 The Latest on Deep Vein Thrombosis ♦ Deep vein thrombosis has long been a thorn in the sides of orthopedic surgeons. Now, thanks to novel research into both anticoagulants and an innovative portable device, there is hope for patients and surgeons alike.



picture of success

29 Dr. Larry Hull ♦ Dr. Larry Hull, winner of the 2010 AAOS Humanitarian Award, has crafted a life out of the beauty of giving. Dr. Hull has affected multitudes, employing hundreds of people, establishing a local clinic, and building a school. Read on....



breaking news

- 20 New Stryker Subpoenas and Smack Down**
- CareFusion's Medtronic Suit On the Ropes**
- Stryker Expands Footprint Into Neuro**
- Helmets No Help?**
- Approaching LHB Tendinopathy**
- 510(k) for Vertebral Technologies' InterFuse**
- SAS Issues Reimbursement Alert**

For all news that is Ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Financial performance and valuation are, on some level, linked. Report better than expected sales, earnings and cash flows, pay down debt and strengthen stockholders' equity and valuations should rise. Not in this emotional market. OFIX is exhibit A. Too much healthcare uncertainty, we suspect.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Orthofix	13.51%	(4.33%)	On average OFIX has beat estimates by 16% each quarter for the last year. Cash flows up, debt down, cheapest valuation in ortho.
2	3	Medtronic	32.59	3.69	Second least expensive company in ortho, yet with 32% operating margins and the #1 share in spine MDT should rebound in 2011.
3	4	Integra LifeSciences	15.37	8.06	Market is looking for rising margins at IART. Despite only 5% sales growth, consensus is calling for 21% jump in earnings.
4	5	Stryker	24.71	3.14	Cash balances now at a whopping \$4.5 billion. How many small technology companies can \$4.5 billion buy?
5	6	Zimmer	27.69	(0.30)	Once upon at time, Big Blue was \$90/share with #1 large joint share and 27% operating margins. Today it is third cheapest ortho stock.
6	1	NuVasive	6.51	(33.40)	Spine is so out of favor. NUVA expected to post 280% jump in 4Q earnings (by analyst consensus) but still trades at 0.6 PEG.
7	8	CONMED	8.76	(2.30)	Second lowest price-to-sales ratio in ortho and is posting up very large earnings surprises.
8	9	Smith & Nephew	22.83	8.87	Plenty of buying interest and SNN is one of the best performing stocks. Pays a great dividend too.
9	NR	Exactech	10.79	14.20	Extremity revenues were the only bright spot this past quarter—up 31%. That plus attractive valuations prompted EXAC's return to Power Rankings.
10	7	Alphatec	1.59	(13.69)	Looking for a bottom. Every time (four times and counting) ATEC hits \$2 it bounces. Earnings are the key long term.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg	
1	TiGenix	TIG.BR	\$2.91	\$90	49.3%
2	Exactech	EXAC	\$16.65	\$215	14.2%
3	ArthroCare	ARTC	\$30.60	\$827	11.9%
4	Smith & Nephew	SNN	\$46.91	\$8,320	8.9%
5	Integra LifeSciences	IART	\$43.18	\$1,220	8.1%
6	Mako Surgical	MAKO	\$11.33	\$386	5.5%
7	Synthes	SYST.VX	\$123.54	\$14,662	4.0%
8	Medtronic	MDT	\$34.60	\$37,360	3.7%
9	Stryker	SYK	\$51.64	\$20,510	3.1%
10	Average			\$11,866	1.6%

Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg	
1	NuVasive	NUVA	\$23.75	\$936	-33.4%
2	TranS1	TSON	\$1.93	\$40	-18.9%
3	Alphatec Holdings	ATEC	\$2.08	\$184	-13.7%
4	CryoLife	CRY	\$5.77	\$163	-7.8%
5	RTI Biologics Inc	RTIX	\$2.49	\$136	-7.4%
6	Symmetry Medical	SMA	\$8.61	\$309	-6.8%
7	Kensley Nash	KNSY	\$27.12	\$234	-6.3%
8	Wright Medical	WMGI	\$13.96	\$547	-5.0%
9	Orthofix	OFIX	\$27.42	\$486	-4.3%
10	CONMED	CNMD	\$22.12	\$622	-2.3%

Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E	
1	Medtronic	MDT	\$34.60	\$37,360	10.33
2	Zimmer Holdings	ZMH	\$50.51	\$9,970	12.02
3	Kensley Nash	KNSY	\$27.12	\$234	12.07
4	Wright Medical	WMGI	\$13.96	\$547	12.28
5	Average			\$11,866	13.35

Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E	
1	Smith & Nephew	SNN	\$46.91	\$8,320	64.60
2	Synthes	SYST.VX	\$123.54	\$14,662	34.53
3	RTI Biologics Inc	RTIX	\$2.49	\$136	32.57
4	Symmetry Medical	SMA	\$8.61	\$309	22.49
5	NuVasive	NUVA	\$23.75	\$936	19.51

Lowest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG	
1	Orthofix	OFIX	\$27.42	\$486	0.59
2	NuVasive	NUVA	\$23.75	\$936	0.63
3	Medtronic	MDT	\$34.60	\$37,360	1.10
4	Zimmer Holdings	ZMH	\$50.51	\$9,970	1.18
5	Smith & Nephew	SNN	\$46.91	\$8,320	1.18

Highest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG	
1	Kensley Nash	KNSY	\$27.12	\$234	3.36
2	CryoLife	CRY	\$5.77	\$163	2.42
3	Johnson & Johnson	JNJ	\$63.83	\$175,290	2.18
4	CONMED	CNMD	\$22.12	\$622	2.09
5	ArthroCare	ARTC	\$30.60	\$827	2.02

Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR	
1	RTI Biologics Inc	RTIX	\$2.49	\$136	0.84
2	CONMED	CNMD	\$22.12	\$622	0.86
3	Orthofix	OFIX	\$27.42	\$486	0.88
4	Symmetry Medical	SMA	\$8.61	\$309	0.90
5	Alphatec Holdings	ATEC	\$2.08	\$184	1.07

Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR	
1	TiGenix	TIG.BR	\$2.91	\$90	321.16
2	Bacterin Intl Holdings	BIHI.OB	\$7.40	\$263	27.67
3	Mako Surgical	MAKO	\$11.33	\$386	10.12
4	Synthes	SYST.VX	\$123.54	\$14,662	8.13
5	Kensley Nash	KNSY	\$27.12	\$234	2.99

Advertise with Orthopedics This Week




[Click Here for more details](#)

or email tom@ryortho.com

Tom Bishow: 410.356.2455 (office)
or 410.608.1697 (cell)

Best Orthopedic Hospital in U.S.?

By Biloine W. Young



Dr. John Drawbert

How does a 15 bed physician-owned surgical hospital in fly-over country beat out every other hospital in the United States—3,414 of them—to be ranked number one in patient satisfaction? It would be tempting to ascribe the extraordinary 2009 ranking of the Oakleaf Surgical Hospital to the fact that some of the doctors there barter for payment with their Amish patients—exchanging rocking chairs for the setting of broken bones. But the answer is more complicated.

The Oakleaf Surgical Hospital of Eau Claire, Wisconsin, population 61,700, had its beginning in the 1990s when a group of independent surgeons reacted to the arrival at Eau Claire's Sacred Heart Hospital of the Marshfield Clinic, a huge multi-specialty clinic with 52 locations in Wisconsin. Believing that they "had to do something to get some

strength in numbers" the doctors made the bold and perhaps brave decision to compete with both Sacred Heart and Eau Claire's Luther Midelfort, which was a part of the Mayo Health System.

One of the founding orthopedists in a group of about 50, Dr. John Drawbert, remembers, "We knew we were going to alienate the big hospitals where all of us had worked but we also knew that our future with them was not on great ground. The biggest difficulty initially," he said, "was having the guts and gumption to do it. We had to convince the folks who for years had depended on the big hospitals that this was the right way to go."

Why a physician-owned hospital? Drawbert, who is also board chairman, says, "If I were a physician contemplating this I would ask, 'What is

the advantage?' The answer is that you can control the quality of care, you can control the quality of staff. You can control your environment—the way things flow. Any one of us who has worked in a big hospital knows that there you are thrown in with some staff members who care and with some who do not. Things can run incredibly slowly. The environment may not be great but you have no chance to improve it. Here [in your own hospital] you can completely change the environment to your liking. That to me is the best thing that a place like this has to offer."

Drawbert now does the same number of surgeries in one day that took him



Solutions for the Aging Spine

WWW.ALPHATECSPINE.COM




A source for information on the aging spine for physicians and patients brought to you by Alphatec Spine

www.agingspinecenter.com

Advertisement



Dr. John Drawbert

two or two and a half days to do in other hospitals. When he learned of the hospitals' Picker score ranking of 98%, he was not surprised. His response was to wonder what the staff could do to move it to 100%.

The Oakleaf Surgical Hospital, which opened in 2001, is located next to a shopping mall. The staff performs just under 8,000 surgeries a year, about 40% of which are orthopedic procedures. The hospital is licensed for 13 inpatient beds and 15 outpatient—defined as 23-hour beds. Approximately 80% of the patients are outpatient. There are seven operating suites, six of which run all day every day with the seventh reserved as back up in case of an emergency or overflow.

Drawbert credits the hospitals' philosophy of putting the patient first with its success. "We tell nurses and surgeons who come here from other hospitals that if you work here as you would in a normal hospital, it won't work. The goal here is to treat patients with the



Oakleaf Surgical Hospital

utmost respect." He also requires efficiency. He tells new hires, "Be very efficient, move things along quickly. We tell an employee that when you are doing a procedure that you should be thinking about step two and anticipating step three. You should be visually thinking about step four. If you cannot do that, you will not do well here."

The costs for surgery at Oakleaf are lower than at the other two hospitals in Ea Claire. As Drawbert explains it, "We feel that to be competitive, we need to be financially competitive. When we built this place it was to establish a quality of life for our patients and staff, not to make large distributions to the docs. We try to keep our costs less than the others."

