VOLUME 6, ISSUE 1 | JANUARY 5, 2010

Orthopedics This Week

week in review

05 **The $1 Billion Lobbying Feast** ♦ Combatants in the healthcare debate will spend over $1 Billion to make sure they have a seat at the table and not end up an item on the menu. See who is spending big, raking in campaign contributions and who may end up on the menu before it's all over.

09 **Administrative Data: What's the Use?** ♦ We have all heard the orthopedic drumbeats of "quality" and "cost" of late. Dr. Kevin Bozic of UCSF discusses the benefits and limitations of administrative claim data to study costs, trends in utilization, and outcomes.

12 **Biologic Product Myths** ♦ God doesn't make mistakes. So when a surgeon needs a replacement part—go to the source. Well, maybe. Do we REALLY understand biologics? This week we examine five myths about biologic grafts.

the picture of success

23 **Dr. John McGraw** ♦ He owns a cattle farm, is a preacher, and serves in the military. Dr. John McGraw, a partner at the Knoxville Orthopaedic Clinic, has crafted a life of service and variety.

breaking news

16 **BioCart Study:** Growing New Cartilage

OA Drug Seeking European Approval

AAOS, NASS Targeted by **Grassley**

Ablynx Initiates RANKL Study

Medicare Payment **Cuts** Postponed

Bullseye for **CONMED**

MiMedx Launches First Product

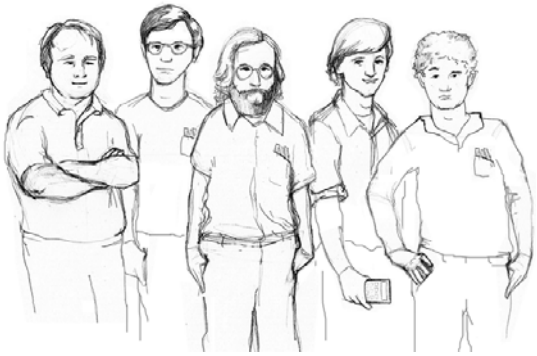
For all the news that is Ortho, read on.

RY Publications

1-877-817-6450 | www.ryortho.com

Ever Pay $6,000 for $950 of Market Forecasts?

PearlDiver
unfathomably deep data retreival



Call Heather at 260-469-4161 or email one of the data guys at www.pearldiverinc.com.

Don't Waste Your Money on Market Forecasts. Buy what you need – not what you don't!

Is that anterior cervical fusion procedure forecast buried in a massive $6,000 spine market report? When all you need is a cruciate ligament repair market analysis or a rotator cuff repair procedure forecast—why pay 6 times more than you have to?

For $950 you get what you need—not what you don't. Get complete and detailed forecast and analysis of the specific surgical indications. No other market intelligence company has more detailed or accurate market forecasts. PearlDiver's data guys have built the largest database of patient records (private payer and Medicare)in the United States.

Each report details the U.S. procedure volumes and forecasts to 2013, reimbursement rates, associated procedures, private payer AND Medicare data, patient demographics, regional charging data, state charging data, associated diagnosis, state reimbursement data and comorbidities for each of the following specific surgical indications. Get what you want—not what you don't. Just $950.

Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Spine Refusion	
Posterior lumbar refusion	81.38
Other Spine Procedure	
Discectomy	80.51
Decompression	03.09

Large Joint Reconstruction	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revision of Knee Replacement	81.55
Excision of Semilunar Cartilage	80.6
Cruciate Ligament Repair	81.45
Synovectomy of the Knee	80.76
Removal of Implanted Device Tibia/Fibula	78.67
Hemiarthroplasty	81.52
Hip Resurfacing	00.85

Extremity Market Reports	Code
Ankle Fusion	81.11
Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	83.63
Total Ankle Replacement	81.56
Open Reduction of Fracture Radius & Ulna w/ Internal Fixation	79.32
Open Reduction of Fracture Humerus w/ Internal Fixation	79.31
Open Reduction of Fracture Tarsals & Metatarsals w/ Internal Fixation	79.37

(2004-2008 U.S. Procedure, Sales, Charging and Demographic Data as derived from Medicare AND Private Payer datasets)

3 Orthopedics This Week
VOLUME 6, ISSUE 1 | JANUARY 5, 2010

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: We start 2010 with a new #1 company in the Power Rankings—Integra LifeSciences. In IART we have three components that, we think, are the keys to orthopedic success from 2010-2020: reliance on biologic technologies, exemplary operating management, and a propensity to acquire companies or assets.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Integra LifeSciences	15.37%	12.58%	Stu Essig and his team show how M&A works—use operating leverage to justify purchase then manage integration obsessively.
2	1	Medtronic	31.09	3.02	There is something about Medtronic at 14x P/E that's just wrong, especially when ROE is 17%.
3	3	Exactech	12.61	8.94	Most analysts are expecting that sales growth rate will rise about 300 basis points in 2010.
4	4	CONMED	6.92	7.95	It may be frigid in Utica, but CNMD sales heat up in 2010—4th least expensive ortho company; #4 in the Power Rankings.
5	6	Smith & Nephew	22.42	4.04	Sales in 2009 fell about 3% (consensus view) but are expected to rebound neatly in 2010.
6	5	Wright Medical	6.61	3.61	A $4 million charge to relocate French operation to Amsterdam. Clean the decks before a rebounding year in 2010.
7	8	Zimmer	28.10	0.61	Valuation up 50% in the last six months! A $1 billion war chest. Sales growth rates rising.
8	7	Johnson & Johnson	26.94	1.42	Buffet cut stake in JNJ by 50% in 2009. We understand. JNJ is too large. An independent DePuy would rock.
9	9	Stryker	23.50	(0.47)	New analyst report recommends SYK. Smart, savvy M&A activity raises SYK profile with its hospital customers.
10	NR	Symmetry	11.48	2.41	The least expensive public orthopedic company. Been down so long, it looks like up to SMA.

Orthopedics This Week

VOLUME 6, ISSUE 1 | JANUARY 5, 2010

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Mako Surgical	MAKO	$11.10	$368	21.1%
2	TranS1	TSON	$3.95	$82	20.9%
3	Osteotech	OSTE	$3.20	$58	16.1%
4	Integra LifeSciences	IART	$36.87	$1,050	14.0%
5	Alphatec Holdings	ATEC	$5.34	$281	10.9%
6	Kensey Nash	KNSY	$25.50	$283	8.2%
7	Exactech	EXAC	$17.31	$222	8.1%
8	CONMED	CNMD	$22.80	$664	7.6%
9	CryoLife	CRY	$6.42	$183	7.5%
10	Capstone Therapeutics	CAPS	$0.72	$29	7.3%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.PK	$0.12	$1	-76.0%
2	TiGenix	TIG.BR	$5.45	$134	-14.7%
3	Orthovita	VITA	$3.51	$269	-6.4%
4	RTI Biologics Inc	RTIX	$3.84	$209	-5.9%
5	Synthes	SYST.VX	$130.35	15,469	-1.0%
6	Stryker	SYK	$50.37	$20,030	-0.5%
7	Zimmer Holdings	ZMH	$59.11	$12,590	0.6%
8	NuVasive	NUVA	$31.98	$1,220	1.1%
9	Johnson & Johnson	JNJ	$64.41	177,710	1.4%
10	***Average***			***$11,627***	***1.6%***

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$8.06	$289	7.94
2	Medtronic	MDT	$43.98	$48,580	13.81
3	Johnson & Johnson	JNJ	$64.41	$177,710	14.14
4	Kensey Nash	KNSY	$25.50	$283	14.85
5	***Average***			***$11,627***	***14.86***

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$51.25	$9,050	82.92
2	RTI Biologics Inc	RTIX	$3.84	$209	47.04
3	Synthes	SYST.VX	$130.35	$15,469	40.53
4	NuVasive	NUVA	$31.98	$1,220	29.28
5	CONMED	CNMD	$22.80	$664	23.66

