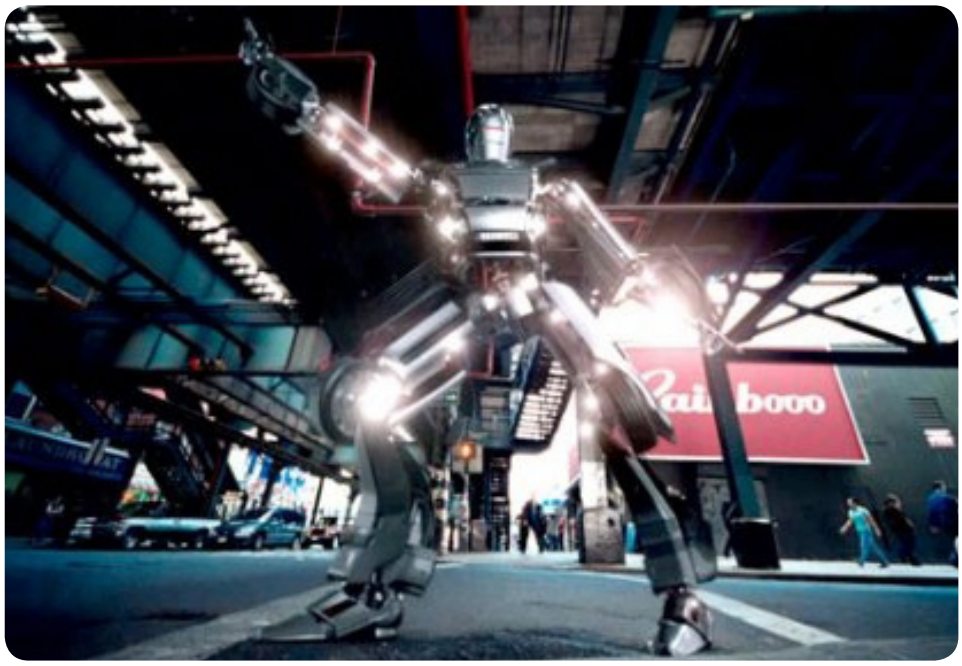
VOLUME 5, ISSUE 18 | JUNE 9, 2009

Orthopedics This Week

week in review



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VOLUME 5, ISSUE 18 | JUNE 9, 2009

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Can we do well by doing good? A *New Yorker* article studies the paradox of why increased per-patient spending results in poorer patient outcomes. Their answer? A focus on hospital/surgeon revenue maximization hurts patient outcomes. Too many tests. Too many procedures. Washington agrees.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Integra LifeSciences	12.35%	4.28%	At these prices (1.2 PSR and 0.8 PEG) maybe Stu should buy his own company.
2	4	Exactech	13.42	8.99	By all measures, EXAC is the 4th least expensive company in orthopedics. Most all institutional investors are looking past 2Q.
3	5	Orthofix	8.14	37.20	Up 37% in just 30 days—after the downgrade by Wachovia. Ramius put OFIX in play and management delivers improved operating news.
4	6	Symmetry	11.05	18.40	Also recently downgraded by Wachovia, SMA is not acting like a downgrade. Insiders are buying. Estimates rising.
5	9	ArthroCare	16.87	40.59	Settles with State Farm for $2.5 million and admits nothing. Slowly, getting the pieces put back together. Up 4 spots.
6	2	Zimmer	29.96	(0.66)	Cheap dollars here. What should investor's pay for a business making 30 cents on every sales dollar? 10x earnings?
7	NR	CONMED	9.80	22.90	High fixed costs hurt in 1Q and will likely depress 2Q. But 2nd half of the year should see rebound as hospital spending recovers.
8	7	Stryker	23.18	1.48	How ironic would it be if CONMED, little old CONMED, became a leading indicator for mighty Stryker?
9	3	Johnson & Johnson	25.36	3.80	FREE DEPUY! Let Our Orthopedic People GO!
10	10	Medtronic	31.68	4.85	PR Jolt? When a company is laying off a couple thousand employees…the danger is that reality will overwhelm PR.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Orthovita	VITA	$4.39	$334	43.9%
2	ArthroCare	ARTC	$11.50	$306	40.6%
3	Orthofix	OFIX	$25.19	$431	37.2%
4	CONMED	CNMD	$16.42	$477	22.9%
5	RTI Biologics Inc	RTIX	$4.48	$242	18.8%
6	Kensey Nash	KNSY	$25.82	$293	18.7%
7	Alphatec Holdings	ATEC	$2.67	$127	18.7%
8	Symmetry Medical	SMA	$8.75	$313	18.4%
9	I Flow Corp	IFLO	$6.22	$152	18.0%
10	TiGenix	TIG.BR	$5.97	$145	18.0%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.OB	$2.50	$24	-16.4%
2	CryoLife	CRY	$5.61	$159	-1.8%
3	Zimmer Holdings	ZMH	$43.48	$9,350	-0.7%
4	Stryker	SYK	$40.48	$16,080	1.5%
5	TranS1	TSON	$8.00	$164	2.2%
6	Johnson & Johnson	JNJ	$55.93	$154,120	3.8%
7	Integra LifeSciences	IART	$27.03	$768	4.3%
8	*Average*			*$9,343*	*4.3%*
9	Medtronic	MDT	$33.95	$37,850	4.8%
10	Osteotech	OSTE	$3.89	$70	5.1%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	ArthroCare	ARTC	$11.50	$306	6.76
2	Symmetry Medical	SMA	$8.75	$313	7.59
3	Zimmer Holdings	ZMH	$43.48	$9,350	10.67
4	Medtronic	MDT	$33.95	$37,850	11.58
5	Johnson & Johnson	JNJ	$55.93	$154,120	12.18