Bob Lindberg, chief nursing officer, expands on the many ways Oakleaf caters to its patients. Impressions, he said, begin in the lobby, which, with its overstuffed chairs and couches, its rugs defining conversation groups, its desk with a computer for client use and the

prevalence of dark wood cabinetry give the lobby the look of a boutique hotel instead of a hospital.

ORTHOFIX RESPONDS

*Customer Focused, Patient Driven,
Always Responsive.*

www.orthofix.com

Cervical | Thoracolumbar | Interbody
Biologics | MIS

ORTHOFIX®
Spinal Implants

Advertisement



Dr. John Drawbert

When patients are checked in each is given a plush teddy bear along with a bag of toilet articles designed to make their stay more pleasant. When patients return from surgery, they are met in their rooms by their nurse bearing a vase of fresh flowers—delivered daily to the hospital by a local florist. A professional chef is in charge of the kitchen and patients order their meals, which are prepared to order, from menus.

Patient's rooms look more like hotel rooms than they do rooms in a hospital. Medical equipment and the ever-present TV are hidden in the same dark wood cabinets that are featured in the lobby.

Before patients are discharged from the hospital they are escorted from the recovery area to a café called the “bistro,” which resembles a Paris side-walk café. As Lindberg explained, “They sit down and have a meal with their fam-

ily before we release them to go home.” The menu lists burgers, patty melts, turkey and ham sandwiches, chef salads. Patients and one family member eat free. Lindberg explained that “the nursing staff wants to make certain that patients are eating before leaving the hospital.”

Lindberg credits the remarkable patient approval rating with the way the staff is treated at Oakleaf. “We make sure the staff needs are met which in turn allows them to take better care of their patients.” While the pay scale at Oakleaf is the same as that in the other hospitals in Eau Claire, Lindberg credits the hospital's success with the fact that “starting at 6 a.m. every morning we feed the staff and feed them well.”

In a small dining room equipped with steam tables and four round dining

When you need a cover which would you choose?

Synthetic Barriers

Allograft Membrane

Allograft Membrane Transplants for Surgical Coverings

The Change is Natural.

afcellmedical.com

AmnioClear
FROM
AFcell

Advertisement

tables the chef has Canadian bacon and sausage, cereals, a hot entree, rolls, juices and coffee available for all of the staff until 10:30 a.m. Everyone, the surgeons, housekeeping staff, nurses, eat here together. As Lindberg says, "We do not differentiate, our staff is our staff. All are sitting at the same table eating together." The breakfast is removed at 10:30 to make room for the lunch which consists of a salad bar and hot entrees. This remains in place until 2 p.m. when the afternoon snack is brought in. On the day this reporter visited, the snack was freshly baked chocolate-chip cookies. From 6 a.m. until three in the afternoon there is fresh food, constantly being replenished and brought in to the dining room for all of the staff. Drawbert notes, "We all eat together, same place and same food. There is no doctors' or nurses' lounge. That is what makes this flow so well—a team approach."

In 2007 the doctors sold 60% of the hospital to National Surgical Hospitals, in Chicago, which engages in the management of surgery centers concentrating in orthopedic surgery in partnership with physicians. "We knew there were going to be some Stark rule changes (the federal Physician Self-Referral Law) and we felt this was our best protection against Stark rules and our relationship with them," said Drawbert.

Oakleaf is growing. It just opened a wound care and hyperbaric chamber with two dive chambers. It will soon begin construction on a replacement facility. By law it cannot have any more operating rooms or inpatient beds but, as Drawbert noted, "we can put in an unlimited number of 23-hour beds." When the replacement is completed the wound and hyperbaric center will move into the present facility

along with administrative offices and a planned pain center.

Drawbert believes the legislation against physician-owned hospitals is "short-sighted and very slanted. Many studies of physician-owned hospitals show that the infection rate is about half that of a community hospital and the customer satisfaction scores are frequently double. It is not about cost and quality. It is purely a lobbying effort by the hospital association. I feel strongly that it is a bad piece of legislation."

And then there are the Amish who, in the main, do not buy health insurance. "The Amish will come in and ask what we charge," Drawbert reports. "We are able to take someone who does not have insurance and will do the procedure for less—depending on the needs of the patient. We have to run it through the business people first and

make sure that it is fair for the patients and everyone else." Drawbert added that he has gotten "some nice furniture from them."

A native of Florida, Drawbert received his medical degree from the University of Wisconsin and did a sports medicine fellowship in Salt Lake City. He is the team physician for the University of Wisconsin at Eau Claire and he and his partner have a sports medicine program that takes care of students at about 20 local high schools. He is a boyish 56 years old, with a full head of brown hair and a slim mustache. Married and a father of three, he moved to Eau Claire in 1986, planning to stay for a couple of years before moving to Madison. He has since fallen in love with the Eau Claire community and plans to remain here for the rest of his professional life. ♦

XIAFLEX[®]
collagenase clostridium histolyticum

To view the Full Prescribing Information, enroll for procedure training, access the product, and get information on administration and reimbursement...

Visit XIAFLEX.com or call
1-877-XIAFLEX (1-877-942-3539)



© 2010 Auxilium Pharmaceuticals, Inc. 0510-005.b

Advertisement

ACOs and the Creative Destruction of Health Care

By Walter Eisner

Could the next few years be a period of “creative destruction,” as the fragmented fee-for-service system will be transformed into a more coordinated system of care?

ACOs, otherwise known as Accountable Care Organizations (ACO) which were established in the Affordable Care Act (Act) to improve the quality of care for Medicare beneficiaries, are shaping up as the key change agent in health care service delivery.

According to an article by Robert Kocher, M.D. and Nikhil R. Sahni, B.S. (Kocher) in the November edition of the *New England Journal of Medicine*, how ACOs will affect physicians and patients depends on whether or not physicians are able to get themselves organized to influence how ACOs develop.



Robert Kocher, M.D./University of Washington

If physicians fail to organize, their interests will likely be usurped by hospitals, argues Kocher.



T.J. Takahashi/Wikimeida Commons

Profound Implications for Physicians

Under the Act, Medicare is launching a Shared Savings Program for groups of health care providers that join forces, with or without hospitals or health plans, to form ACOs that agree to take responsibility for the quality, cost, and overall care of a population of patients.

“The actions of physicians and hospitals during this period,” writes Kocher, “will determine the structure of the delivery system for many years. The implications will be profound for hospitals’ dominant role in the health care system and for physicians’ income, autonomy, and work environments.”

Will physicians control the ACOs by affiliating and contracting with hospi-

tals or will hospitals control them by employing physicians? Kocher says that whoever gains control will capture the largest share of any savings.

AMA Principles

The American Medical Association (AMA) thinks this development is important enough that the Association’s House of Delegates adopted principles regarding the establishment and operation of ACOs at the Association’s 2010 interim meeting of the House of Delegates, November 6-9 in San Diego.

The AMA principles emphasize that ACOs must be physician-led, place patients’ interests first, enable independent physician participation and ensure voluntary physician and patient participation.

Cecil B. Wilson, M.D., the group's president said:

"The AMA is committed to ensuring physicians in all practice sizes can lead and participate successfully in new models that allow them to provide the best care to their patients. For this to happen, significant barriers must be addressed, including a lack of resources, existing antitrust rules and conflicting federal policies."

The delegates asked the AMA to develop a toolkit that provides physicians with best practices for starting and operating an ACO, including how to develop governance structures, organizational relationships, and quality reporting and payment distribution mechanisms.

"Creative Destruction"

Kocher wrote that the next few years will be a period of "creative destruction," as the fragmented fee-for-service system will be transformed into an efficient and coordinated system of care.

That transformation, continued Kocher, will be driven by incentives for the development of the information systems and infrastructure necessary for better and more efficient management of chronic conditions. "Outpatient changes will be reinforced by hospital readmissions policies that improve handoffs and by initiatives to reduce the occurrence of hospital-acquired infections and 'never events'. The desired consequence of these changes is enhanced tertiary prevention, leading to substantial reductions in unnecessarily expensive specialty referrals and tests and avoidable complications."

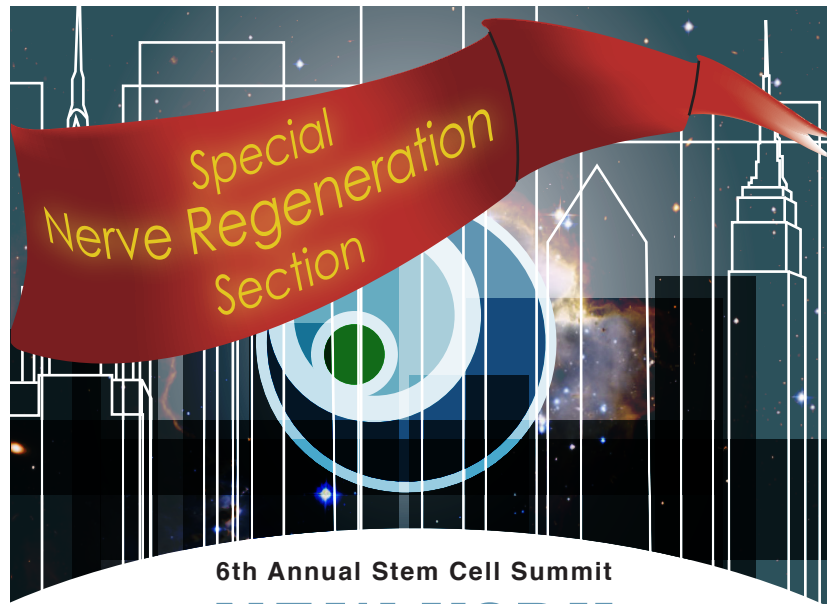
How specialty procedures such as hip and knee replacements will fare will depend on the data the new information systems gather. Medical device manufacturers and orthopedic providers have often told us that orthopedic procedures are preventative in nature and allow patients to mitigate or postpone long-term chronic conditions caused by musculoskeletal injuries. Bad knees, hips and spines don't do much to help a diabetic patient do their exercises.

Physician Controlled ACO

Specifically, Kocher describes what an ACO run by physicians might look like.