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$30.93	$530	0.85
2	CryoLife	CRY	$6.42	$183	0.86
3	Symmetry Medical	SMA	$8.06	$289	1.03
4	Exactech	EXAC	$17.31	$222	1.15
5	Medtronic	MDT	$43.98	$48,580	1.26

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$31.98	$1,220	3.05
2	RTI Biologics Inc	RTIX	$3.84	$209	2.00
3	Johnson & Johnson	JNJ	$64.41	177,710	1.86
4	Zimmer Holdings	ZMH	$59.11	$12,590	1.82
5	Wright Medical	WMGI	$18.94	$732	1.67

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$3.20	$58	0.59
2	Symmetry Medical	SMA	$8.06	$289	0.76
3	CONMED	CNMD	$22.80	$664	0.99
4	Orthofix	OFIX	$30.93	$530	1.01
5	RTI Biologics Inc	RTIX	$3.84	$209	1.30

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$5.45	$134	187.12
2	Mako Surgical	MAKO	$11.10	$368	14.63
3	Synthes	SYST.VX	$130.35	$15,469	9.46
4	NuVasive	NUVA	$31.98	$1,220	3.65
5	Kensey Nash	KNSY	$25.50	$283	3.55

Orthopedics This Week

VOLUME 6, ISSUE 1 | JANUARY 5, 2010

The Billion Dollar Lobbying Feast

By Walter Eisner

There is an old saying in Washington: "If you're not at the table, you're on the menu."

According to the Center for Responsive Politics (CRP), the healthcare sector spent nearly $400 million in the first nine months of 2009 to have a seat at the table and lobby the federal government over healthcare reform.

The Billion Dollar Lobbying Effort

Add in the insurance industry's $122 million, another $200 million spent on television advertising for and against overhauling healthcare and independent expenditures from the "527" advocacy groups and you quickly approach more than a billion dollars.

For all industries, 14,808 lobbyists spent $3.3 billion teaching and, with a bit of sweat, influencing official Washington in 2008. The American Medical Association (AMA) and the insurance industry bought excellent seats at the table.

The Centers for Medicare and Medicaid Services (CMS) say we spend about $8,000 per person on health care in the United States each year. The money spent on lobbying for health care would pay for one year's worth of health care for 125,000 citizens—roughly ten times the population of Warsaw, Indiana.

David Levinthal of the CRP told PBS's Gwen Ifill on December 22 that the money spent on healthcare lobbying this year, "could potentially be...the biggest lobbying effort ever on a single piece of legislation the U.S. has ever seen."

One of the reasons cited by Levinthal for the billion lobbyist bill is that this healthcare issue has been in play ever since President Obama took office early in the year. In addition, with 16% of the economy at stake, many players have a lot to lose or gain.

"When you have so many different entities vying for a piece of this pie, trying to control the trajectory of this legislation, trying to insert this or take out that, and the process lasts literally a year, that's why you have these dollar figures that are really unprecedented," said Levinthal.

What's the money buying?

In a word says Levinthal: Access. In other words, if you don't pay, you don't get a seat.

Once you've paid for your seat, you have to be heard. To get heard, the healthcare players hire lobbyists who are former Congressmen and staffers to make their case. The lobbyists in turn fund congressional campaigns.

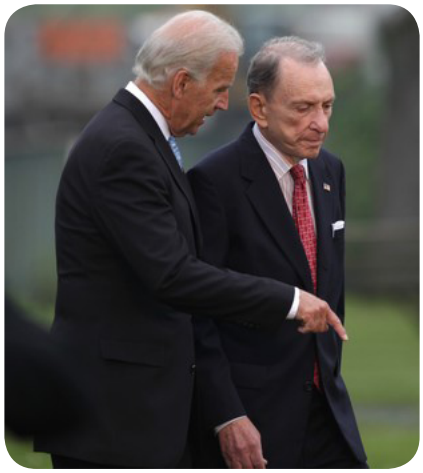
Targeted Contributions

Healthcare lobbyists increase their effectiveness by strategically targeting their campaign contributions or the donations of the interests they represent. According to the CRP, health industry contributions to congressional candidates more than doubled this past decade, rising to $127 million in the 2008 election cycle from $56 million in the 2000 election, with disproportionate sums going to the party in power and to members of committees that oversee health care.

Campaign Contribution Leaders

CRP found that many senators in the healthcare debate have been among the top recipients of campaign contributions from health insurance and health-related companies, trade associations and groups.

- Between January and September of this year, Senate Majority Leader Harry Reid collected the most from these interests via his campaign committee and leadership PAC, with $718,575. During the same time, he also raised $252,350 from labor interests.



Senator Arlen Specter and Vice President Joe Biden

Senate Majority Leader Harry Reid Announces Senate Passage of Healthcare Bill
http://reid.senate.gov/

- Pennsylvania Senator Arlen Specter ranks second, with $562,000 in contributions from health and health insurance-related interests during the first three quarters of 2009, in which he also collected $28,500 from labor interests.

Senator Blanche Lincoln

- Senator Blanche Lincoln of Arkansas ranks third, with $561,550 in such contributions between January and September. She's raised $35,600 from labor interests during the same period. Arkansas, according to the CRP, was one of the most targeted places for TV advertisements from both supporters and opponents of healthcare legislation.

- Senator Chuck Schumer collected $509,500 from health and health

Senator Charles Schumer

insurance-related interests between January and September. In that time, he's also collected $205,000 from labor.

Senator Charles Grassley

- And finally, Senator Chuck "Sunshine" Grassley, the ranking member of the Senate Finance Committee rounds out the top five Senate recipients of health care campaign cash. Grassley collected $458,500 from health and health insurance-related interests during the first three quarters of the year and has not collected any money from labor. (In fact, notes the CRP, he refunded one $1,000 labor-related contribution.)

Revolving-Door Lobbyists

According to *Bloomberg News*, there are 3,300 healthcare lobbyists registered to influence Congress. With 535 members of Congress, that's about six lobbyists per lawmaker.

Of those 3,300 lobbyists, more than 1,400 used to work for Congress, the White House or federal agencies. Fifty-five are former lawmakers themselves and 166 are former aides from the congressional leadership offices and committees considering the healthcare bills.

Government employees and lawmakers make a fraction of what lobbyists get paid. With a revolving door of staffers and lawmakers joining lobbying firms, the guests at the table resemble a large incestuous family.

Congressional salaries currently top out at $174,000 annually for lawmakers and $156,000 for aides, though committee staff members can earn slightly more.

Said Levinthal,

> ***"If you do come in and you have…working on your behalf former members of Congress or former high-ranking congressional staffers, that's certainly going to help your case. And so many clients who employ lobbyists are hiring people who have worked in Congress before, because they know the system. They know the players. And they are intimately familiar with the issues.***
>
> ***So, all these things put together are very expensive, but they also can definitely pay dividends for the people who are hiring the lobbyists."***

Alan Abramowitz, an Emory University political scientist told the *Chicago Tribune* recently, "There's always a worry they may be thinking about their future employment opportunities when dealing with these issues…"

AdvaMed at the Table

One example of a former insider is AdvaMed's Senior Vice President David Nexon who was a staffer for the late Senator Edward Kennedy.

AdvaMed's David Nexon

Nexon and AdvaMed took the lead in lobbying against a proposed $40 billion medical device tax in the healthcare bill spread out over the next ten years. AdvaMed and Nexon's

efforts, along with objections from Senators from medical device-heavy states like Indiana and Minnesota, got the device tax lowered to $20 billion over ten years.

This revolving-door culture wouldn't raise concerns if there was a clear and transparent picture of all the relationships. ***As we recall, Senator Grassley of Iowa demands the same of surgeons and device companies.***

What lawmakers preach is not what they practice.

"Sometimes you don't know what the effect has actually been by the lobbying efforts," said Levinthal. "That's because the laws don't allow you to find out, for example, who has actually lobbied whom. So, if you want to find out, for example, if a lobbyist for a large healthcare firm has spoken to Max Baucus or Joe Lieberman or this senator or that congressman, you're not going to be able to find that out, because it's not federally required for the client of the lobbyist to disclose that."