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Osteotech	OSTE	$3.89	$70	125.73
2	Smith & Nephew	SNN	$38.23	$6,750	68.35
3	I Flow Corp	IFLO	$6.22	$152	64.61
4	NuVasive	NUVA	$41.78	$1,520	48.05
5	RTI Biologics Inc	RTIX	$4.48	$242	38.46

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$11.50	$306	0.27
2	Symmetry Medical	SMA	$8.75	$313	0.74
3	Integra LifeSciences	IART	$27.03	$768	0.81
4	Exactech	EXAC	$14.91	$190	0.83
5	CryoLife	CRY	$5.61	$159	0.89

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$41.78	$1,520	9.32
2	RTI Biologics Inc	RTIX	$4.48	$242	2.34
3	Johnson & Johnson	JNJ	$55.93	$154,120	1.59
4	*Average*			*$9,343*	*1.47*
5	CONMED	CNMD	$16.42	$477	1.47

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	CONMED	CNMD	$16.42	$477	0.67
2	Osteotech	OSTE	$3.89	$70	0.70
3	Symmetry Medical	SMA	$8.75	$313	0.74
4	Orthofix	OFIX	$25.19	$431	0.84
5	ArthroCare	ARTC	$11.50	$306	0.91

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$5.97	$145	329.52
2	Mako Surgical	MAKO	$8.70	$218	34.59
3	Regen Biologics	RGBO.OB	$2.50	$24	18.40
4	TranS1	TSON	$8.00	$164	5.86
5	NuVasive	NUVA	$41.78	$1,520	5.35

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VOLUME 5, ISSUE 18 | JUNE 9, 2009

Extremity Repair Market: Stayin' Alive

By Dev Joshi, PearlDiver Extremities Analyst

The extremities implant and repair market is staying strong despite the economic recession. The market may not be growing at its previous rapid pace, but growth remains reasonable and steady.

The first quarter of 2009 (1Q09) picked up where companies left off in 4Q08 when the market saw a slowdown in all sectors of orthopedics. Compared to the 18% growth rate in 1Q08, the 11.8% year-over-year (YOY) growth in 1Q09 represents a significant decline in sales growth rates, but the total quarterly revenue of $262 million still rose from $236 million in1Q08. We estimate that the total annual growth rate for the extremities implant and repair market will come close to 13% for the year 2009 and increase slightly to a respectable rate of 15% for 2010.

Although the extremities repair and device market dropped to growth rates in the low teens (down from the prior year's growth in the high teens and low twenties), it still fared better than other areas in orthopedics such as the large joint reconstruction market, spinal repair and implant market, and the trauma market.

Smaller companies also reported higher growth rates and closed in on the bigger companies that are showing the strains of the economic slowdown. Zimmer Holdings Inc. and DePuy Orthopedics Inc., for example, reported slower rates of extremity revenue growth while smaller companies like Wright Medical Group Inc, Tornier Inc., Exactech Inc., and Biomet Inc. reported higher revenue growth rates.

We believe that Wright Medical is the outright winner in terms of sales in the foot and ankle implant market while Tornier and DePuy are still fighting closely for the #1 spot within the sales of shoulder implants and instruments. We still find DePuy holding the largest piece of the shoulder implant market which in 2008 was worth approximately $500 million worldwide. The foot and ankle implant market, now led by Wright Medical, represents anywhere from $250 to $300 million worldwide. Zimmer, on the other hand, was again the worst performer among the major extremity product suppliers reporting a sales growth rate of only 4%.

The following table shows the major extremity companies with their 1Q09 earnings and future estimates through 2012.

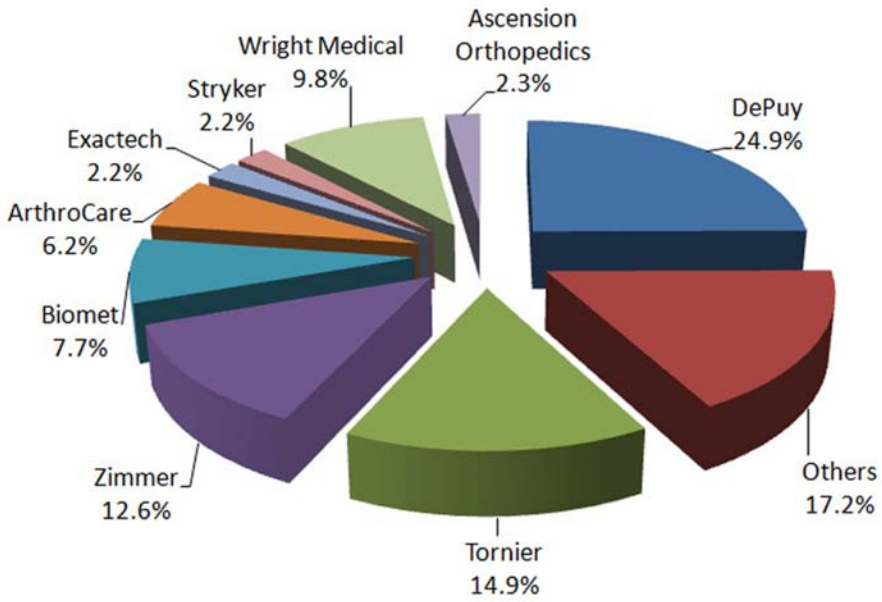
Despite slower revenue growth rate in 1Q09, DePuy still holds the #1 spot in total extremity implant sales and holds one-fourth of the total market share. Coming in at a close second and third are Tornier and Zimmer, respectively. Currently, DePuy, Wright Medical, Tornier, Zimmer, and Biomet make up 70% of the total extremity market.