Such an ACO will "incorporate primary care practices structured as patient-centered medical homes and that can support new investments in information systems and care teams and can maintain service hours resembling those of retailers." According to Kocher, this will mean "major changes in the structure of physicians' practices, since even physician-group-based ACOs may include one or more hospitals, though they may instead contract with hospitals for specific services chosen on the basis of their relative value."

He says larger ACOs are likely to be contracted directly by payers to man-



6th Annual Stem Cell Summit
**NEW YORK
 STEM CELL
 SUMMIT '11**

Register Early and Save

If you haven't already saved the date of March 1, 2011, mark your calendar now. And if you want to ensure your spot at 2011's Stem Cell Summit AND save more than \$500, take advantage of our low early bird registration rate today. Preregistration is now open!

www.stemcellsummit.com

Advertisement

age the continuum of care. He says they are also likely to bear greater financial risk by receiving greater payments for the care of chronically ill patients and accepting at least partial responsibility for the costs of specialists' visits, tests, emergency room visits, and hospitalizations.

To control ACOs, physicians will have to overcome several hurdles, says Kocher.

The first is collaboration. "ACOs will require clinical, administrative, and fiscal cooperation, and physicians have seldom demonstrated the ability to effectively organize themselves into groups, agree on clinical guidelines, and devise ways to equitably distribute money. Nearly three quarters of office-based physicians, representing nearly 95% of all U.S. practices, work in groups of five or fewer physicians. Since much of the savings from coordinating care will come from successfully avoiding tests, procedures, and hospitalizations, the question of how to divide profits among primary care physicians and specialists will be contentious. Proceduralists who would end up losing income are likely to resist key structural changes."

Primary Care Docs v Surgeons

One needs look no further than the split between primary care physicians and surgeons during last year's health care debate. Or, the current debate over how the "doc fix" should be addressed.

According to a study conducted by researchers at the Mount Sinai School of Medicine in New York City and the James J. Peters Veterans Administration Medical Center in the Bronx, New York, published in the October 25 *Archives of Internal Medicine*, most doctors supported a shift in payments toward



RRY Publications

counseling and management compared with only 17% of surgeons. Support for shifting payments was less likely to be expressed by physicians in office-based settings, practice owners and those with fewer patient care hours.

Another hurdle identified by Kocher involves the sophisticated information technology (IT) systems and skilled managers needed in order to hold clinicians accountable. "Historically, doc-

tors have not shown the willingness to assume more capital risk or to invest in overhead. Finally, memories of the failed capitation models of the 1990s may make some physicians hesitant to participate."

Hospital Challenges

The hurdles for the hospitals, according to Kocher, will be their need to trade near-term revenue for long-term sav-



Advertisement

ings. “Hospitals are typically at the center of current health care markets, and by focusing on procedures and severely ill patients, most have been fairly profitable. Building an ACO will require hospitals to shift to a more outpatient-focused, coordinated care model and forgo some profits from procedures and admissions. Hospitals’ decisions will be further complicated if payers do not change their payment models similarly and simultaneously.”

Another hurdle for hospitals is that they have generally struggled to operate outpatient practices effectively and may have difficulty designing ACOs. “Acquiring practices and hiring physicians as employees typically reduce the physicians’ incentive to work long hours and, therefore, reduce their productivity,” said Kocher.

Which model wins out will likely be determined by local market conditions. In geographic areas where physician are scarce and well-established hospital-based health systems exist, hospitals are likely to dominate, says Kocher. In areas where well functioning physicians

groups with working IT systems and effective management systems exist, physicians are likely to dominate.

Crossroads

Sitting on the sidelines will be a bad long-term strategy for physicians, says Kocher.

“First, health care reform has passed, bringing extensive changes, and it would be very difficult to repeal or modify the [Act] so as to delay reforms. Congress’s pay-as-you-go rules would require lawmakers to find equivalent savings if they discarded ACA provisions that were expected to save health care dollars—especially at a time when there is tremendous pressure to use any available savings to reduce the deficit. Moreover, policies pursued by the new Independent Payment Advisory Board will probably increase the pressure on providers to coordinate care and form ACOs. Finally, private health plans are facing even more pressure from employers and state insurance commissioners to control premiums.”

Kocher says once the new payment system and other changes included in the ACA transform the relationship between hospitals and physicians, the new order will become entrenched and persist until the next period of creative destruction. Therefore the actor who moves first effectively is likely to assume the momentum and dominate the local market.

Health care systems changed dramatically in the early 20th Century with the introduction of antisepsis and the increasing safety and success

of surgery. “Hospitals gained power as they became associated with hope and health rather than fear and death. Now, after decades of hospital hegemony, we stand at another crossroads; physicians may be able to gain market leadership if they move first. How the development of ACOs plays out over the next few years is likely to have lasting implications for the practice of medicine, patients’ experience of health care, and health care costs in the United States.” concluded Kocher.

For more information regarding ACO’s on the CMS Web site, click here:

<https://www.cms.gov/OfficeofLegislation/Downloads/AccountableCareOrganization.pdf> ◆

Recon Revenue Growth Rates Drop

By Scott Ellison, PearlDiver Large Joint Reconstruction Senior Analyst

Large joint industry suppliers sold \$2.7 billion of products in the third quarter of 2010 (3Q10), missing our forecast of \$2.9 billion. We have, therefore, lowered our forecast for the large joint reconstruction industry to \$3.1 billion from 3.3 billion for the 4Q10. We have decreased our forecast for the year from \$12.0 billion to \$11.6 billion as a result of both the third quarter results and our new fourth quarter estimate.

Before this past quarter's report, large joint implant suppliers were stating that sales growth rates in 2Q were, in fact, slowing after what had appeared to be six months of rebounding sales growth rates. At the end of March 2010, large joint reconstruction revenues had grown 8.9% year-over-year (YOY). But as suppliers added up the numbers for the June quarter, they found that growth rates had slipped to 4.5%. The double whammy of slower procedure volume growth and pricing pressure really hit in the September quarter.

For the three months ended September 30, 2010, sales of large joint reconstruction products grew 0.8% on a YOY basis. Both knee and hip revenues increased at the same rate, growing at 0.8% YOY excluding the impacts of foreign currency.

The First Drop

As Chart 1 illustrates, industry sales rebounded significantly during the fourth quarter of 2009 and continuing into the first quarter of 2010. During the second quarter, growth, while



Morguefile

lower, was still respectable. Then came the third quarter. Looking at this chart, the first thought is that the large joint industry is on a growth rate roller coaster—UP and DOWN, with stomach churning g-forces.

Of course, the down turn from 3Q08 to 2Q09 was the First Drop on the Large Joint roller coaster ride. That was a 9.3% plummet which makes this year's 3.7% dip in 3Q10 seem much more benign.

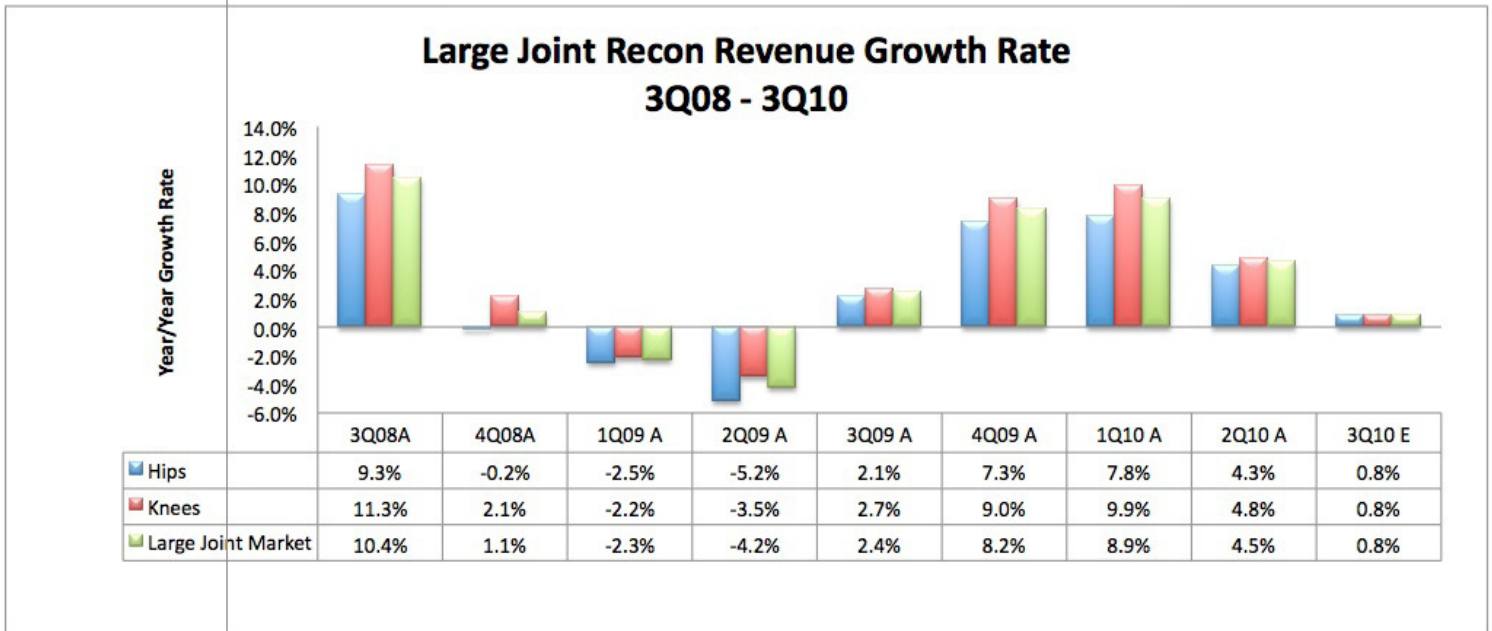
Much of the differences in the magnitude of growth rate change can be attributed to different macro factors. In late '08, for example, Zimmer reported that its revenues had declined by 4.8% on a YOY basis. Wright Medical reported that overall large joint reconstruction implant sales had increased 16.1%, while Biomet reported that its large joint implant sales were higher by 8.3%. So, while the overall num-

bers during '08 First Drop were negative in the aggregate, the impact on specific suppliers was much more varied and lumpy.