AMA Versus Surgeons

So are physicians at the table or on the menu?

It depends. A schism has opened between the AMA and surgeon societies.

The American Medical Association definitely paid for its seat at the table. AMA supported the healthcare measure passed by the Senate on Christmas Eve and it is one of the top political action committees to make campaign contributions.

In the last ten years, the AMA was outspent only by the U.S. Chamber of Commerce in lobbying expenditures, spending over $212 million over that period of time. The American Hospital Association, the Pharmaceutical Research and Manufacturers of America, and AARP round out the top six spenders. (General Electric was the other.)

What has the AMA gotten for its money? The AMA supports the legislation because it increases the number of people who will be insured for receiving healthcare. It is also maintaining its monopoly on reimbursement codes and will see its members who are primary care physicians see higher reimbursements. What it didn't get was a permanent fix to the flawed Medicare reimbursement formula.

What about the orthopedists and spine surgeons?

The surgeons may feel like they are on the menu because they oppose the legislation passed by the Senate. They fear access to their specialty services will be reduced at the expense of primary care services.

A look at the top political actions committees on the CRP Web site shows the AMA, dentists and ophthalmologists are the largest healthcare provider contributors. There is no sign of the orthopedic and spine societies in the top 50 lists of campaign contributors.

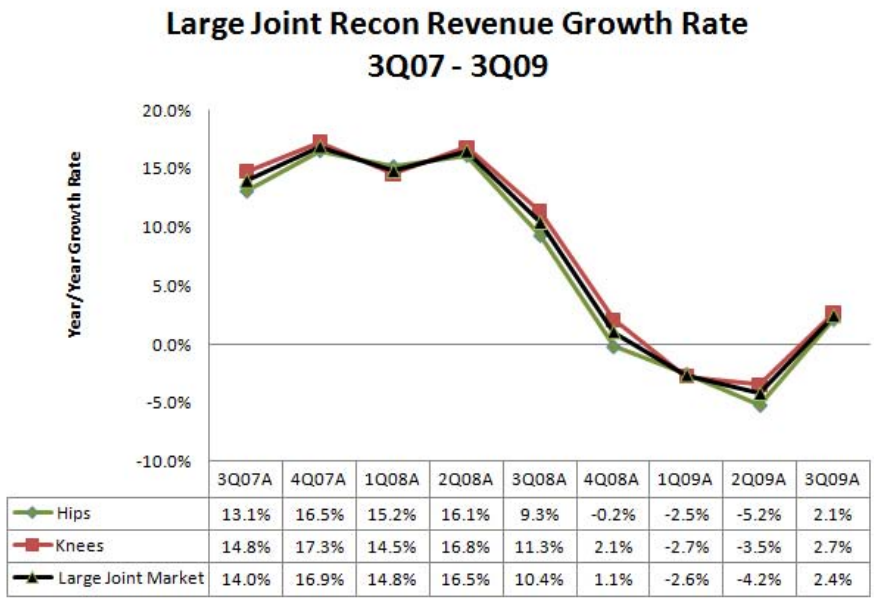
Congress will have to finish its healthcare bill when it returns from the holiday recess. So far the apparent winners have paid their way fair and square to decide who will be on the menu. The AMA and surgeons will have a lot of sorting out to do after the feast is over.

Orthopedics This Week

VOLUME 6, ISSUE 1 | JANUARY 5, 2010

Administrative Data: What's the Use?

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



	3Q07A	4Q07A	1Q08A	2Q08A	3Q08A	4Q08A	1Q09A	2Q09A	3Q09A
Hips	13.1%	16.5%	15.2%	16.1%	9.3%	-0.2%	-2.5%	-5.2%	2.1%
Knees	14.8%	17.3%	14.5%	16.8%	11.3%	2.1%	-2.7%	-3.5%	2.7%
Large Joint Market	14.0%	16.9%	14.8%	16.5%	10.4%	1.1%	-2.6%	-4.2%	2.4%

PearlDiver Technologies, Inc.

Fifty years ago orthopedic surgeons didn't have to worry about the cost of their treatments…there likely was no one looking over their shoulder. Now, however, with increased scrutiny of both the cost and quality associated with orthopedic procedures, the field is paying more attention to the bottom line…and getting more than a little help from administrative data sets.

"Clinicians and clinician scientists have a responsibility to determine not only the quality, but the cost effectiveness of any given procedure," says Dr. Kevin Bozic, an orthopedist at the University of California, San Francisco (UCSF) and an acknowledged health policy expert. "By utilizing administrative claims data sets—information submitted as part of an insurance claim as a result of a patient encounter—we can link clinical information with financial information. This means that we can examine specific diagnoses and procedures, along with their associated costs."

Rich Sets of Data

"Administrative claims data is a rich source of clinical and financial information," states Dr. Bozic, "including information about multiple diagnoses, multiple encounters and procedures. As our healthcare system gets more complex, the data required for payment is more sophisticated—good news for researchers because we can access that data and use it to study healthcare delivery processes and outcomes. For instance, in 2005, an optional modifier code for total hip replacement (THR) procedures was added which allows surgeons and hospitals to specify which type of hip replacement bearing surface was used in the procedure. Having this information from the administrative claims allows us to study trends in utilization and outcomes associated with specific THR bearings."

If you're going to make bold statements about what works and what doesn't, ideally you would have backup from data…*lots* of data. Dr. Bozic: "The primary advantage of these data sets is that they capture the entire U.S. population. You can, for example, look at the entire Medicare population or single out those who are privately insured. The sample sizes are enormous, therefore the generalizability of the findings can be very broad. This is in contrast to randomized, controlled trials (RCTs) which tend to be focused

on a much smaller population and aim to answer a specific clinical question. Although RCTs provide the highest level of evidence regarding the efficacy of a particular treatment, the generalizability of the results can be limited by the small numbers of patients who are studied in an idealized setting—which may or may not be like real life."

It's the scientific version of yin versus yang. "This gets to the questions of efficiency and effectiveness," states Dr. Bozic. "How an intervention performs in real life is the fundamental issue, such that even if something works in 100 patients who are observed closely, they may or may not be treated in the same way in every practice in the U.S. The broad generalizability of the administrative data sets comes in part from the fact that they capture a large cross section of patients in different settings, as opposed to randomized controlled studies which are typically conducted in academic practice settings. The former include rural and urban settings, teaching and nonteaching hospitals, different states, etc."

Working Through Limitations

With all of their flexibility and richness, administrative data sets have their limitations. "The disadvantage of this data is that until 2005, the codes used to represent different types of hip replacements and failure of hip replacements were vague. There was only one code used for all causes of hip replacement failures and all types of revision hip replacements. My colleagues and I approached the Centers for Medicare and Medicaid Services, and were able to convince them to add more administrative codes such that we now have a series of codes related to hip and knee replacement procedures which specify the cause of failure and type of revision procedure performed."

But will the codes—and other information—arrive on the page correctly? "This information is not typically submitted, vetted, or reviewed by a clinician. It is captured by those on the administrative end of things, and the accuracy is therefore at times in question. Additionally, it may or may not accurately reflect the clinical record in that every single clinical condition does not have a corresponding administrative code; the relevance of the code may not be sufficiently nuanced. All of this detailed data is only getting more complex, and many clinicians are not familiar with what it means, how to use it, or how to access it."

Learning this process, says Dr. Bozic, could involve an informal apprenticeship, as well as hiring people outright.

> ***"Those interested in pursuing this line of research should join up with methodologists who have the related expertise. You can purchase all of the data yourself, but this gets costly. If you want 10 years' worth of data, at $10,000 per data set, that's $100,000. It's more efficient to find a group of methodologists who own and have experience with the data. Our research group includes both clinicians, who develop clinically appropriate research questions and hypotheses, and methodologists, who understand how to mine and analyze the data."***

Delineating a difference between two kinds of data, Dr. Bozic notes, "Clinical data and administrative data are complementary, in that clinical data can often be used to evaluate the efficacy of a procedure (e.g., how a procedure performs under controlled circumstances), while administrative data can be used to evaluate the effectiveness of a procedure (e.g., how a procedure performs under real world conditions)".