Table 1: Worldwide Extremity Product Earnings by Company (2009-2012E)

Extremities Market	2009E			2010E	2011E	2012E
	1Q09	2Q09E	2009E			
DePuy	$65.6	$49.4	$233.0	$262.6	$293.1	$326.2
YOY Growth	7.5%	7.4%	8.9%	12.7%	11.6%	11.3%
Tornier	$39.2	$35.5	$157.5	$181.2	$206.8	$234.7
YOY Growth	11.2%	11.0%	12.0%	15.0%	14.1%	13.5%
Zimmer	$33.3	$32.5	$128.1	$139.5	$151.0	$162.8
YOY Growth	4.1%	4.8%	5.9%	8.9%	8.2%	7.8%
Wright Medical	$25.9	$27.0	$110.5	$132.2	$157.6	$186.0
YOY Growth	26.3%	23.3%	24.3%	19.6%	19.2%	18.0%
Biomet	$20.3	$22.6	$85.7	$101.2	$116.6	$132.7
YOY Growth	12.8%	12.4%	15.3%	18.1%	15.2%	13.8%
ArthroCare	$16.2	$17.5	$70.2	$78.7	$87.0	$94.5
YOY Growth	6.6%	7.4%	9.5%	12.1%	10.5%	8.6%
Ascension Orthopedics	$6.1	$5.5	$24.6	$32.0	$40.8	$50.6
YOY Growth	36.6%	34.1%	35.4%	30.1%	27.5%	24.0%
Exactech	$5.8	$5.6	$24.8	$33.5	$43.5	$54.4
YOY Growth	56.8%	43.6%	47.6%	35.1%	29.9%	25.1%
Stryker	$5.8	$5.2	$23.4	$25.2	$27.6	$30.1
YOY Growth	7.4%	6.1%	7.3%	7.7%	9.5%	9.1%
Others	$45.2	$40.8	$181.7	$208.8	$236.0	$264.3
YOY Growth	12.7%	11.5%	13.1%	14.9%	13.0%	12.0%
Total	$263.4	$241.6	$1,039.5	$1,194.9	$1,360.0	$1,536.3
Total Growth	11.8%	11.4%	12.9%	15.0%	13.8%	13.0%

Source: SEC filings, PearlDiver estimates and press releases. ArthroCare has not reported sales since 1Q07. Stryker sales represent just their shoulder sales. Ascension and Tornier represent estimates.

Chart 1: 1Q09 Extremity Product Market Share



Source: Company's SEC filings and press releases

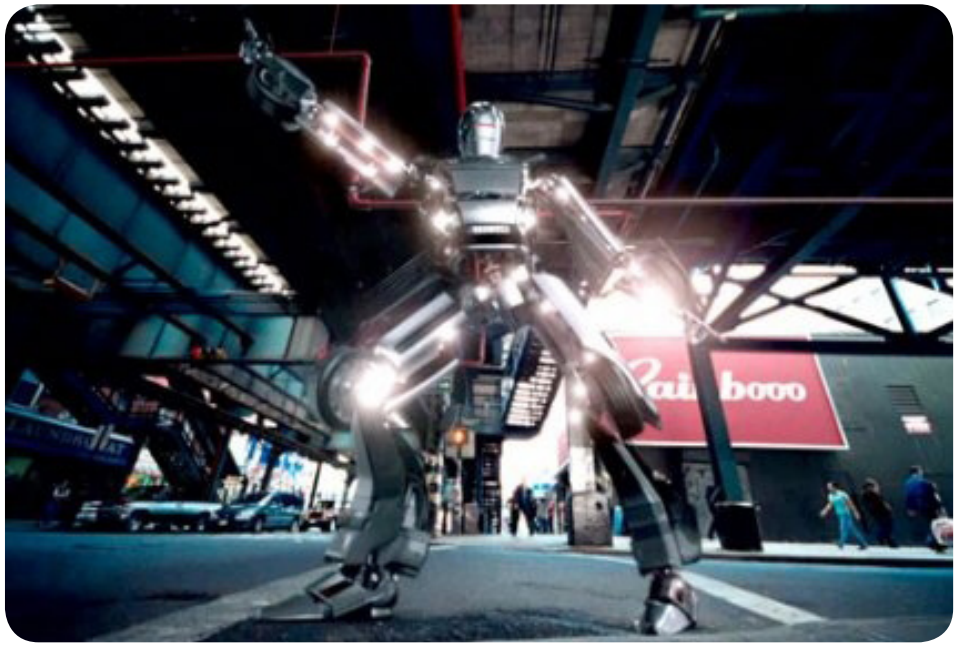
Chart 1 illustrates the market share by company for 1Q09.

Wright Medical Group Inc.

Wright Medical Technologies' strong extremity product sales performance continues despite the market slowdown. One of the key reasons behind their success is the tremendous momentum Wright Medical has gained in foot and ankle product sales in the U.S. While the acquisition of INbone Technologies Inc. and A & M Surgical Inc.'s foot and ankle products injected fresh sources of revenue into the company, the sales figure reflects primarily its in- house products from the CHARLOTTE and DARCO lines of foot and ankle products.