This time, however, the pressure on sales growth appears to be more universal. This time, for example, the fastest grower among all large joint implant suppliers was Biomet with a (still modest) 2.3% rate of growth. Similarly, the greatest decline was reported by (again) Zimmer and that was 2.1% (of manufacturers with market shares of 2% or greater). So, unlike the period from 3Q08 – 2Q09, market pressures were more evenly distributed and seemed to affect a broader swath of the industry. Finally, we would note that all of these changes are occurring in the seasonally slow third quarter.

David Dvorak, President and CEO of Zimmer, probably summarized the

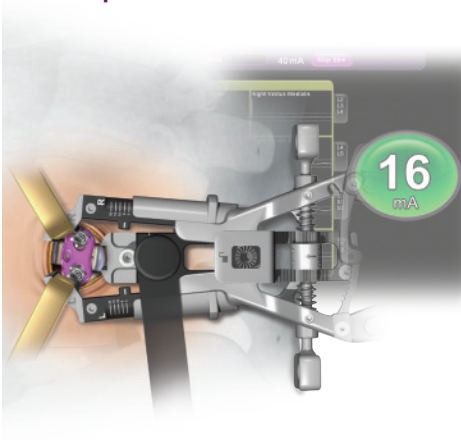
Chart 1: Large Joint Reconstruction Market Revenue Growth (YOY)



Source: Company reports

XLIF® – Expanded applications with procedural sophistication

eXperience counts.



Corpectomy | Deformity | Spondylolisthesis | Degenerative Disc Disease | Adjacent Segment Disease

eXperience it for yourself at www.nuvasive.com/experience



©2010, NuVasive, Inc. All rights reserved.

Advertisement

macro environment for large joints well when he pointed to “High unemployment has resulted in expiring health insurance and COBRA subsidies in the U.S., as well as a decline in enrollment in private health plans” as the principal reasons for slower procedural growth and more difficult pricing. Dvorak continued; “Demographic analysis suggests that these trends have had a particularly notable impact on the non-Medicare potential patient base for joint replacement procedures, those between 45 and 65 years of age.”

Dominic Caruso, Chief Financial Officer of Johnson & Johnson, also cited many of these same factors but went a little further when he said; “we did see a slowdown overall in hospital admissions and also in elective procedures.”

In our view, high unemployment rates will continue to depress procedure growth rates. Specifically, the respected

economic forecasting firm, Financial Forecasts Center LLC., is stating that unemployment rates in the U.S. are likely to remain between 9.5% and 9.6% during the remainder of 2010.

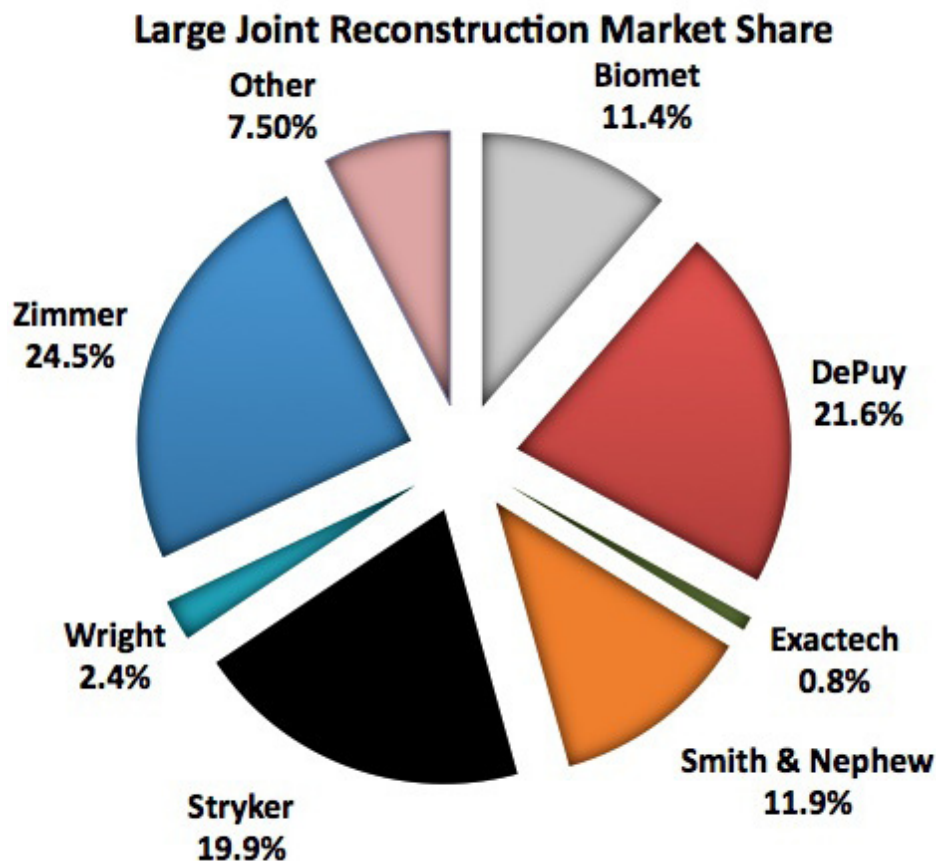
Louise Mehrotra, Vice President of Investor Relations at Johnson & Johnson, commented that U.S. pricing in hips and knees had declined 1% to 2% from levels reached in Q210 versus the previous quarter while international pricing was down 1%. Zimmer’s management stated that their average selling prices declined 1.4% and Biomet’s management reported that they also experienced pricing decreases in both the U.S. and abroad.

Pricing pressures and flattening procedure growth combined to create the flat revenue growth rates in 3Q10. The following list ranks all major large joint implant suppliers according to their 3Q10 sales growth rate.

• Biomet	+ 2.3%
• DePuy	+ 2.5%
• Smith & Nephew	+ 3.2%
• Stryker	+ 0.9%
• Wright	(0.9%)
• Zimmer	(2.1%)

These manufacturers combined accounted for 0.9% YOY revenue growth in overall large joint reconstruction, 0.8% in hips, and 1.1% in knees. Looking at specific companies, while Zimmer remains the leader in large joint reconstruction by market share, this position has continued to erode. Two years ago, Zimmer held 26.2% of the large joint reconstruction market. This percentage had fallen to 24.8% as of 3Q09, and now sits at 24.5% as shown in Chart 2.

Chart 2: Large Joint Reconstruction Market Share as of 3Q10



Source: Company reports and PearlDiver Technologies, Inc. estimates

Individual Company Commentary

Zimmer, Inc.

Zimmer, Inc. reported that its shipments of large joint reconstruction products resulted in \$690.0 million revenue for the September quarter which was down 2.1% from prior year levels and well below our \$770.2 million estimate. Sales of hip recon products fell 0.3% from prior year levels to reach \$287.0 million. One bright spot in the quarter was the rising sales contribution from Zimmer's Continuum Acetabular Cup System. Sales of knee recon products fell 3.4% from prior year levels to reach \$403 million despite advances in the rollout of Patient Specific Instruments.

DePuy, Inc. (a Johnson & Johnson company)

DePuy, Inc. reported that revenues for shipments of large joint reconstruction products reached \$656.2 million for the September quarter which represents a 2.5% rise over the prior year levels but also came in below PearlDiver's \$695.1 million sales estimate. Sales of hip recon products rose 2.0% to \$301.9 million on the bases of rising acetabular and cementless system sales. Sales of DePuy's knee recon products increased 3.0% to \$354.3 million.

Stryker, Inc.

Stryker, Inc. reported that sales of large joint reconstruction products reached \$597.2 million for the September quarter, up 0.9% from prior year levels. Stryker's reported sales also fell short of PearlDiver's estimates. Sales of hip recon products rose 2.0% YOY to \$286.1 million while sales of knee recon products remained flat at \$311.1 million.

Smith & Nephew, Inc.

Smith & Nephew, Inc. reported large joint reconstruction product sales of \$344.6 million, a 3.2% over the third quarter of 2010 falling below PearlDiver estimates of \$360.6 by 4.4%. Hip repair product sales remained flat YOY at \$158.0 million with continued efforts to show differentiation of the Birmingham Hip Resurfacing System. Smith & Nephew reported knee repair product sales at \$186.6 million, an increase of 6.0% YOY with contributions from the Verilast bearing technology.

Biomet, Inc.

Biomet, Inc. reported that sales large joint reconstruction product rose 2.3% to \$350.6 million for the August quar-

ter (Biomet's first quarter of fiscal 2011). Sales of hip recon products remained essentially flat although both the Taperloc and Ringloc product contributed to sales in the quarter. Sales of knee recon products rose 4% on continued sales growth of the Vanguard Complete Knee System and the E1 antioxidant tibial bearings.