As far the accuracy of the data sources, Dr. Bozic states, "Clinical data that comes from a chart review is not

necessarily more or less accurate than administrative data. Someone has abstracted that data, put it in a spreadsheet, and coded it in terms of how many people had infections, etc. Because of concerns about fraud and abuse, administrative data is strictly audited by several parties, including payers."

Data Mining and its Future Value

In taking this "clean" data on the road, Dr. Bozic has noticed a new trend in the research world. "For the last several years, I have presented studies at AAOS in which I've utilized administrative data sets. As the Program Chair for the American Association of Hip and Knee Surgeons, I have seen that approximately 25% of the abstracts selected for presentation at the 2009 Annual Meeting came from administrative data, a significant increase from, say, five years ago.

There has obviously been a shift toward understanding and acceptance of the value of this type of data. The reality is that you need both types of information…administrative data and data from well controlled clinical studies."

Next, he would like to take it to the community—the community practitioners, that is. "Going forward I think we will see more robust data sets, accompanied by an increased interest in this type of research tool. And ideally, rather than spending tens of thousands of dollars on the data, those with less training will be able to access the data in a less expensive, more usable, form. A significant challenge that remains to be solved is to be able to track patients over time in administrative data sets using a unique identifier, something which involves issues of patient privacy."

You could say that a good clinician scientist wears a miner's hat…he or she must extract all of the information possible from a given set of data. Dr. Bozic:

> ***"There are still a multitude of questions that can be asked using administrative data. For example, what are the risk factors for infection following orthopedic procedures, and which types of treatment are most likely to be successful? The ultimate advantage of this data is that you can connect clinical and financial information, meaning that we can look at types of diagnoses and procedures along with their associated costs. That, ideally, will help drive down costs and make orthopedic care more accessible to a greater number of people."***

Biologic Product Myths

By Robin Young

In 2009, more than 1.5 million patients received a human biologic product or implant as part of their surgery (dental included). Depending on your definition of "sales," biologic products generated well in excess of $2 billion in annual revenues. And, if you asked most CEO and surgeons what they think about "biologic" products they will say something along the lines of: "it is the product category of the future."

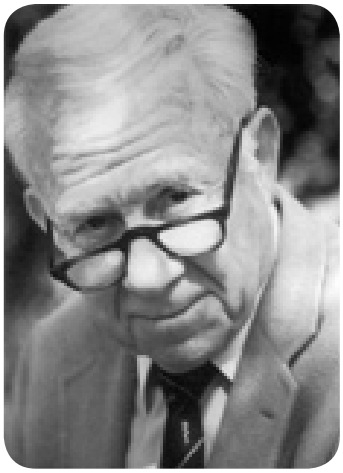
Yet, the "future" of biologic products, from the perspective of most suppliers, continues to stretch into a barely discernible future. With the exception of a Pickard/Lukianov run at Sofamor Danek 20 years ago, no major orthopedic supplier has rushed to embrace biologics as a product category.

Do we REALLY understand the purpose, power and functionality of biologics as a product category?

The following are five commonly held myths about biologic grafts:

Myth #1: Efficacy is the key to allograft biologic products

Allograft products taught two generations of surgeons about bone morphogenic proteins and laid the foundation for Medtronic's InFuse. At UCLA in the 1960s, Dr. Marshall Urist worked for the U.S. Atomic Energy Commission to research strontium 90, tetracycline, and the treatment of osteogenic sarcoma (bone cancers). Answering the question of, "Why does bone grow?"



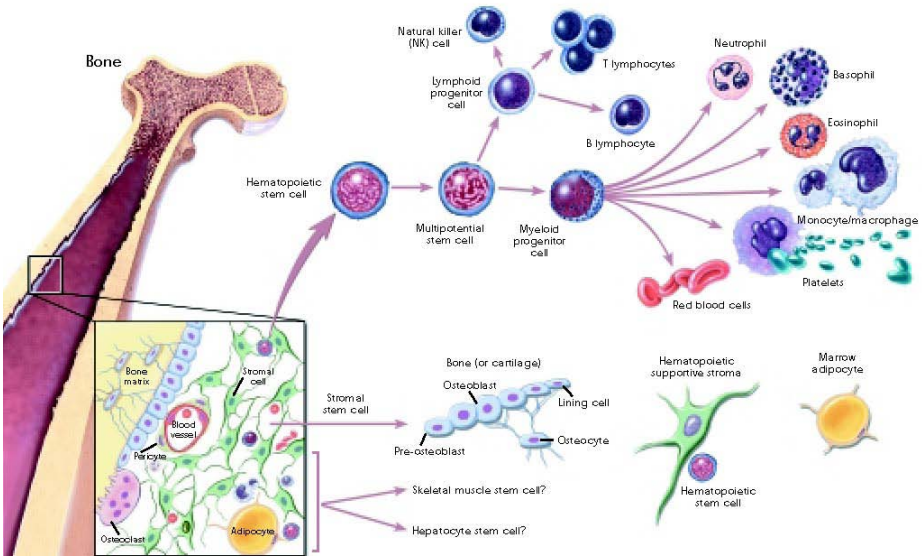
Dr. Marshall Urist

Dr. Urist was able to unravel the biochemical and cellular mechanics of osteoinduction. To prove his theories, Dr. Urist used demineralized human allograft bone matrix (which had small amounts of bone morphogenic protein[BMP]) and proved in his seminal 1965 article in Science—"Bone: Formation by Autoinduction"—that BMP induced bone to grow under the skin of a rat. Dr. Urist's work led to his nomination for the Nobel Prize in Medicine in 1991. Demineralized bone matrix (DBM) became the delivery mechanism for BMP.

Demineralized bone

But, and this is the key point, the amount of BMP in DBM is low. Surgeons weren't going to hurt their patients with this new biologic graft. The real question was donor safety. Efficacy in the form of BMP was mild. Ironically, this created the conditions for widespread use. Since efficacy existed at low levels, the learning curve for surgeons entailed figuring out how to maximize its mild effects. Surgeons learned to use DBM as an extender for harvested bone and the small amounts of BMP worked very well with the progenitor cells and BMP in the patient's own bone marrow.

After a decade and a half of using BMP with various versions of demineralized



A diagram of bone stem cells

bone matrix, surgeons were prepared and comfortable with the pure form of BMP—InFuse.

The same effect is currently occurring with allograft stem cells. Products like Osteocel (NuVasive) or Trinity (Orthofix) or NuCel (NuTech) are allograft products that preserve the progenitor cells of the donor. All three deliver safety, consistency and reliability to the surgeon. They also deliver small numbers of progenitor cells. So the key issue for surgeons is to learn how best to use the materials in order to maximize the mild effect of those cells in their patients. These materials, in turn, will train a generation of surgeons in the use of donated, living progenitor cells before the purer, more powerful forms of stem cells come to market.

Myth #2: Biologic products are supported by an intense R&D investment

RTI spends 5.5% of sales on R&D. Osteotech spends 6.7%. These are biotech firms? Amgen, one of the largest biotech companies in the world spends 20% of sales on research. Mid-cap biotech firms like Gilead spend about 13% to 15% of sales on R&D. Actually; suppliers of orthopedic biologic products spend about the same as their metal/plastic cousins—or roughly 5% to 8% of sales on R&D. Like Stryker, Zimmer, et al., biologic suppliers to the orthopedic industry aim for the least onerous regulatory path to market.

Myth #3: Biologic products are not cost effective

Good old polypropylene was developed in 1962 and is a strong, chemically inert, sterilizable, hypoallergenic material that resists the body's fluids and is easily accepted in the body. As a mesh to repair soft tissue damage, it found markets in hernia repair and to a limited extent, shoulder repair. Then came AlloDerm/GraftJacket, a human skin allograft. AlloDerm is a biologic graft and is classified by the FDA as banked human tissue. When it came to market it did so under the 361 rules which do not require clinical study—even though many, many studies have been conducted on these materials.