For 1Q09 Wright Medical reported that sales of extremity products grew 26.3%, bringing quarterly revenues to $25.9 million, up from 1Q08 revenues of $20.4 million. The company drove its year-over-year growth with the continued success of the CHARLOTTE Foot and Ankle system and increased sales of the DARCO plating systems, SIDEKICK external fixation systems and the recently added INBONE products acquired in 2Q08. Domestic extremity product sales increased by 34% in 2009, while the international extremity sales growth was comparatively low at 3%.

The company may not be able to repeat its 2008 annual growth of 42.7% anytime in the near future, but we still estimate a strong growth rate for 2009 in the range of 24%, which should bring Wright Medical across the $100 million extremity product sales mark. Sales of extremity products now represent 21.5% of Wright Medical's total sales. The company's share of the extremity repairs and implants market spiked close to 9.8% in this quarter, up from 8.7% in 1Q08, and we expect continuing improvements into 2010.



Wright Medical's management stated that its goal is to become the market leader in foot and ankle product sales, and, based on reported sales results for 2008 and the first quarter of 2009, we estimate that Wright Medical has edged out DePuy as the leader in the overall foot and ankle product market worldwide. Wright Medical's strong performance in the last few years has set it apart from other extremity product companies, and we believe Wright will most likely hold the position of leader in the foot and ankle market well into the future.

DePuy Orthopedics Inc.

For the first quarter ending March 30, 2009, Johnson & Johnson's DePuy, the leading extremity product company worldwide, reported a 7.5% YOY growth (down from the previous year's growth rate of 13%) with $65.6 million in product shipments. The growth rate was slightly higher than our prior forecast of 6%, probably due to the company's strong growth in shoulder product shipments. Domestic extremity product sales represented the majority of its total sales for the first quarter.

DePuy's share of the extremity product market is, we estimate, now 24.9%, down slightly from the prior year's first quarter of 25.8%. For 2Q09, we estimate DePuy's extremity sales will continue to grow at almost the same rate of 7.4%. Given DePuy's higher-than-expected growth and with a strong double-digit growth in its shoulder product division (which represents 80% of its market), we have increased our forecast from a moderate 6.5% to 8.9% for the full year of 2009.

The company's two product spotlights are the Agility Ankle System and the Delta Shoulder System, which contributed significantly to DePuy's extremity product sales. DePuy still reigns as the shoulder division leader with more than one-fourth of the total shoulder product market share. Tornier, Biomet, and Zimmer are, however, closing the gap and increasing competition in the market. Tornier's reverse shoulder system and Wright Medical's ankle system already pose a stiff challenge for DePuy. With Biomet's new second generation of reverse shoulder products, the competition will get even more intense.

Zimmer Holdings Inc.

Zimmer Holdings reported minimal growth again in its extremity product sales for 1Q09, coming in as the slowest growing company in the market. Sales growth for 1Q09 was 4.1%, only slightly better than the 4Q08 growth of 3% and a staggering drop from the 1Q08 growth of 28%. Zimmer's first quarter extremity product revenue contributed $33.3 million to overall Zimmer sales of $993 million and account for 3.3% of Zimmer's total revenues, up slightly from 3% in 1Q08.

In 2008, 77% of Zimmer's extremity product sales were in the domestic market which grew by 10% YOY. Zimmer's European extremity sales reported a negative growth of 16% and so did the Asian market with a decline of 3% YOY. European sales represented 18% and Asia Pacific accounted for just 5% of total extremity product sales.

Even with a weak two quarters, Zimmer held on to its #3 rank in the extremity product market with 12.6% market share, down slightly from its 13.2% share in 4Q08. 1Q09 sales were driven by Zimmer's Bigliani/Flatow Shoulder Solution and the Zimmer Trabecular Metal Reverse Shoulder System in the North America division, while the Anatomical Shoulder System and the Coonrad/Morrey Total Elbow lead extremity product sales in Europe. The Coonrad/Morrey Total Elbow lead the Asian market.

Given the recent decline in Zimmer's growth, PearlDiver estimates Zimmer's

2Q09 sales growth will be only around 5%, a much slower growth rate than the 19% YOY growth reported in 2Q08. Zimmer's decline in market share is due mostly to competition from Tornier, DePuy and Biomet. Zimmer also lacks involvement in the lower extremity product market, causing them to loose share in the total market. For the full year of 2009, we estimate that Zimmer will experience less than a 6% annual growth earning them close to $128 million.

Biomet Inc.

For the first quarter of the calendar year 2009 (December 2008 to February 2009), Biomet, which became a private company in 2007, made, we estimate, $20.3 million in extremity product sales. Almost all of those sales were from shipments of implants and instruments for upper extremities. Compared to 1Q08, when Biomet reported a 16% YOY growth, the company dropped slightly in 1Q09 to a 13% growth rate. Biomet's market share worldwide in 1Q09 was about 7.7%. The company's primary products, such as the Bio Modular shoulder system and the Copeland Humeral system, helped carry the slowed but steady growth. Biomet's upper extremity division has been engaged in fierce competition with strong product offerings from Tornier, DePuy, and Zimmer.

Biomet rolled out its new Comprehensive Reverse Shoulder System in May, the next generation reverse shoulder prosthesis that offers intra-operative flexibility. The reverse shoulder procedure is growing at such a fierce pace that the new generation products will undoubtedly accelerate Biomet's future growth. We estimate Biomet will deliver over a 15% sales growth rate earning it $85.7 million for the year 2009. Since we anticipate the new products will be targeted for sales in the third and fourth quarter, we believe the growth in 2Q09 will be in the proximity of 12.4%, similar to 1Q09.