Looking Forward

Clearly macroeconomic forces are and will continue to dampen procedure growth rates and pricing. As a result, we are forecasting that the fourth quarter's revenues will be less than we'd originally forecast and that the outlook for 2011 and 2012 will also be more modest. In summary, we expect that:

- The large joint reconstruction market will grow at a slower rate of 3.1% YOY
- The hip reconstruction market will grow at a slower rate of 3.2% YOY
- The knee reconstruction market will grow at a slower rate of 3.0% YOY
- Gains on a per company basis shown in Table 1 ♦

Table 1: Forecasted Hip and Knee Repair Global Revenues (\$ in millions)

	3Q10 E	4Q10 E	2010 E	2011 E	2012 E
Zimmer	\$690.0	\$807.6	\$3,044.8	\$3,129.9	\$3,269.8
Hips	\$287.0	\$336.3	\$1,256.6	\$1,288.0	\$1,326.6
Knees	\$403.0	\$471.2	\$1,788.2	\$1,841.9	\$1,943.2
DePuy	\$656.2	\$724.6	\$2,703.7	\$2,902.8	\$3,080.1
Hips	\$301.9	\$332.5	\$1,225.0	\$1,298.5	\$1,363.4
Knees	\$354.3	\$392.1	\$1,478.7	\$1,604.4	\$1,716.7
Stryker	\$597.2	\$693.3	\$2,517.2	\$2,719.3	\$2,904.1
Hips	\$286.1	\$326.4	\$1,188.4	\$1,277.5	\$1,354.2
Knees	\$311.1	\$366.9	\$1,328.8	\$1,441.8	\$1,549.9
Smith & Nephew	\$344.6	\$395.0	\$1,495.3	\$1,567.7	\$1,664.5
Hips	\$158.0	\$183.5	\$692.6	\$716.9	\$745.5
Knees	\$186.6	\$211.5	\$802.7	\$850.9	\$918.9
Biomet*	\$350.6	\$369.9	\$1,471.6	\$1,569.7	\$1,692.6
Hips	\$143.2	\$153.5	\$598.8	\$622.7	\$652.2
Knees	\$207.4	\$216.4	\$872.8	\$947.1	\$1,040.3
Wright	\$69.5	\$78.0	\$302.2	\$317.8	\$339.1
Hips	\$40.0	\$46.0	\$176.4	\$184.8	\$196.8
Knees	\$29.5	\$32.1	\$125.8	\$133.1	\$142.4
Exactech	\$22.2	\$28.9	\$107.2	\$112.3	\$119.4
Hips	\$6.6	\$7.0	\$29.3	\$30.2	\$31.7
Knees	\$15.6	\$21.9	\$77.8	\$82.1	\$87.7
Total	\$2,730.3	\$3,097.3	\$11,642.0	\$12,319.6	\$13,069.5
YOY % Growth	0.8%	3.1%	4.3%	5.8%	6.1%
Hips	\$1,222.8	\$1,385.2	\$5,167.0	\$5,418.4	\$5,670.4
Knees	\$1,507.5	\$1,712.1	\$6,475.0	\$6,901.1	\$7,399.1

* adjusted to match fiscal year of Jan 1 to Dec 31

Source: Company reports and PearlDiver Technologies, Inc. estimates

The Latest on Deep Vein Thrombosis

By Elizabeth Hofheinz, M.P.H., M.Ed.

There are many stages at which a successful operation can be deemed unsuccessful—in the OR, during physical therapy, even later. Most times, however, the unsuccessful event doesn't involve death. In the case of the longstanding problem of deep vein thrombosis (DVT), however, this may be the case. Now, say our experts, there are new, inventive options for dealing with this dangerous condition.

Even if you have performed joint replacement surgery—the most likely operation in which DVT could occur—thousands of times, you must still be vigilant with regard to this serious condition. Dr. Rick Strain, President of Orthopaedic Associates of South Broward and a DVT expert, states, “The rate of DVT—a blood clot that typically occurs in the thigh or calf—in joint replacement surgery is an amazing 40 to 50%. Before we started using prophylaxis we had many patients dying from DVT because of pulmonary embolism.”

So what brings on this ominous situation? “DVT typically occurs,” says Dr. Strain, “when the blood flow rate of blood decreases, if the walls of the blood vessels are somehow damaged, or if there is coagulation. Things are only made more dangerous if the patient is obese, is a smoker, or has had DVT in the past. The classic situation in orthopedic trauma is where prolonged immobility leads to DVT and increases the chance of a pulmonary embolism. This, and because our surgeries are at such high risk for the condition, are why orthopedists—and the American



Medical Compression Systems Inc.

Academy of Orthopaedic Surgeons (AAOS) in particular—have taken the lead in this arena.”

Unfortunately with DVT, there aren't always obvious signs that alert the surgeon to the problem. Dr. Strain: “While

patients may report pain in the area of the clot, very often DVT is asymptomatic. For this reason, the majority of our efforts have been focused on preventing the condition before it arises. To this end, orthopedists usually employ some combination of anticoagulant, com-

“At present there are several trials comparing new medications against Lovanox, the most widely used DVT prophylaxis. One of the most promising now underway is a blinded pharmacokinetics trial on an oral 10a inhibitor.”



Medical Compression Systems Inc.

pression socks, and early postoperative movement.”

Dr. Strain, who has worked on drug trials for DVT, notes, “Aspirin and Coumadin are frequently used as anticoagulants, and can help prevent DVT in the right patients. Both have side effects that are documented in the AAOS guidelines. At present there are several trials comparing new medications against Lovanox, the most widely used DVT prophylaxis. One of the most promising now underway is a blinded pharmacokinetics trial on an oral 10a inhibitor. The plus here is that with an oral 10a inhibitor you don’t have to do a blood test. Compare this to Coumadin, which is tried and true, but requires regular blood draws and monitoring; this means that you run the risk of the patient not being sufficiently anticoagulated and developing a clot. And Cou-

madin may have other issues. Fifteen years ago a form of Coumadin was used to make rat poison; it was considered so dangerous that they don’t even make rat poison out of it anymore.”

So how to predict who is at the highest risk of developing DVT? “Risk profiling is mandatory in most hospitals these days, and includes things such as the patient’s weight, mobility, previous history of DVT, cancer, and use of birth control pills. Low risk patients tend to be given compression stockings, as opposed to those at higher risk, who are most often treated with low molecular heparin.”

But, says Dr. Strain, the best is yet to come...and it has nothing to do with a drug. “When I was a resident at Massachusetts General I worked alongside Dr. William Harris, the originator of

DVT research. At that time—it was the 1970’s—he used a sequential compression device that was showing promise. Now there is a new device that is similar, but much improved. In fact, in total hip replacement it seems to be as or more effective than any drug agents—with no side effects. This could be a real game changer for orthopedic surgery.”

The principal investigator on the aforementioned device trial is Dr. Clifford Colwell of Scripps Health in San Diego, California. He states, “External devices that increase blood flow and decrease the risk of DVT are the future, avoiding the risks of anticoagulants. They have been, however, hard to develop to the

Win the battle for spinal space.

Superion™

The future of Interspinous Spacers is out there...
VertiFlex® is currently seeking Superion IDE Clinical Trial Investigators. If you are interested, please contact us at (949) 940-1492 or email us at clinical@vertiflexspine.com.

Investigational Use Only in the USA
www.vertiflexspine.com

VertiFlex®

Advertisement

“Now, an Israeli company has developed a portable device, Active Care plus AFT, that is so successful that many physicians in our hospital no longer use anticoagulants...we only use this product.”

point where patients can wear them continuously because their motors tend to be bulky (you can't use them out of bed or take them home from the hospital). Now, an Israeli company has developed a portable device, Active Care plus AFT, that is so successful that many physicians in our hospital no longer use anticoagulants...we only use this product.”

The randomized, prospective research on this external pneumatic device, published in the *Journal of Bone and Joint Surgery*, was initiated by a pilot study at Scripps. Dr. Colwell: “We then enrolled 400 total hip arthroplasty patients in an expanded trial in nine centers in the U.S. The safety record has been outstanding and the device has been equal in efficacy (rate of DVT/PE) to the anticoagulants. We found that when compared to the low-molecular-weight heparin, commonly used in orthopedic surgery, this device resulted in significantly less major bleeding.”

And while it may not know where you live, this device is somewhat brainy. Dr. Colwell: “The device is Velcroed from the ankle to below the knee, and has a motor that can clip on to someone's belt like a cell phone. The cardiac surgeon who designed the device created a chamber in the device itself that is sensitive to the blood flow in the veins. The blood gets to the heart by way of the veins and the heart's pump takes it out to all parts of the body and then due to muscle contractions it is returned again to the heart. The device's chamber reads the flow and coordinates the

greatest—during inspiration at which time you increase the pressure in the right chest—and the expiration phase during which you decrease pressure in the right chest and thus increase flow in right heart. The chamber senses whether someone is in an inspiration or expiration phase and determines when the flow is highest and lowest; during inspiration it doesn't pump...during expiration it pumps.”

“This product has been shown to be 10% more efficient than other devices that are currently available. Also remarkable is that it has an LCD monitor to record patient compliance. If the person doesn't wear it, then it will not work; thus, it will be obvious to the doctor if the patient is not complying with treatment. If the person devel-

many hours they used the device. This is obviously something that insurance companies are glad to see; anywhere from one-half to three quarters of American insurance companies are now paying for it. The bottom line is that we're interfering with nature's protectiveness. You have a big wound and then you throw an anticoagulant into the mix...mechanical devices are where we need to go.”

To help the orthopedic community get there, Dr. Colwell (who has no financial involvement in the project) is participating in a nationwide registry to help validate the Active Care plus AFT. “Several centers across the country are using the device with up to 3,000 patients to ensure that in the hands of 'regular, treating' orthopedists, i.e., those not



Medical Compression Systems Inc.

involved in a trial, that it is as good as it was in the trial. We are creating a registry in order to establish exact rates of clinical DVT/PE up to three months post surgery using the device in the routine hospital setting.”

But Dr. Colwell knows that there is still a place for use of anticoagulants in the orthopaedic population. “This device is only for the prevention of DVT/PE and not for established DVT/PE. Another example are patients with atrial fibrillation—and there are many—who need to be on anticoagulants. The problems with the oral drug we have available now are the increased bleeding, the requirement of constant monitoring, the fact that many drugs and foods interfere with the anticoagulants, and the overall cost. The oral direct10a and thrombin inhibitor trials underway now are very exciting because they address two of these issues: they don’t require constant monitoring and should be less expensive. The bleeding risk is similar to the existing anticoagulants, however.”

With regard to the selection of a drug to prevent or treat DVT, Dr. Colwell gives a bit of history, “In 1985 there was an NIH [National Institutes of Health] conference on DVT that included a review of the related literature; the finding was that there was a gross underutilization



**SOLVED^{BY}
SYMMETRY**

Symmetry Medical is your single source for solutions delivered on time, on target and on budget. **No matter what challenges you're facing, consider them SOLVED by Symmetry Medical.**

Implants • Instruments • Cases
Design • Development • Production
www.symmetrymedical.com

Advertisement

of prophylaxis in orthopedic surgery. At that point NIH recommended that guidelines be developed so that patients would be at reduced risk of DVT. I participated in a number of drug and device trials that were part of establishing the best methodology to prevent this phenomenon in orthopedic populations. There have been guidelines developed by way of both The American College of Chest Physicians and The American

Academy of Orthopaedic Surgeons that help the patient, the doctor and the hospital in utilizing the best practice now available.”