The first problem with the poly materials is that they can't be used in infected fields. They also erode and may trigger scar in the surrounding tissue. True, poly materials are inexpensive, strong and extremely biocompatible, but they are not perfect. Humans are, um, biologic materials and polymers are not.

Biologic products run the gamut in pricing—from very cheap cancellous chips to premium priced allograft soft tissue mesh/support or progenitor cells. But the vast majority of routine biologic products like DBM, bone void fills and allograft skin coverings are comparable to synthetic prices in

terms of $$ per cc or $$ per square centimeter. Then there are actual savings available because biologic products interact with surrounding tissues.

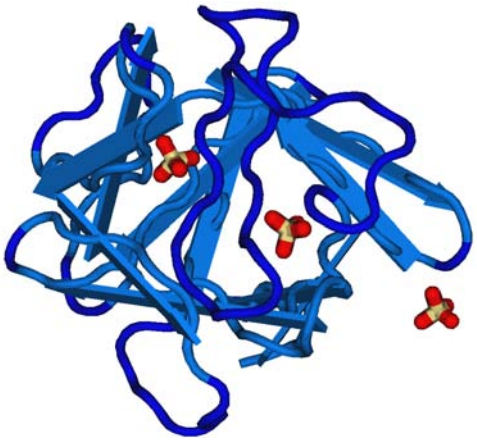
These are the BMPs in demineralized bone matrix which create an osteogenic environment. Using BMPs in whatever form help minimize or even avoid altogether an additional harvest surgery. Allograft progenitor cells have been shown to be immune privileged and are capable of delivering anti-inflammatory effects. Biologic grafts are resistant to infection and will remodel with surrounding tissues. Biologic products have the ability to communicate with the body, signal surrounding tissues to grow in their scaffold or recruit other proteins or cells.

Myth #4: Biologic implants help grow bone and that's about it

We know about the existence of bone morphogenic proteins in DBM, but the remodeling ability of GraftJacket is remarkable and the anti-inflammatory and immune privileged affects of allograft progenitor cells raise the possibility of a multi-functional biologic product.

In several peer review journal articles (for example the *Journal of Cell Biochemistry,* August 2006 issue, pages 1076-1084), Dr. Arnold Caplan of the Department of Biology, Skeletal Research Center, Case Western Reserve University, has shown that bone marrow progenitor cells (aka: mesenchymal stem cells [MSCs]) are capable of dividing and differentiating into osteoblasts, chondrocytes, myocytes, marrow stromal cells, tendon-ligament fibroblasts, and adipocytes. They have regenerative capabilities and can grow bone, cartilage, muscles and tendons.

However, these same cells, as they are dividing, secrete a variety of cytokines and growth factors that have both paracrine and autocrine activities. To put it bluntly, Caplan and others have shown that the bioactive factors coming from the MSCs can suppress the local immune system, inhibit fibrosis (scar formation) and apoptosis, enhance angiogenesis (capillary growth), stimulate mitosis and differentiation of tissue-intrinsic reparative or stem cells. Bottom line, the surgeon may use allograft MSCs to help regenerate bone but may also experience these highly beneficial trophic effects.


Growth Factor Protein

Myth #5: To get a permanent repair, you need a synthetic material

We've heard that most surgeons feel more comfortable with permanent implants and, in the case of soft tissue repair, mesh. But even permanent synthetic polymer or metal implants are not as permanent as one might expect. These materials react and change in the body and are not entirely inert. Living bone, ironically, gets stronger with stress. Metal fatigues with stress. Polymers can erode with stress. Because biologic products incorporate into the surrounding tissue (for example allograft mesh like GraftJacket/AlloDerm or DBM in a spine fusion model), the average strength of the repaired segment should come very close to that of native tissue. For most surgeons, what they want to see is a biologic graft that is eventually indistinguishable from the patient's own healthy, living tissue.

The dilemma, however, is that biologic grafts cannot be used in patients the same way as synthetic grafts. They require different clinical considerations and surgical techniques. It is, for example, important that biologic

grafts come in close contact with vascularized native tissues and that there is an ingrowth of blood vessels and that living cells can proliferate and cell signaling is robust. Securing a biologic graft can take more time and attention. It's not like slapping in a poly patch or screwing down a plate.

Biologics' Special Appeal

There is an old saying: "God doesn't make mistakes."

So when a surgeon needs a replacement part—go to the source. Yes, synthetic materials are excellent and will be required in modern surgery for as long as we can forecast. But biologics have a special appeal to both patients and their physician. Human biologic products signal the body, are resistant to infection, remodel completely, have long-term strength and do not cost appreciably more than the synthetic alternative—particularly when considering the effects of infection risk, an additional harvest surgery or the trophic effects of many biologic grafts.

company news

MiMedx Launches First Product

Atlanta-based MiMedx Group announced the launch of its first product on December 23. The company also announced the hiring of Michael Carlton to bring the product to market.

The product, cleared by the FDA last April, is the Paradis Vaso Shield. According to the company, the shield is a permanent and transparent hydrogel that is used as a cover for vessels following anterior vertebral surgeries.

The company's press release states that upon completion of an anterior spinal implant procedure, the physician places the shield between the spinal implant site and the vessels and then sutures it to the perivertebral, non-vascular soft tissue to secure the implant. The device is designed to protect the vessels in subsequent anterior revision surgeries.

Carlton will be the company's Vice President of Sales and Marketing. The announcement said Carlton brings an extensive background in the management of orthopedic and vascular implant sales and marketing. No other information was given regarding Carlton's previous experience.

Carlton said the company's two new biomaterials, its hydrogel and collagen fiber, "have the potential to improve patient outcomes and significantly reduce costs."

MiMedx Chairman and CEO Pete Petit said, "This is an exciting day for MiMedx Group because it represents the commercialization of our first in a series of new products from our hydrogel material.

"With the hiring of Mike Carlton, we have added another experienced executive to our team. His expertise and leadership will be instrumental in developing our distribution network for our hydrogel spine products and for our future sports medicine collagen fiber products. We look forward to reporting the progress of our market acceptance and the growth of our revenues from Vaso Shield beginning in our first calendar quarter of 2010."

The company says this step moves it from being a development stage company to an operating company. The company's assets include intellectual property protecting a collagen-based technology for augmentation of soft and connective tissue diseases and trauma and intellectual property protecting a durable hydrogel technology.

—WE (December 30, 2009)

legal & regulatory

AAOS, NASS Targeted by Grassley

Looks like Senator Charles Grassley of Iowa is moving up the food chain.

Thirty-three health care organizations, including the American Academy of Orthopaedic Surgeons (AAOS), the North American Spine Society (NASS), the American College of Surgeons and the American Medical Association, received letters from the Senator on December 7, asking them to provide information about money they receive from industry.

Grassley gave the organizations until December 21 to pony up accounting information dating back to 2006. He wants details about grants, donations and meeting sponsorship. He also wants to know details about the organizations' disclosure requirements for its leaders and board members.

If form holds true, the information sent in by the organizations will be leaked to *The Wall Street Journal* sometime early in 2010.

Specifically, the Grassley asked the following:

- Policies for accepting industry funding and whether or not companies are allowed to place restrictions or provide guidance on how funding will be spent

legal & regulatory

- Explanations of all restrictions and/or guidance for each transfer of value from industry
- Policies the organizations plan to adopt to ensure transparency of funding in order to provide a greater public trust in the independence of the organization
- Policies on disclosure of outside income by top executives and board members
- Disclosures of outside income filed with the organizations by its top executives and board members

"These organizations have a lot of influence over public policy, and people rely on their leadership," said Grassley.

Grassley said he wants the targeted organizations to follow the lead of the National Alliance on Mental Illness (NAMI).

A previous review by Grassley of the Alliance's funding had shown that it receive almost two-thirds of its funding from the drug companies. In response, NAMI began posting specific amounts received from the companies.