Exactech Inc.

Exactech is a small, rapidly growing orthopedic company that is quickly gaining market share within the orthopedic market, especially in the extremity product market. For 1Q09, Exactech reported a massive growth of 57% in its shoulder division and is climbing the ladder quietly but quickly. Exactech reported that its extremity product shipments reached $5.8 million, and the company easily surpassed our growth rate estimate of 38%.

We believe that Exactech's extremity product sales will continue to grow at strong double-digit rates on the success of the increasingly popular Equinoxe shoulder system (which doctors use for total shoulder replacement, reverse shoulder replacement, and other shoulder-related procedures) as well as its introduction of new shoulder and humerus lines of products in the late third and fourth quarters of 2009.

While we may not see the 2008 growth rate of 78% again, with the significant earnings in recent quarters, we now estimate Exactech extremity product sales for 2009 will grow in the neighborhood of 48%. This will earn the company close to $25 million. The year 2010 also looks promising with new products scheduled to be launched later this year.

Tornier Inc.

Tornier, the second largest extremity product supplier, was founded in France but, due to a private equity buy-out in 2006, is now based in Minneapolis, Minnesota. Sales in

2008 were $141 million. We estimate sales for this quarter place the company in the 11% growth range. Strong competition from Biomet, Wright Medical, and Exactech played a role in holding Tornier's 1Q09 growth rate at 11%. Tornier's lead products are the Aequalis Shoulder System and the NexFix MTP Fusion System. Product sales include large joint sales in Europe and extremity product repair implants and instruments. For the year 2009, we estimate the company will grow at a rate of 12%, with sales close to $157 million. We estimate the second quarter growth will hold at approximately 11% to 12%.

Other Extremity Companies

The remaining companies in the extremity product market are mostly privately held companies or public companies which do not report extremity product sales separately.

There are some with potential for fast growth. Ascension Orthopedics Inc., a privately held company, will grow at an estimated 30% rate in 2009 and earn close to $24.6 million in sales. Small Bone Innovation Inc. (SBi), Arthrex Inc., Integra LifeSciences Holding Corporation, Orthofix International N.V., Smith & Nephew Inc., and Acumed LLC have also established a good foundation in the extremity product division. Integra LifeSciences' first quarter extremity product sales revenue grew in the low teens. We estimate its first quarter growth was in the range of 10% to 12%, representing an estimated $25 million in sales.

With the close of the first quarter, the extremity repair and implant market as a whole is staying alive in 2009 despite economic woes. Growth rates are down but still stable. Larger companies like Zimmer are feeling the strain of the market slowdown, and smaller companies like Wright Medical are using strong product lines to drive up growth rates and capture top spots in their individual market niches. New product releases in the second half of the year promise to turn up the heat for the competition, and we'll be watching for changes in the weather as we continue to forecast this competitive market in 2009.

For more articles by this author, please select the following link: http://www.pearldiverinc.com/pdi/ext.jsp.

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Many thanks and very best regards,

Robin Young
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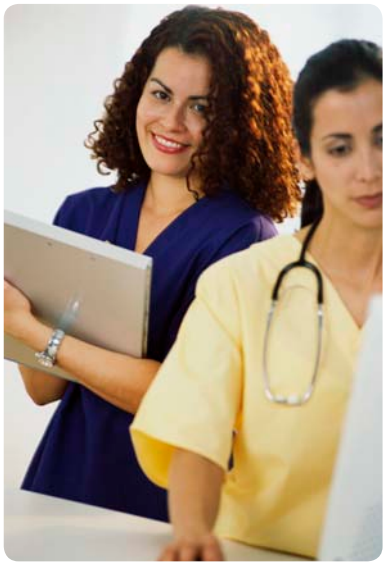
Coding: Not Sexy, Just Necessary

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

If given the choice between attending a seminar on coding or undergoing dental work, many orthopedic surgeons would choose the latter. Coding is one of those things that falls into the "not why I went to medical school category," and many view it as tedious and only peripherally relevant to a surgeon's daily life. But one educated look at the balance sheet can motivate any physician to learn more.



Margaret M. Maley, B.S.N., M.S., a consultant with KarenZupko & Associates, has led coding seminars for the American Academy of Orthopaedic Surgeons (AAOS) for 13 years. Maley, who has not only kept her audiences awake, but knows how to convince them of the value of coding, states, "Orthopedic surgeons often want to run the other way when the issue of coding arises, which, of course, it does all the time. Every day in thousands of practices across the country surgeons are leaving money on the table because they either avoid or don't fully understand coding."

Maley, who obtained a masters degree in orthopedic nursing from Rush University, has worked with orthopedists for nearly 25 years, the last 15 of those being focused on the business aspects of the field. She observes, "The biggest mistake orthopedic surgeons make is that they don't do their own coding, but instead, delegate it to a certified coder or front office person. Any certified coder would tell you, however, that unless the procedure has been properly documented in the record then they can't code for it. So to have someone retrospectively looking at the documentation and trying to determine the appropriate code isn't accurate because the documentation may not be correct."

"But if a surgeon understands what needs to be documented then coding is not particularly difficult. The problem is that most surgeons don't understand the intricacies of coding so they don't know what needs to be documented. The bigger issue, however, is that they just don't want to do it."