As we move forward with new trials and options, it is likely that the recommendations for the prevention and treatment of DVT will be altered to some extent. But alas, that is progress. ♦

company

\$1.6 Million for RepRegen

Michael Connors/MorgueFile

Maybe *this* will make those palace guards smile...London-based RepRegen Ltd., a company using technology to mend and regrow tissue in vivo, has announced that it has raised \$1.6 million to further its growth. The financing, led by existing investor Imperial Innovations, included Longbow Capital and others. RepRegen will use the funds to further the product development pipeline, including regulatory approvals, commercialization programs and preparation for relevant post market clinical studies.

RepRegen has repair and regeneration technology in two platforms, one of which is focused on bone and other hard tissue. The second platform is focused on muscle and other soft tissue. RepRegen is now commercializing the first product of its hard tissue repair and regeneration platform, StronBone bone graft substitute bioactive glass with strontium. StronBone is targeted for trauma and spine applications, as well as craniomaxillofacial applications.

“This cash infusion positions us to accelerate other product development and commercialization plans for our product platforms,” said Ian Brown RepRegen’s CEO, in the news release.

“This funding demonstrates the strong support for the company and our ‘smart’ biomaterials represent great new medical device products for the medical biomaterials sector,” added Chairman Dr. Stephan Rietiker.

Ian Brown told OTW, “StronBone has already received European CE Marking approval. The team at RepRegen is currently in the process of preparing a U.S. FDA submission which we anticipate will be completed in December 2010. The team has developed clinical study protocols to be initiated following the launch of StronBone in Europe.”

—EH (November 17, 2010) ♦

Stryker Expands Footprint Into Neuro

juditu/morgueFile.com

Stryker leader Stephen MacMillan is fond of metaphors. He’s been telling investors that Stryker’s large medical device “footprint” is allowing the company to prosper in tough economic times.

Stryker’s footprint is about to get bigger as the company recently announced it will use some of its \$4 billion in cash to acquire Boston Scientific’s Neurovascular unit for \$1.5 billion. Boston Scientific is run by former Zimmer CEO Ray Elliott.

The neurovascular business makes devices used to treat stroke, aneurysm and other vascular conditions in the brain.

The worldwide market for neurovascular products, which include implantable devices used for the minimally invasive treatment of hemorrhagic and ischemic stroke, is about \$900 million and is growing 9% to 10% annually, according to a Stryker statement. Sales in 2009 for the division reached \$348 million.

Extension of Core Business

MacMillan told analysts that he views the acquisition of the neurovascular business as an extension of Stryker’s core business, but on a new platform. MacMillan stated Stryker already offers complementary neurosurgery products to many of the same customers called on by Boston Scientific Neurovascular. “Going forward, the proposed acquisition allows us to substantially broaden our product offerings and relevance to these customers,” said MacMillan.

Diversification From Ortho

This move, according to Jefferies analyst Raj Denhoy, further diversifies Stryker away from orthopedics.

“From Stryker’s perspective, one could question the rationale of the transaction given the diversion from its current end market competencies and a lack of cost synergies. However, man-

agement made clear that diversification of the portfolio was a key driver in its pursuit of the asset. One need only to look at Zimmer's [recent quarterly] results, specifically the continued deterioration in the orthopedic markets, to justify this strategy," wrote Denhoy in an investor note.

Stryker noted that the neuro business has operating margins in excess of 30%, above Stryker's 25% range. The deal is expected to close before the end of the year. The business will be headed by Mark Paul, who is currently President of Boston Scientific Neurovascular. He will report to Stryker's CFO, Curt Hartman.

—WE (November 17, 2010) ♦

legal

Medtronic Launches European Inventor's Portal



Light bulb/morgueFile.com

Medtronic is seeking to increase innovation in medical technology...in Europe.

The company announced the launch of Medtronic Eureka on November 15. Eureka is a European web-based portal for inventors to submit their ideas to Medtronic for evaluation.

According to a company press release, the portal is a "streamlined, single entry point for idea submissions, to enable strong partnerships between Medtronic and European inventors to bring novel product concepts to market. It responds to the need of physicians for a clear, simple process to have the potential of their ideas evaluated by professionals."

The program can be accessed at www.MedtronicEUreka.com. A statement on the site states that all idea submissions are reviewed by highly trained experts and inventors are offered the same legal protection no matter where he or she is working.

Inventors are informed of Medtronic's initial decision regarding their idea within approximately three months of submission. If evaluation doesn't reveal a fit for Medtronic, inventors can consent to allow the same idea to be evaluated by MD Start, an independent medical device incubator based in Switzerland.

Should Medtronic be interested in a submitted idea, the company will contact the inventor to discuss arrangements to obtain legal rights to the idea.

—WE (November 18, 2010) ♦

InQu®
BONE GRAFT EXTENDER & SUBSTITUTE

INTRODUCING
MATRIX moldable strips

- Unique biosynthetic polymer structure
- Supports endochondral bone formation
- Easily cut or shaped for combination with autograft in spinal fusion procedures
- Compressive resistant
- Demonstrated biocompatibility

ISTO
Technologies, Inc.

www.istotech.com
1-888-705-ISTO

Advertisement

New Stryker Subpoenas and Smack Down

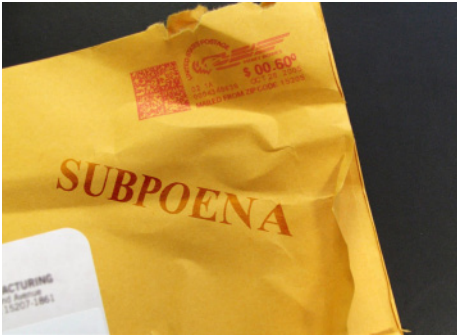


Photo manipulation by RRY Publications. Source: MorgueFile

Stryker has received two subpoenas from the U.S. Department of Justice related to the sales and marketing of the company's "PainPump" and the OtisKnee device. The company disclosed the subpoenas in its third quarter SEC filing.

The OtisKnee subpoena pertains to alleged issues prior to the company's acquisition of OtisMed in November 2009. The OtisKnee device is not on the market as it awaits FDA approval.

Boston Smack Down

On another legal front in Boston, where the feds are prosecuting the company and former employees of the company's Biotech division for allegedly lying to the FDA and illegally promoting OP-1, prosecutors are taking Stryker to task for a motion the company and defendant Mark Phillip filed to have charges dismissed.

"[The] motion labors under the misapprehension that neither he [Phillip] (nor Stryker Biotech who employed him as its president) had a duty to the FDA, the government agency that regulated Stryker Biotech's medical devices, to make truthful disclosures and/or keep truthful documents regarding the num-

ber of patients treated with OP-1 Putty," the prosecutors stated. "Stryker Biotech had such a duty, and [broke the law] by taking steps, including procuring a bogus legal opinion, to cover up the falsity of Stryker Biotech's 2007 annual report to the FDA regarding OP-1 Putty, and conceal facts in connection with the to-be-filed 2008 annual report."

—WE (November 16, 2010) ♦

CareFusion's Medtronic Suit On the Ropes

CareFusion Corporation has failed to prove that Medtronic tried to illegally dominate the vertebroplasty and kyphoplasty markets.

Judge Lucy Kohl of the U.S. District Court for Northern California issued the ruling in early November, but gave CareFusion a month to amend the company's original complaint.

Kohl ruled that the complaint fails to show how Medtronic's allegedly anti-

competitive conduct harms both competition and CareFusion.

CareFusion announced its entry into the kyphoplasty market on March 15, 2010, with its own product and a lawsuit against Medtronic. CareFusion waited to enter the market until the original kyphoplasty patents had expired and then launched a preemptive legal strike to convince a federal judge that Medtronic/Kyphon used invalid patents to gain a near monopoly in the market.

Judge Kohl: Where's the Harm?

Judge Kohl didn't buy it. She wrote:

"CareFusion's only allegations are that Defendants made public statements about protecting and enforcing their intellectual property rights. CareFusion has not alleged that Defendants made direct threats of litigation against them or exacted a license agreement in exchange for not bringing suit. Thus, Defendants' conduct does not rise to the level of bad faith patent enforcement."



Photo by David Kitchenham/Source: MorgueFile

“Moreover, it is not clear how Defendants’ public statements regarding defending its intellectual property have caused any injury to CareFusion,” she wrote. “CareFusion is not defending itself in a suit, but rather is the party initiating the litigation.” Waiting for the kyphoplasty patents to expire before entering the market and claiming damages seemed to hurt CareFusion’s case as Judge Kohl wrote:

“CareFusion did not enter the kyphoplasty market until April 2010, leaving its allegations of harm highly speculative and indirect. CareFusion does not explain why it did not enter the market when, on its own allegations, it was ready to do so ‘for at least two years’ prior to the expiration of the patents in February 2009. ...[I]t is not clear to the Court how CareFusion can plausibly allege lost sales from Defendants’ acquisition of patents and other companies at a time when CareFusion was not in the market.”

For now, CareFusion’s strategy to couple its product introduction with a lawsuit against the largest competitor in the market appears to be on the ropes.

—WE (November 16, 2010) ♦

large joints

Window of Opportunity to Prevent Falls

Falls during the recovery period in a hospital can mean complications and setbacks for patients and serious consequences for the facility. A new study presented at the 2010 Annual Meeting of the American College of

Rheumatology in early November offered some new insight into the specific risk factors that contribute to falls.

The study, by the Quality Research Center from the Hospital for Special Surgery (HSS) in New York, including rheumatologist Lisa A. Mandl, M.D., looked at patient records from HSS dating back from 2000 up to last year.

They found that patients who underwent total hip replacement had higher rates of serious falls during recovery time at the hospital. This was in contrast to other orthopedic surgeries.

According to AAOS (American Academy of Orthopaedic Surgeons) over 190,000 total hip replacements are performed each year in the United States. And the CDC (Center for Disease Control and Prevention) says falls are a major risk for seniors, with one out of three adults over 65 sustaining a fall each year. The CDC also reports

that among this age group, falls are the leading cause of injury death, with over 18,000 older adults dying from injuries sustained from unintentional falls.