"It'd be good for the system if other organizations would follow NAMI's lead in this area," Grassley concluded.

—WE (December 28, 2009)

biologics

BioCart Study: Growing New Cartilage

It's New Year's Eve, and ProChon Biotech, Ltd. has a resolution for 2010: to prove the safety and efficacy of the BioCart Cartilage Regeneration System. Earlier this month, company officials announced the expansion of their randomized, double-arm, open-label, multicenter Phase II clinical study, which compares BioCart to microfracture in the treatment of cartilage defects, especially in the knee. Here at the end of 2009, ProChon now has ten clinical study sites in the U.S. and Israel.

In the company's December 14th press release, Dr. James Gladstone, associate professor of orthopaedics at Mt. Sinai School of Medicine in New York City and an investigator in the clinical study, says, "Orthopedic surgeons have long sought a safe, long-term solution for regenerating cartilage injuries with real articular cartilage rather than the fibrous cartilage generated by the microfracture procedure. The BioCart System is exciting technology as it harnesses the patient's own resources to help restore their quality of life."

How Does it Work?

Microfracture treatment also makes use of the patient's own resources (bone marrow stem cells), but the procedure does have some drawbacks. When a patient has a small cartilage injury which does not respond to conservative treatment such as physical therapy or anti-inflammatory medications, microfracture can be a useful surgical option. Doctors use the patient's bone marrow stem cells to make a natural patch over the cartilage defect. Then the surgeons bore small holes into the bone underneath the damaged

biologics

BioCart scaffold / ProChon Biotech, Ltd.

cartilage so that blood and marrow will fill the area of missing cartilage and aid in the healing process. This "patch" forms scar tissue, called fibrocartilage, which effectively protects the damaged cartilage, but fibrocartilage lacks the normal strength of articular cartilage. It may only last a few years, even though rehabilitation can take up to one year, and patients may need revision surgery.

ProChon's answer to the limitations of microfracture is BioCart. In the first step of the procedure, surgeons arthroscopically remove a small piece of healthy cartilage from a non-weight-bearing area of the patient's knee. They send this sample to ProChon's labs, where scientists separate the cartilage cells, called chondrocytes, from the biopsy. With the help of a proprietary fibroblast growth factor (FGF2), scientists can quickly grow a substantial amount of chondrocytes in about two weeks. The scientists then seed the cells into the BioCart biological scaffold and send the implant back to the hospital. In the second step of the treatment, surgeons perform a minimally invasive procedure to shape and implant the scaffold over the damaged cartilage. By six weeks after the surgery, the patient should be able to walk normally again, and the new cartilage cells should last longer than the fibrocartilage produced by microfracture treatment.

Looking Ahead

BioCart is already commercially available in Israel (where ProChon houses its R&D facility) and in Greece. Company officials hope that the Phase II study will also allow the FDA to open the doors to the U.S. market. Although the BioCart system currently requires two separate surgical procedures, researchers may find a way to complete the operation with just one surgery. As we reported in July of this year, Dr. Avner Yayon, founder and chief science officer of ProChon won the Genzyme Award for Excellence in Cartilage Research. If his work is successful, Dr. Yayon could develop a method for using a patient's bone marrow stem cells instead of taking a cartilage biopsy. For now, however, ProChon is concentrating on the current study, and officials hope for successful results in 2010.

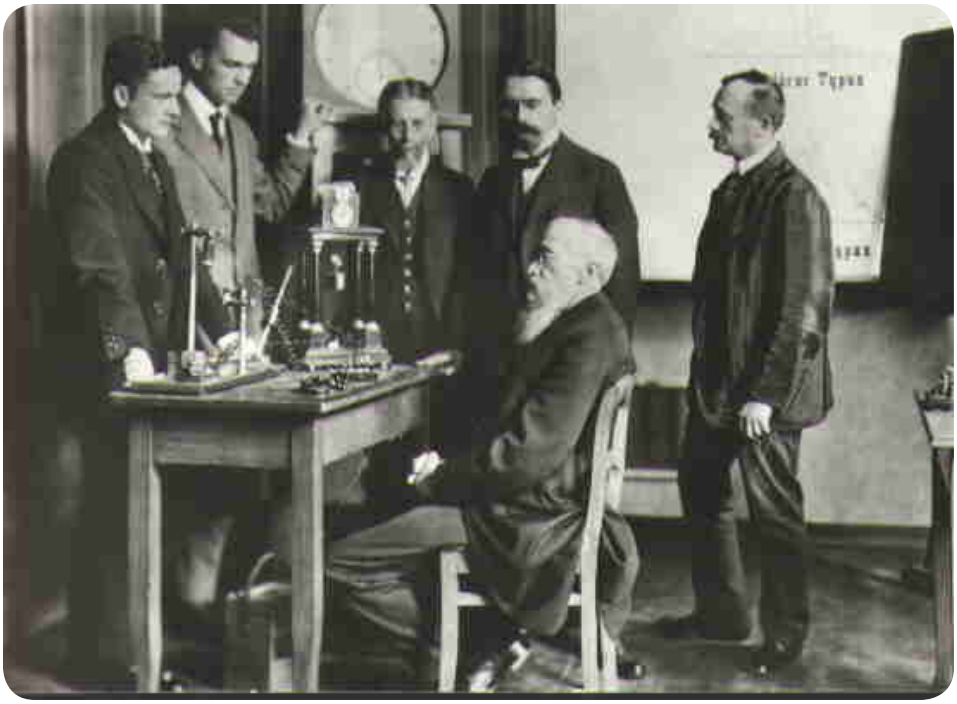
—DK (December 31, 2009)

large joints

Ablynx Initiates RANKL Study

Much as the Belgian chocolatiers are prickly about their confections, the folks at Belgium-based Ablynx are particular about their research. The company has just begun a double-blind, randomized, placebo-controlled Phase I study with ALX-0141, a Nanobody targeting Receptor Activator of Nuclear Factor kappa B Ligand (RANKL), in healthy postmenopausal women.

large joints



commons.wikimedia

According to the company, the anti-RANKL Nanobody has the potential for therapeutic application in the treatment of degenerative bone diseases, such as post-menopausal osteoporosis (PMO), rheumatoid arthritis and cancer driven bone deterioration.

Eva-Lotta Allan, Chief Business Officer of Ablynx, told *OTW,* "This is a double blind, placebo controlled, 3:1 randomization study which will investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of sub-cutaneous administrations of our anti-RANKL Nanobody. The treatment design consists of a single ascending dose of ALX-0141. There will be six different dose levels. We expect to recruit a maximum of 42 healthy post-menopausal women."

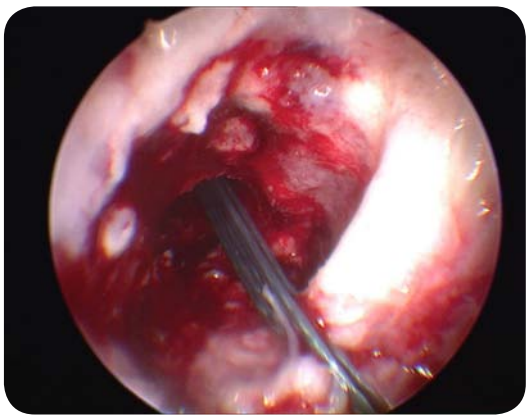
Concerning which bone biomarkers will be measured and how, Allan commented to *OTW,* "The study endpoints are tolerance of the study drug, safety and pharmacology endpoints. We have implemented an efficacy endpoint with a bone biomarker, CTX-1, which will provide an early indication of the effectiveness of ALX-0141. We will be able to determine the MTD and/or biological effective dose after this single sub-cutaneous administrations."

In the news release, Dr. Edwin Moses, CEO and Chairman at Ablynx, commented, "We are delighted to advance ALX-0141 into the clinic within just 3.5 years of initiating this programme. There are now four Nanobodies in clinical trials including Pfizer's anti-TNF-alpha Nanobody which entered Phase II in September 2009 in patients with rheumatoid arthritis."