Leaving Money on the Table

Setting the motivation issue aside temporarily, Maley gives examples of when understanding the value of documentation could make a difference. "If during a hip revision surgery you use bone graft, it is important to know that bone graft is not reportable for reimbursement unless you document that you harvest it through a separate incision. Even the certified procedural coder cannot report the codes for services unless they are properly documented. Surgeons who do revision surgery know the code for bone graft, but don't know the importance of documenting that the graft was harvested through a separate skin or fascial incision. For example, let's say the doctor is doing a meniscectomy and chondroplasty. If he or she does not document that the chondroplasty was done in a separate compartment of the knee, the chondroplasty is not reportable for reimbursement. Many surgeons may not understand this documentation nuance."

Surgeons have a bent toward efficiency. "To have someone take the time to sit down, read the notes, and assign codes when the surgeon could do it in seconds, is just not a good use of staff time. Also, in most situations, surgeons know exactly what they will do in the OR, so they can do the coding beforehand. We suggest that the surgeon gives the business office diagnosis and CPT (Current Procedural Terminology) codes when a surgery is booked," states Maley.

Another way surgeons can ensure they have funds to pay the bills and meet any monthly economic surprises, says Maley, is to get clear on the importance of diagnosis coding. "This is another whole set of coding rules, which, unfortunately, relies on a book that isn't user friendly. The

ICD-9 system was not created for the purpose of reporting services… it was made for statisticians and adapted for physicians. The purpose of diagnosis coding is to communicate to payers the complicated nature of the patient you're treating. Payers screen off the diagnosis code. For example, if someone comes in with a simple problem with no complicating factors and a high level evaluation & management code is reported, the payer will wonder about this discrepancy. 'How can a simple problem require such a high level of service?'"

She continues, "Generally speaking, orthopedists are lax about assigning diagnosis codes if they're not orthopedic in nature. And this will leave money on the table. For example, if someone in her 30s presents with numbness in the fingers, and has no other symptoms, the surgeon may consider carpal tunnel syndrome as a possible diagnosis. However, a different set of evaluative questions and physical examination would be in order if the same type of patient comes in, but is also an insulin dependent diabetic. If the orthopedic surgeon doesn't document and submit the diagnosis code for insulin dependent diabetes then the payer will wonder why the more extensive history, examination, and medical decision making was necessary."

"Sometimes payers reimburse for services rendered for a specific problem. For example, certain types of injections are only paid for if they are given in the knee as opposed to the shoulder. It is important to link the diagnosis code to the CPT service/procedure code. If, for example, a claim is sent in for an ACL repair, but the surgeon also did a meniscal repair, you will need a diagnosis for both on the claim ticket. An ACL repair doesn't treat the problem of a meniscal tear so you must have another code. Not doing this properly lengthens the amount of time that it takes for collections, meaning, of course, that you don't have the money in the bank to cover your bills."

The Big Picture

For most orthopedists, the fun is found in the OR. Fixing fractures and righting rotator cuffs are exactly why they set out to become surgeons. But in the end, OR time is only part of the picture. "Careful documentation and correct coding for evaluation and management (E&M) services is critical," says Maley. "When orthopedists do not take into account the contribution of E&M services to their bottom line, they ignore a significant source of income. Most orthopedists are not inclined to pay attention to the business side of medicine, even if it's surgically driven. So ignoring office related services is a common mistake."

In today's climate, says Maley, business offices are fighting harder than ever to get the appropriate reimbursement. "If the surgeon is actively involved in reimbursement it can free up the business office and coding personnel to work on getting the reimbursement that is due instead of poring over documents and assigning codes. Coders are very important and they need to be freed up from the basics of coding in order to do other things that impact the bottom line. These things include examining how reimbursement comes in, seeing if something is not paid properly, appealing claim denials, etc. Those are things the surgeon could not and would not do."

Still skeptical? Put your research hat on and track reimbursements before and after you get involved in coding. You might be left wondering how much money you forfeited in the past.

Regenerative Medicine From Stem Cells To The Market Place

2nd Annual Business Education Course Case Western Reserve University July 13-16

Course Organizer—

Arnold I. Caplan is a pioneer in the fields of Regenerative Medicine and adult stem cell biology. He founded Osiris Therapeutics, Inc. in Cleveland in 1992 and thus, set in motion a series of events that resulted in numerous cell-based therapies coming to the market place. He has served on Scientific Advisory Boards, Boards of Directors and has consulted with business entities ranging from startups to multi-billion dollar multi-national corporations. Academically he has published over 350 scientific papers, received several prestigious awards and has trained over 125 science and medical professionals.

Learning Objectives—

The prime learning objectives will provide exposure to the new scientific and medical logics, the newest economic pricing and marketing models and investment logics that make the traditional big-pharma models obsolete. New leadership and initiatives in government, academia, venture capital and public policy will be discussed on the fabric of entrepreneurial principles (both inside and outside corporations and both in the US and Europe). The learning objectives involve both understanding and projecting the next wave of innovations and products with road maps requiring profitability on a backdrop of creativity and medical innovation.

To register for this exceptional course or to view the program go to:
http://case.edu/entrepreneurship/regen_med/

Or contact our course administrator: tammie.lee@case.edu

Case Western Reserve University
College of Arts and Sciences

Skeletal Research Center

Case Western Reserve University
Weatherhead School of Management

Faculty—

The teaching faculty are world renowned scholars and business people in the field of Regenerative Medicine who bring their business perspectives to this new healthcare sector.