But the review also revealed other specifics that could help hospitals and doctors identify where prevention efforts should be focused.

The data showed that patients recovering from total hip replacement suffered more serious falls and that these serious falls happened more often at two days post-op, as compared to when less serious falls occurred, generally four days after surgery.

Mandl said in a press release statement that total hip replacement patients should be closely monitored, especially during this window of time when serious falls generally occurred. The study noted no association between fall rates and demographic specifics like age, gender and body mass or hospital



Window/Wikimedia Commons

that the study was appropriately powered for statistical analysis.”

He also told *OTW*, “Biceps tendon pathology is [a] very common source of shoulder pain. If a patient continues to have bicipital pain after non-surgical treatment, there are surgical treatment options have been shown to effective. There are a variety of surgical procedures that have been described, but the author’s preferred technique is the open subpectoral tenodesis with interference screw fixation in the appropriate patient.”

—EH (November 18, 2010) ♦



Baby on Stork/Creative Commons

trauma

New Arrivals in Wound Care

This week saw two companies announce launches of new wound care products.

3M Skin & Wound Care welcomes back its line of wound products known as the 3M Cavilon Professional Skin Care line. It encompasses a full range of products, all designed to shield skin from adhesive trauma, moisture and friction. In preparation for the re-launch, 3M surveyed both caregivers and clinicians and created a system of identification on the packaging to ease the selection process.

Cavilon antifungal cream will be the first new product launched from the line, with more planned for 2011. These will join Cavilon’s No String Barrier Film which is used to prevent friction and the risk of pressure ulcers.

According to the National Nursing Home Survey of 2004 up to 28% of nursing home residents have pressure ulcers, with about 160,000 residents suffering from some type of ulcer, stage 2 being the most common.

From one company with a history in the wound care market, to Teva UK Limited. This British pharmaceutical supplier is just entering the wound market with PolyHeal. Introduced at this week’s Wounds UK conference, PolyHeal is being marketed for hard-to-heal wounds. The company’s press release states that the product has been clinically shown to significantly reduce wound size after approximately one month of treatment.

PolyHeal is made up of negatively charged polystyrene microspheres. These microspheres are held in a nutrient-rich medium and help to inspire inflammatory and proliferation in the healing process. According to Teva, PolyHeal is clinically proven to treat a variety of wounds, even those with

exposed bone and tendon. PolyHeal has a planned release of early 2011.

—JR (November 16, 2010) ♦

Kuros Scores Bone Application Rebound

Kuros Biosurgery AG, the Zurich, Switzerland-based biotechnology company, announced last week they had regained rights to a set of biomaterials that had been in the development process since 2005 with Baxter International Inc.

The original agreement’s plan was to combine Kuros’ KUR-112, KUR-212 and KUR-213 with Baxter’s Tisseel fibrin sealant. The three biomaterials are applicable to orthopedic and wound-healing therapies. KUR-112 for instance, is made with a protein derivative from the human hormone parathyroid and can help with the formation of bone. It is also in development as a solitary bone cyst therapy. With Baxter’s collaboration on hold, in 2007 the drug



Basketball Rebound/Creative Commons

received an orphan drug designation from the FDA.

Today, plans have not been released for future developments or trials.

But Baxter is still retaining some rights for development and commercialization. Kuros biomaterial technology KUR-111, for example, is still retained by Baxter. This material is currently being examined in the treatment of tibial plateau fractures. Similarly KUR-113, another material held by Baxter is being studied for healing open tibial shaft fractures. Both of these biomaterials are currently in Phase IIb.

Although about a quarter of tibial plateau fractures or “fender fractures,” involve slow speed collisions with a car’s bumper, over half of sufferers are over 50 years old, with women, because of osteoporosis, making up the majority of patients. One study, released at the Annual Meeting of the American Orthopaedic Society for Sports Medicine, showed that women were at three times a greater risk for the injury.

—JR (November 16, 2010) ♦

Helmets No Help?

The NFL conceded this past week: Helmets don’t adequately prevent concussions. And even worse, there’s

little hope of them being a preventative solution in the foreseeable future.

According to The National Athletic Trainers’ Association, between 43,000 and 67,000 concussions are sustained each year by football players across the country. However the Association also warns that this statistic masks an even



Football Tackle/Creative Commons

higher rate as many injured players still don’t seek treatment and concussions go unreported.

Representatives from the NFL, players’ union and all four helmet manufacturing companies that supply the NFL sat down with The Associated Press for a series of interviews. The overriding message? Helmets aren’t the brain protector they’re commonly thought to be. The NFL said this knowledge was a deciding factor in its decision to implement a series of stiff fines and suspensions for dangerous hits. There’s also a two-day meeting planned for December

where the NFL’s head, neck and spine medical committee will discuss the possibilities for future helmet design and testing. The Department of Defense and leading scientists will be a part of this event. Ideas will be brainstormed, from new materials and the possibility of installing sensors on players to a review of current return-to-play guide-

lines. The standardization of side-line evaluations across all teams will also be considered.

With each NFL game averaging one to two concussions, player behavior and education is becoming the bigger focus, rather than helmet capabilities. There are several factors that have been identified that contribute to a concussion being sustained, including previous hits to the head on the same day, hydration levels, the area of the head that was hit and if the player was able to brace himself and tense the neck muscles before the hit occurred.

Helmets used by players from high school through college and into the NFL are supposed to pass a test created by the National Operating Committee on Standards for Athletic Equipment (NOCSAE). These are voluntary tests however that manufacturers test independently. The NOCSAE model itself dates back to the 1970s when only eliminating the most serious of brain injuries was the goal. But no changes to the guidelines are in sight, with the NOCSAE waiting for science to dictate what further guidelines would be beneficial and how those can be woven into the current safety standards.

For helmet developers there are a whole host of challenges to designing a better helmet. It can't weigh too much because of risks to the neck, it also can't be too padded because of the danger of overheating and there's still no design that protects the brain (because it moves independently in the skull) rather than just the head.

—JR (November 16, 2010) ♦

reimbursement

SAS Issues Reimbursement Alert

SAS, the International Society for the Advancement of Spine Surgery, alerted their members on November 17 about changes that North Carolina Blue Cross/Blue Shield Insurance is implementing on January 1, 2011, regarding a more restrictive policy for lumbar fusion procedures.

SAS hasn't waded into such reimbursement issues since joining other societies a couple of years ago regarding

kyphoplasty and vertebroplasty reimbursement. As an international organization, the Society has stuck to scientific issues.

SAS Advocacy

The society jumped on this because, as past SAS President Chun-Kun Park, M.D., Ph.D., said in the alert, "Bad news travels fast." A SAS spokesperson told us that this action is indicative of the society's desire to be more proactive on such access questions and sees the society increasing its influence and working with other surgical societies to better represent the interests of patients and surgeons.

The alert stated the new BC/BS policy is overly restrictive and may adversely impact patient access and may make it more difficult for patients suffering low back pain due to spondylolisthesis to receive needed surgeries.

SAS cited various scenarios of concern:

- *Patients with degenerative spondylolisthesis who don't have as much leg pain as back pain.*
- *Patients with isthmic spondylolisthesis that is not progressive but nonetheless painful.*
- *Patients where fusion for spondylolysis may be necessary/beneficial in situations where there is no slip and only back pain.*
- *Patients where fusion is the only procedure that will relieve pain and immobility associated with degenerative disc disease, after six months of exhaustive conservative measures have failed.*

Please click here to read the BC/BS policy: http://www.bcbsnc.com/assets/services/public/pdfs/medicalpolicy/lumbar_spine_fusion_surgery.notification.pdf

—WE (November 19, 2010) ♦



T.J. Takahashi/Wikimedia Commons

spine

510(k) for Vertebral Technologies' InterFuse

It's sort of like getting a ship in a bottle...Vertebral Technologies, Inc. (VTI), has announced that the FDA has given the 510(k) clearance nod for the InterFuse T interbody fusion device, a product that allows surgeons to assemble a large fusion implant through a transforaminal, minimally invasive surgical (MIS) approach. This approach means less tissue dissection and nerve root retraction, along with a larger and more stable footprint.

The InterFuse T device is implanted through a transforaminal approach and uses the same proprietary Intraoperative Assembly technology as VTI's InterFuse P device, which has been used in over 1,000 cases in the U.S. utilizing a unilateral posterior paramedial approach. According to Vertebral Technologies, the InterFuse T enhances VTI's InterFuse Fusion System by allowing surgeons to achieve the largest endplate coverage through the most applicable and preferred surgical approach for the patient.

In the news release, Jason C. Tinley, M.D. of DFW Center For Spinal Disorders said, "Since I began using the InterFuse Fusion System, I have virtually been able to avoid ALIF's altogether and rarely have to use traditional PLIF/TLIF spacers as they have significantly

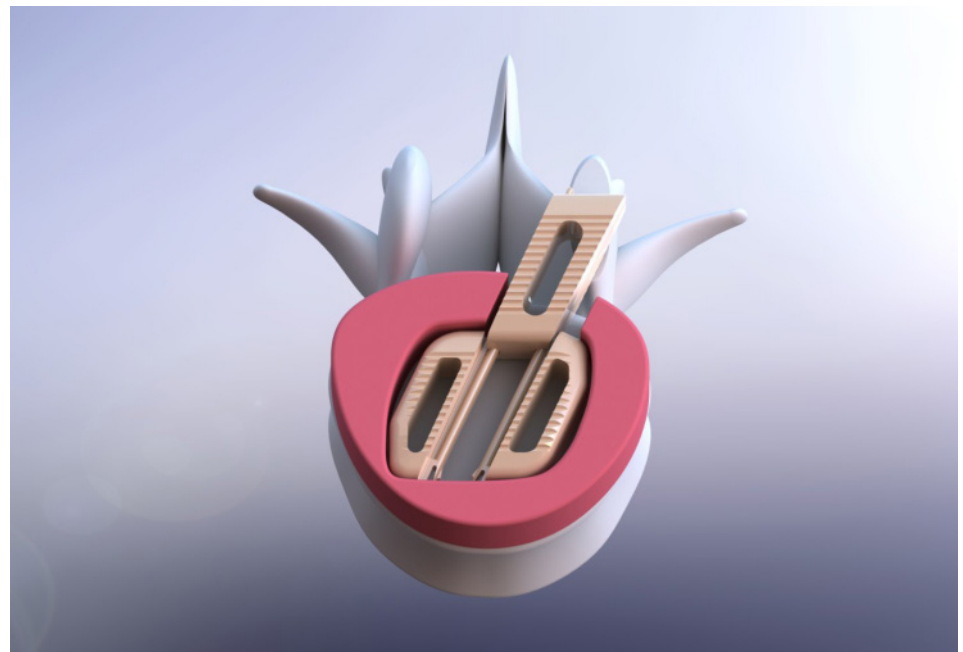
less anterior column support and endplate coverage in comparison to the InterFuse products. Due to the customization of this implant to ensure the maximum endplate coverage, my patients have had greater stability post-op resulting in more rapid recovery times and less post-op pain. In addition, it makes intuitive sense that a much larger surface area for bone graft would have a higher fusion rate."