—EH (December 28, 2009)

Bullseye for CONMED

Connecting with excellence… CONMED Corporation's CONMED Linvatec arthroscopy unit has just released the Bullseye Anatomic Cruciate Reconstruction System, a guide system for anatomic cruciate ligament (ACL and PCL) reconstructions of the knee. Accompanying this release is the CONMED Linvatec Matryx Biocomposite Interference Screw, a new product that is, according to the company, the smallest biocomposite interference screw available on the market today for primary fixation of ACL and PCL grafts.



ACL Repair/Wikimedia Commons

With the Bullseye, says CONMED, surgeons can more precisely do anatomic single bundle and double bundle cruciate reconstructions with a flexible and intuitive guide system.

large joints

The Bullseye will be supported with new sizes of advanced Matryx biocomposite interference screws. A new method of repairing these ligaments utilizes an anatomic approach via the insertion of the replacement ligament grafts into the anatomic footprint of the original ligament—enter the Bullseye, which means that grafts can be placed more precisely in the correct anatomic position.

Regarding the research behind the Bullseye, Robert D. Shallish, Jr., CFO of CONMED, commented to *OTW,* "We did extensive 'Voice of Customer' research to ensure we address the needs of our customers. In addition, our research is supported by literature that describes the 'footprint' approach."

"The Bullseye System supports accurate and reproducible tunnel positioning in anatomic reconstructions," said Dr. John Xerogeanes, Chief of Sports Medicine at Emory Orthopedics and Spine Center, in the news release. "The footprint shape of the guides allows me to visualize the exact location of graft placement and to ensure that the size of the tunnel and ligament are appropriate for the native ACL. In my practice, I generally perform anatomic single bundle reconstructions, and

large joints

these guides are an intuitive way to perform this operation."

The Matryx brand of biocomposite screws are composed of self-reinforced bioabsorbable 96L/4D Poly-Lactic Acid polymer imbued with Beta-TCP particles. Matryx screws are absorbed by the body over time and foster new bone formation around the repaired ligament. The new smaller diameter screw sizes (5.0 - 6.5mm diameters) are comprised of novel processing technology that allows CONMED Linvatec to provide the smallest Biocomposite interference screws currently on the market.

"The Bullseye System, along with the related Matryx interference screws, provides our customers with an innovative complete system solution for performing anatomic knee reconstructions, an area of medical need," said Joseph Darling, President of CONMED Linvatec, in the news release. "We now have a complete product line for both traditional trans-tibial reconstructions, and the more recently developed anatomic single and double bundle techniques. We continue to demonstrate a commitment to innovation for orthopaedic surgical procedures and sports medicine with the launch of the Bullseye System, and the previous release and successful market adoption of our new Shoulder Restoration System."

Both of these products were rolled out at the Fall Arthroscopy Association of North America (AANA) meeting on November 19-21, 2009.

Commenting on the reception for the Bullseye at the meeting, Shallish told *OTW*, "Surgeons who do anatomic ACL recognized the utility of the new Bullseye System and believe it makes a lot of sense. They also believe it is a simple and elegant approach to tunnel identification and placement. They asked about the anatomic portal approach, where to place this portal, and how the instrument was designed to fit flush on the condyle. They liked the combination of the guide and how it is used in conjunction with the Sentinel Drill Bit that will allow them to approach the surgery in an anatomic manner while still protecting important structures like the PCL and condyles."

As for how the Matryx was received at the AANA meeting, Shallish told *OTW*, "Surgeons who do anatomic double-bundle were very happy that they now have a new biocomposite screw that will allow them to achieve strong fixation. They no longer have to up-size tunnels or use metal fixation when they need a 5mm biocomposite screw (since we have the smallest on the market for ACL/PCL reconstruction). In addition, they also expressed interest in using the new screws due to the new Micro-TCP technology and its inherent strength."

When asked how many facilities/surgeons are using the Matryx and what they are saying about it, Shallish commented to *OTW*, "A number of facilities and surgeons are now using the Matryx screw and it continues to increase as we communicate the message on the benefits of the product. Surgeon feedback to us has been that it gives good solid fixation and proven bone in-growth."

—EH (December 30, 2009)

OA Drug Seeking European Approval

Europeans with disappearing cartilage have a new treatment option in the pipeline. The French pharmaceutical company NicOx S.A. has announced that a Marketing Authorization Application (MAA) for naproxcinod, a drug meant for the treatment of osteoarthritis (OA), has been submitted to the European Medicines Agency (EMEA). This corporate sigh of relief comes after the September 2009 submission of a New Drug Application (NDA)

Osteoarthritis of Left Knee/Wikimedia Commons

large joints

to the FDA; it has recently been accepted for filing.

According to the company, naproxcinod is its lead investigational compound and the first in a new class of anti-inflammatory agents known as CINODs (Cyclooxygenase-Inhibiting Nitric Oxide Donators). The MAA application is supported by data from 34 clinical trials involving more than 4,000 subjects treated with naproxcinod. The program evaluated the efficacy of naproxcinod in relieving signs and symptoms of osteoarthritis, as well as its safety, with a particular care given to its effect on blood pressure.

In the news release, Philippe Serrano, Vice President Regulatory Affairs at NicOx, commented: "As planned, we have ended 2009 with the regulatory submissions for naproxcinod both in Europe, where we have just submitted an MAA through the centralized procedure, as well as the United States, where the FDA has recently accepted our NDA for filing."

Pascal Pfister, Chief Scientific Officer and Head of Research & Development at NicOx, added: "We are proud of all the achievements of our team during these last few years, including the completion of these important milestones on time. We will enter 2010 with confidence and are looking forward to working with the FDA and the EMEA during their review of the naproxcinod data."

The FDA plans to complete the filing review by July 24, 2010. The company indicates that it is refraining from making any claims in regard to naproxcinod's safety or efficacy prior to its potential approvals.

—EH (December 30, 2009)

reimbursement

Medicare Payment Cuts Postponed

It's official. Physicians will not see a mandated 21% payment cut from Medicare...until March 1, 2010.

President Obama signed the defense budget bill on December 19. That bill contained language freezing Medicare physician payments for two more months. Without that provision, the mandated cuts would have gone into effect on January 1, 2010.

The Patient Protection and Affordable Care Act, approved by the Senate on Christmas Eve, does not include a long-term fix to Medicare's Sustainable Growth Rate (SGR) formula and Congress will have to take up the issue after it returns from its holiday break.

The lack of a long-term fix in the Senate bill is one reason the American Academy of Orthopaedic Surgeons and the North American Spine Society have opposed the current legislation. The American Medical Association, which has supported the Senate bill, warned Congress that it will withdraw its support unless Congress works to reform Medicare's "fatally flawed physician reimbursement formula, the Sustainable Growth Rate."

The House voted to eliminate the SGR formula in its version of the health care bill, but the Senate turned down a similar measure in October because the $245 billion cost would have added to the national debt.

—WE (December 29, 2009)

Blogspot.com

The Picture of Success: Dr. John McGraw

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

A preacher who owns a cattle farm doesn't typically fit the profile of an orthopedic surgeon. But there is little that is typical about Dr. John McGraw. A surgeon and partner at the Knoxville Orthopaedic Clinic in Tennessee, Dr. McGraw grew up with a father who spent 31 years in the infantry and a mother who left nursing to be a stay-at-home mom.

"I grew up in Greenville, South Carolina, and spent my Sundays at church," says Dr. McGraw. "One day I heard a missionary nurse speaking about someone who is a hero for Baptist doctors, Dr. Bill Wallace, a man martyred by the communist Chinese. A light bulb went off, and I began to consider a career not as a minister, but as a physician. As it turned out, my science grades were better than my theology grades."

Theology, the Air Force and Medical School

Still convinced he could forge a career from both areas of interest, John McGraw persevered. "I enrolled in William Carey College as a ministerial student, but then in 1974 entered the University of Mississippi School of Medicine. It was the only medical school I applied to, and I was rather surprised to be admitted as I had not even taken high school chemistry."