Arnold I. Caplan, Ph.D,
Case Western Reserve University

Stephen Badylak, DVM, PhD, MD,
University of Pittsburgh Medical Center

Scott P. Bruder, MD, PhD,
Becton, Dickinson & Company

Christopher M. Coburn,
Cleveland Clinic Foundation

Chris Ehrlich, BA, MBA,
InterWest Partners

Stanton Gerson, MD,
Case Western Reserve University

Robert D. Hisrich, MBA, PhD,
Thunderbird School of
Global Management

Robert Hariri, MD, PhD,
Celgene Cellular Therapeutics

Peter Johnson, MD, Scintellix, LLC

William Lehmann, JD, Athersys, Inc

C. Randall Mills, PhD,
Osiris Therapeutics, Inc.

Gail Naughton, PhD, S
an Diego State University

Stephen W. Potter, MBA, BS, Genzyme

Glenn Prestwich, PhD,
University of Utah

Brock C. Reeve, MBA,
Harvard Stem Cell Institute

David S. Smith, JD,
Pepper Hamilton, LLP

Cyrus Taylor, PhD,
Case Western Reserve University

James R. Tobin, Boston Scientific

Clemens van Blitterswijk, PhD,
Twente University, The Netherlands

Intradiscal Society at Crossroads

By Walter Eisner

When we last met with the endoscopic band of brothers of the International Intradiscal Therapy Society (IITS) in Albi, France, we wondered if the group's tools and strategies to treat spine disease would or should ever become mainstream.

At the IITS' most recent meeting in Phoenix from May 18 through May 23, we observed a Society at a crossroads about its future and place in the mainstream of spinal surgery

Anthony Yeung, M.D., Opening Session IITS09

Society Executive Director and former President Tony Yeung, M.D., delivered on his promise to provide a forum for scientific discourse, and allow for collegial presentations of ideas and debates. Given the level of debate we witnessed at the meeting, as well as the enthusiastic participation of spine surgeons and pain specialists during two days of live surgery and cadaver demonstration workshops at the Yeung family's (with son Christopher Yeung, M.D.) Desert Institute for Spine Care (DISC), it was clear that attendees walked away with practical ideas for their practices.

Workshop at DISC

This meeting confirmed our appreciation for small, provocative and intimate gatherings where scientists/physicians can duke out concepts without the restrictions that often come with meetings of the larger societies. In a word, it was fun.

Between the meetings in Albi and Phoenix, the group co-sponsored the first World Congress of Minimally Invasive Surgery and Spinal Techniques (WCMISST) in Hawaii under the leadership of South Korea's Sang-Ho Lee, M.D., Ph.D. During the Society's business meeting in Phoenix, the group voted to have the next joint meeting of the World Congress and the IITS in Las Vegas in 2010. Tony Yeung will serve as president of that Congress.

In a healthy sign for the Society, members from Europe and Asia pushed for holding future meetings on their home turf.

But back to the "mainstream" question.

"Surgeons, especially those in leadership roles at the major spine societies, often have academic appointments," Yeung told *OTW*. "What they see, which is typically patients with complex spine problems, is far different from what a community surgeon who deals with patients in pain typically sees." In their teaching, they [surgeons with academic appointments] have either consciously or unconsciously served to be an obstacle rather than a facilitator. That is why I believe IITS

is needed, and why we can never be as effective being the stepchild of a major spine organization, even if, on the surface, we are accepted by organized medicine."

A Healthy Debate: Rauschning vs. Yuan

Nothing demonstrated that tension more than a staged point/counterpoint discussion between guest speaker Wolfgang Rauschning, M.D., Ph.D., of Sweden's University of Uppsala (invited by Society President Eric Gozlan, M.D.) and famed spine surgeon Hansen Yuan, M.D.

Yuan presented a historic review of what is and is not known about nucleus replacement in the disc. He described the treatment algorithm of the progressive invasiveness from conservative care to discectomy, disc herniations, total disc replacement, and fusion. He argued that in the future disc regeneration and nucleus replacement will provide clinical benefits to patients and address their pain.

Rauschning, one of the world's leading researchers of the anatomy of the disc with a vast collection of slide samples of discs from cadavers, argued that perhaps we should do less at an earlier stage to prevent the progression of the [disease] process.

In a debate that continued after their presentations on the podium, Rauschning told *OTW*, "We do not really understand how this pathology is progressing. Until a few years ago, fusion was all we knew. Now all of a sudden it's motion preservation and people are adopting all types of stabilizing and motion preservation technologies."

Rauschning added, "I am not a spinal surgeon. In my big collection of slides

Rauschning and Yuan, "Mano-a-Mano."

I have pathologies including post-surgical cases, most of which have been completely silent, asymptomatic and benign. So it is not the pathology, but the pain generators in the lumbar spine pertaining to low-back pain and radicular pain syndromes. Yes, you can say this can hurt because of 'this,' but it needs clinical diagnostic means."

Yuan said he agreed with what Rauschning showed, but in the case Rauschning used on the podium, he would not put in a nucleus because it was gone too far. "When it's too far gone, the weight bearing is no longer borne by the central disc, but by the rim," added Yuan.

Yuan continued, "I'm talking about the fact that when the patient has discogenic back pain and total

incapacity, those patients are not going in to 'too-early' surgery. They are totally disabled. Today you do fusion and we know that's not a good thing. Today we should look at things that are less invasive. Nucleus replacement that is done percutaneously and is minimally invasive is very forgiving."