Jeffrey Felt, M.D., Chief Executive Officer of VTI, added, "The introduction of the InterFuse T interbody fusion device has been a highly sought minimally invasive option for surgeons to use our unique rail-and-slot technology from a transforaminal approach. Our initial six month imaging data for our InterFuse-P Fusion System shows an industry-leading fusion rate, which validates our Intraoperative Assembly

approach to implanting large devices through minimal access surgery. VTI continues to develop this concept for other surgical approaches for fusion and for motion preserving devices such as the InterCushion Disc Nucleus Replacement Device."

Commenting on the launch, Dr. Felt told *OTW*, "We plan to go as slowly with the Alpha launch as we did with the InterFuse P launch in 2008-2009. We want to be sure we have the instrumentation as close to perfect as possible before the full scale launch. We estimate this will take about 4 months using 7 to 10 sites and about 100 surgeries. About half will be mini-open and half will be through a tube."

—EH (November 19, 2010) ♦



Vertebral Technologies

THE PICTURE OF SUCCESS

Dr. Larry Hull

By Elizabeth Hofheinz, M.P.H., M.Ed.

It was the days of the Dust Bowl...and it was one long night when a future hero to thousands in need was born at home during a blizzard. Lawrence Hull, M.D., founder of the Washington Orthopaedic Center in Centralia, Washington, and winner of the 2010 American Association of Orthopaedic Surgeons Humanitarian Award, has improved the lives of countless people—not only by providing orthopedic drills equipment, tools and plates, but by founding a nonprofit organization that provides employment, medical care, and education to those in the highlands of Papua New Guinea. Through it all he was listening to his heart...a heart that years ago received a “command and an invitation.” Through it all he could see that there was a place where science and religion could not only coexist, but could radically change people’s lives.

Perhaps it was because Dr. Hull started out with a hardscrabble existence that as an adult he could easily feel the need of those halfway around the globe. Dr. Hull: “My parents, like their neighbors, struggled to make ends meet. We moved from Texas to Oklahoma, to Oregon, where we had a farm (but no indoor plumbing). My brother and I pitched in daily, milking cows, etc....all the while thinking that everyone worked that hard. My parents were excellent role models for compassion. During the polio epidemic—when it was unclear whether the condition was contagious—my

mom volunteered to help patients in iron lungs. That was when I started dreaming of helping others.”

Not long after, Larry Hull would get his calling. “A missionary doctor came to our church one Sunday and talked about how God can use us to help others. It was a calling that I felt I could respond to, and eventually decided that medicine would be the vehicle for me to serve the world. In medical school I drifted toward biomechanics and the science of the musculoskeletal system, with an eye towards helping patients maintain their mobility. It was also appealing that in orthopedics you can usually *do* something about the diagnosis.”

Following three years in the military, in 1973 Dr. Hull found himself looking for a different kind of challenge. “I wanted to go somewhere where no one was doing orthopedics. I selected Centralia, Washington, a small community with 50,000 people and no orthopedists. Over the years the practice grew to 50 employees, including six orthopedists and three physician assistants.”

And these, says Dr. Hull, are the folks who keep things running when he is changing limbs and lives abroad. For over 30 years, Dr. Hull’s faith in his talents and faith in God have come together to benefit many a soul in underserved areas. “On my first trip to Papua New Guinea (PNG) I treated a



Dr. Hull supervising the building of the Madan Health Clinic

man who had been beaten very badly and had a fractured leg. Six weeks after his surgery I watched him *walk* away from the hospital and in front of him was a church spire. I had an epiphany at that moment: this is where science and faith meet. There is indeed a sometimes inexplicable bond of faith and reason.”

No one makes an announcement when an orthopedist shows up for work... except when it’s Dr. Hull. “My church was doing mission work in Nicaragua when I got a call from someone saying, ‘We need you in Nicaragua next week.’ I gathered all of the equipment I could and when my plane landed I learned that my impending arrival had been announced on the radio. Hundreds of people were lined up to receive treatment.”

While Dr. Hull has dedicated his time to the needs of those in several other countries, it was Papua New Guinea where he put down roots...and raised

up a community. “The need there was so great—there were no brace shops in all of PNG, and no orthopedists until 1992. It was necessary to improvise quite a bit, for example, taking hip implants and cutting them down to size to use for other bones. All they had in the way of tools were small hand drills and hand saws; so I brought thousands of dollars worth of equipment and over the years—and with lots of assistance—I have totally equipped the local hospital with plates, screws, external fixators, etc. In addition, my team and I trained a local general surgeon to be very a good orthopedic surgeon.”

And with its local culture having a bent towards skirmishes, PNG needs as many people who know what to do with broken bones as possible. Dr. Hull explains, “The young men are warriors and fight quite often. Even fourth graders carry bush knives, so in this type of environment you see not only open fractures but open wounds. It is a polygamous society so we see situations where wife one and wife two fight each other and do a great deal of damage. Then there are the ‘regular’ conditions such as osteomyelitis; I see more of this condition in the first hour of clinic in PNG than I would see in my career in the U.S. Kids go barefoot a lot there, so we also treat a lot of children with infections in their bones and joints due to dirty water, poor hygiene, scratches and cuts.”

When Dr. Hull looked around PNG, he saw not just problems, but opportunities for the local populace. Then he really put down roots...the roots of coffee plants. “My wife and I purchased a coffee plantation and have been able to employ hundreds of people, build a school, construct wells, and establish a local clinic of some significance (for



Dr. Hull at Anglimp Secondary School...inspecting one of the wells put in by Na Wokabaut

example, we vaccinate more than 5,000 children per year). It has been a privilege to have so many people trust me with their needs...it is truly humbling.”

“My wife and I have largely worked through our nonprofit organization, Na

Wokabaut, which translates to, ‘Now Walk About’ in the local language. It represents this concept of vitality, and is a command and an invitation—you might say a calling—to get up and walk and go on with your life. We work from the premise that every per-



Women and children waiting for immunizations at clinic in Papua, New Guinea

son has valuable skills, even if they are often unknown to him or her. Our goal is to help people use or enhance those skills, which can then be used to generate income or be beneficial in some other way.”

The attitude behind the work is what Dr. Hull says has been the engine that has driven his accomplishments. “I feel that I have been blessed with the gift of encouragement. I try to approach those who are injured with the philosophy of, ‘Let’s talk about your health, your life, and your dreams. I will walk along side of you and we will get through this together.’”

And perhaps Dr. Hull—and those to whom he extends himself—can thank a nurse in small town America for

making him a better doctor. “There was one experience in my career that changed me more than anything else. Early on, I was like many young doctors in that I was a bit arrogant and was always hurrying through appointments. One day a nurse who I had worked with for a long time came into my office and shut the door. She said, ‘Dr. Hull, you need to slow down, sit down, and do a better job of listening to your patients.’ It was the moment when I learned that we are all learners.”

To those young orthopedists out there with an interest in helping others abroad, Dr.

Hull says, “Go where others are in desperate need; you will never be more satisfied with your work. Focus on what you *can* do and don’t be distraught about what you can’t do.”

Dr. Hull and his wife, Arlie, managed to raise not just a village, but their own little community...their family. Dr. Hull: “I am most proud of seeing my five children become great citizens; they are Godly people making a difference in their world. And I am so blessed to have a charming, vigorous, engaged wife who at times is my best counselor. We are both fortunate to have an enormous amount of energy.”

Dr. Larry Hull accomplished an important merger...one of faith and science that resulted in new lives for thousands. ♦

VB

VISCOGLIOSI BROS., LLC

OUR MISSION IS
TO CREATE, BUILD AND
FINANCE COMPANIES
FOUNDED ON INNOVATIONS
DEVELOPED BY SURGEONS.

CONTACT: MARC VISCOGLIOSI
MVISCOGLIOSI@VBLLC.COM

Advertisement

Can't remember the last time you "tuned up" your procedure and reimbursement reports?

A procedure, reimbursement or overall market analysis and forecast is the heart of your sales plan!



data guys
How can we help?

Let the Data Guys tune-up those old forecasts with:

- U.S. procedure volumes and forecasts to 2014
- Regional and state charging data
- Reimbursement rates
- Associated diagnoses
- Associated procedures
- State reimbursement data
- Private payer and Medicare data
- Comorbidities
- Patient demographics

pearliverinc.com

Contact the Data Guys-Matt, Scott or Heather
260-469-4161 or dataguys@pearliverinc.com



PearlDiver
unfathomably deep data retrieval

Orthopedics This Week | RRY Publications LLC

Robin R. Young, CFA
Editor and Publisher
robin@ryortho.com

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Walter Eisner
Senior Writer
walter@ryortho.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Jacqueline Rupp
Writer
jackie@ryortho.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayne Johnson
Production Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

Main Contact Information:

RRY Publications LLC
116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-877-817-6450
Fax: 610-260-6451



Don't miss your chance!
Advertise with Orthopedics This Week

Orthopedics This Week

Click Here for more details or email tom@ryortho.com
Tom Bishow | 410.356.2455 (office) or 410.608.1697 (cell)