Like many who open letters of acceptance, after the initial euphoria, John McGraw thought, "now how am I going to pay for this?" "I could either borrow money or borrow time. I knew the military would cover all of my tuition, books, fees, and a stipend for living expenses—it was a tossup between the Army and the Air Force. I called my dad and said, 'You probably want me to go Army, right?' To my surprise, he advised me to join the Air Force, saying, 'They will take better care of you.'"

But they wouldn't let him write his own ticket. "In medical school I discovered a fondness for reconstructive plastic surgery, but after I started my general surgery internship in Spartanburg, South Carolina, I learned that the Air Force was not going to allow me to pursue plastic surgery. The first two months of the internship was orthopedics, and, since I found that exciting, I started looking for an orthopedic program. The first program I found had come unglued and lost all of its residents. I was assured by the chair, however, that things would improve. After a year there it was clear that I was not getting a good education…I called the Air Force and asked to come in as a flight surgeon."

With thoughts of orthopedics still percolating, but on the back burner, Dr. McGraw took to the skies of northern Indiana.

> ***"I was stationed at Grissom Air Force Base as a flight surgeon where I focused on the physiology of flight. It was a real bunker mentality, with pilots constantly at the ready. Within five minutes they had to be able to jump into an airplane and leave for secret missions. Thus, part of my time was helping them manage the constant stress of living on alert."***

Leaving behind concerns about g-forces, Dr. McGraw leapt at the chance to reprise his orthopedic path. "In 1982 I learned of an opening at St. Louis University and was invited to join their residency program. The Vice-Chair was the famed spine specialist, Dr. Behrooz Akbarnia, who challenged me to take my time in making a diagnosis and not rush through things in the OR."

But then the military came calling again. "Post-residency I was sent to

What If Mother Nature Had Used Polymer Barriers?

Barksdale Air Force Base as a staff orthopedic surgeon. The Chair of surgery, Dr. Frank Dzida, also an orthopedic surgeon, became my lifelong friend. After a year of officer-in-charge of the emergency room and the previous experience as a flight surgeon, in my second year I was made Chief of Services—essentially a medical director and a chief of staff rolled into one. I accepted the position because we had areas of concern in our hospital. But this only left me one day a week for orthopedics—definitely not enough time for something I enjoyed so much."

Battles in the Air and on the Ground

An opening in a small town then took center stage. "My wife, who is from Laurel, Mississippi, was thrilled when I received an offer from the Laurel Bone and Joint Clinic in 1989. We were there for 15 years, during which time I served as team doctor for a local junior college. For seven of those years I was a punter/kicker coach for the football team. Both of these experiences taught me that you need to know your athletes, including their psychological makeup, motivations, etc. Some players will magnify a small injury while others will sweep a significant injury under the rug."

He then went from the game of football to the real field of life and death. "In 1998 and 1999 I flew on combat missions over Kosovo. My efforts there were largely helping soldiers with the stress of combat—stress which would often translate into aches and pains. This could only be alleviated by reducing the anxiety (as much as possible in a combat zone)."

Returning from the air, Dr. McGraw then joined a ground battle.

> ***"This was a time of a serious malpractice crisis in Mississippi, and in 2001 I became President of the Mississippi Orthopaedic Society. I 'lived' at the Mississippi legislature, discussing how the state was losing doctors in droves, how the trial lawyers had run amuck and how the malpractice insurance rates were outrageous. It was so dire that Mississippi made the cover of Forbes magazine. We did get tort reform the following year, and now Mississippi is a relatively safe place to practice, with insurance premiums now one third of what they used to be. To anyone preparing to fight this kind of battle I say, have your facts and figures in order, and be ready to put your ideas across in a succinct manner."***

Having had enough of legislation and explanations, Dr. McGraw found himself pining for the skies. "I missed flying, so when the recruiters approached me, I said 'yes' to a year at Eglin Air Force Base. We flew in AC-130s and I focused my efforts on caring for the hearts, lungs, eyes, and ears of pilots. After the year, I transferred to the Meridian Air National Guard where I served for five

more years as Chief Flight Surgeon." Then, says Dr. McGraw, it was as if a big hand from the sky intervened. "In 2003 I was interim pastor of my second church, our kids were grown and my wife and I decided that we wanted a change. It seemed like divine intervention when I saw an ad for a practice in Jefferson City, Tennessee, the home of Carson Newman College, a Baptist institution. I knew one of the lead doctors at the practice, the Knoxville Orthopaedic Clinic, who told me that the town was not too small for an orthopedic surgeon. Two months later I interviewed and joined the group."

Happily ensconced in a stimulating, supportive practice, Dr. McGraw turned his attention back to military duty at a crucial time in our country's history—after 9/11. "After the attacks I felt compelled to re-enlist in the Air Force. Surprisingly, they said, 'You've given us 28 years. We thank you…and that's enough.' In 2007 I approached the Army, told them about my situation, and the recruiter said, 'Well, you haven't given us 28 years. Welcome aboard.'"

Bringing Faith and Service to Medicine

Now a U.S. Army Colonel, Dr. McGraw brings his sense of calm—and his faith—to his work as an orthopedist. "Part of my time is spent at St. Mary's Jefferson Memorial Hospital, part of Mercy Health Partners, where I was formerly Chief of Staff. I enjoy being in a religious hospital because it's considered appropriate to share one's faith. I think it's important to identify with the physical pain of our patients from a spiritual standpoint. There is ample evidence in the scientific literature that spirituality affects the body. When I led the Southern Orthopaedic Association, my presidential address was on faith and orthopedic health. I'm not proposing that orthopedists have a license to proselytize, mind you, but that we have a responsibility to acknowledge that most people have some type of spirituality or faith—and to listen to patients if they want to discuss such things."

The responsible Dr. McGraw *could* broadcast strong opinions if he wanted to…he is part owner of a radio station. "I produce a local radio show called 'Doctor-to-Doctor' in which I try to educate listeners on a variety of medical topics. I try to ask my guest physicians very open-ended questions which will hopefully allow them to talk about the topic at hand. The best shows are where I only ask several questions and the guest is providing most of the explanations. It's really all about the listeners/patients."

Reflecting on how serving abroad has affected the way he interacts with patients at home, Dr. McGraw notes, "Most of my patients have been very supportive of my military service. They have sent cards and well wishes, and many are praying for me daily. That, along with the fact that some patients check on my wife and family while I'm away, means a lot. My partners at Knoxville Orthopaedic Clinic have forfeited their half day off each week to fill in for me. Everyone doing this is serving their country and is just as patriotic."

As for how the military might attract more orthopedists, Dr. McGraw says, "Some years ago, there was discussion about physicians having their own branch of the military, something I supported. I treat Army, Air Force, Navy and Marines even though I'm an Army Colonel. In Landstuhl, Germany, we have orthopedic surgeons from the Army, Air Force and Navy serving side by side. However, many aspects of our military lives are very different because of our branch of service. It would be much easier if a military orthopedic surgeon were simply military and not a specific branch. We started making progress toward that in some of our hospitals and in the military medical school, Uniformed Services University of the Health Sciences, but more needs to be done."

To the point of misperceptions about being an orthopedist in the military, he states, "Unfortunately, many misperceptions are correct. Taking time away from a busy practice is very costly—and not just from a monetary standpoint. The US is relying far too strongly on reservists to fill the orthopedic surgeon roles. We need more active duty doctors which would keep reserve orthopedists from being deployed so frequently."

Now deployed to Kosovo as part of a NATO peacekeeping force, Dr. McGraw has little time for outside pursuits.

"I will be returning to the U.S. soon, and to my wife of nearly 29 years, Ann. We have two grown children and one perfect granddaughter. I'm looking forward to getting back to my practice, my 65 acre cattle farm, and my church."

Dr. John McGraw…for patients, for country, for God.

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

Julia Cecil
Marketing & Promotions
julia@ryortho.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Production Coordinator
jayme@ryortho.com

Eileen Mesi
Creative Director
Red Line Design
eileen@ryortho.com

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