"Nucleus replacement is less invasive compared to [replacing] a total disc," emphasized Yuan. "For that [fusion] patient, I would do a nucleus replacement, if it is a correct one. Where I disagree [with Rauschning] is that the patient is too far gone for any tissue engineering, gene therapy or regeneration, period."

Finding Pain

Finding the pain was a recurring theme of the meeting, or as Yeung described it, "bridging the gap between pain management and surgery."

David Bradford, M.D., Professor and Chairman of the Department of Orthopaedic Surgery at the University of California, San Francisco, discussed developments in imaging chemical signatures of back pain.

Bradford noted that the recently reported result of a 10-year prospective study by Eugene A. Carragee, M.D., of Stanford University, suggesting that discography can result in accelerated disc degeneration and herniations, is "the first nail in the coffin of discography."

Tony Yeung told *OTW* that it is possible to find and isolate one or more pain generators with the techniques available to surgeons, including discography. "The controversy comes from strong opinions from those who are interested in discography only from a research or academic point of view rather than a clinical position on refining the technique to help the physician decision-maker give the best advice he can give to his patient," said Yeung.

Continued Yeung, "Some of the controversy with discography may be alleviated by new imaging capabilities (with a 3-tesla MRI) that measure the etiologic sources of pain, [such as] the measurement of lactic acid and chondroitin sulfate /keratin sulfate in the disc and correlating those findings with pain generation."

Hansen Yuan was enthusiastic about Bradford's talk on how to be able to identify lactic acid concentrations: "We keep talking about where the pain is coming from. What Bradford talked about is exciting to me. That's chemistry and with chemistry we can measure."

The Return of Chymopapain

Another exciting prospect presented at the meeting was the reintroduction of chymopapain.

Chymopapain was a therapy that soared and crashed during the 1990s. Baxter Laboratories acquired the product in 2001 (marketed as Chymodiactin) but decided to discontinue manufacturing it after some patients reported allergic reactions to the treatment.

The product is an enzyme from the papaya fruit used to treat herniated discs. It is injected directly into a bulging disc and works by eating away the inner core of the disc. Some describe it as a "disc tenderizer." The treatment is called chemonucleolysis and works by breaking down the inner disc, releasing water and shrinking the disc. This takes pressure off the nearby spinal nerve root, the source of the painful symptoms.

Chart Medical

Mike Hurd, the head of Chart Medical, offered attendees an update on his company's efforts to reintroduce the drug in the U.S. and other parts of the world where it had been widely accepted.

The FDA approved Chymodiactin as a pharmaceutical product in 1982. Chart Medical acquired the product in March of this year. Hurd noted that the product was not taken off the market by Baxter in 2001 for reasons related to safety or effectiveness.

According to Hurd, the vast majority of complications occurred in the first two years after the product was released in the U.S. in 1983, and most occurred among the first 10 patients treated by reporting surgeons. Hurd attributed the complications to inexperience with the diagnosis and needle placement by surgeons. In fact, says Hurd, chymopapain injection or chemonucleolysis procedures had fewer adverse reports than lumbar laminectomy for discogenic radiculophathy procedures in the U.S. in 1980.

In international experience with over

43,000 patients who received the drug, the reported complication rate was 3.7% versus 24.8% for patients who underwent surgical procedures.

Chart Medical is currently in the process of pulling together a Chemical, Manufacturing and Control (CMC) Supplemental filing for the FDA to demonstrate that the product it is producing today is substantially equivalent to the product that was being produced by Baxter before it was discontinued. Hurd estimates the funding requirements necessary for initial commercialization of the product to be between $5 million and $7 million.
Hurd told us that the initial launch of the product will be focused on 20 to 30 centers of excellence. Many of these centers have already agreed to participate in the product reintroduction. Distribution will primarily be direct with select regional distributors in the U.S. International distribution will be determined on a country by country basis.

Challenges of Success

Overall, the IITS meeting had more than 60 presentations which ranged from diagnosing and managing spinal pain, endoscopic approaches, surgical techniques, avoiding complications, evidence-based pain management, and stem cells to many other related minimally invasive subjects.

There were also 29 corporate sponsors and a modest exhibition space.

But the notion of this band of brothers still defining themselves as stepchildren to mainstream spine societies will be a challenge for the young surgeons who will assume leadership of IITS in the future. The presence of a sizeable percentage of surgeons from South Korea and China speaks to the reverence in which American surgeons like Tony Yeung and Hansen Yuan are held. The enthusiasm and clinical skills demonstrated by this new generation may hold the seeds for moving this group into the mainstream.

The presence and participation of SAS (The International Society for the Advancement of Spine Surgery) co-founders Hansen Yuan, M.D., and Stephen Hochschuler, M.D., pull like a magnet on IITS society leaders to move closer to incorporating their subspecialty into a larger organization.

Tony Yeung says that minimally

Eric Gozlan, M.D., and Daniel Gastambide, M.D.

invasive surgery should be a true subspecialty rather than a gimmick to get patients to seek out the MIS surgeons. "What we do will likely become a subspecialty because it is difficult to become good without dedication to the art and technique of true MIS surgery," said Yeung.

He also issued a note of caution.

Yeung said his son and surgical partner, Chris, has expressed some concern over teaching non-surgeons because they may get into trouble quickly as they do not have the skills of experienced surgeons. There is no control over their activities since many own their own outpatient facilities that they can convert into surgical centers. Teaching too many too fast could actually end up hurting the cause of MIS.

Challenges of Succession

During a final session of the meeting, Hansen Yuan echoed those remarks. Yuan said that the positive clinical results of exceptional and experienced surgeons like Yeung now have to be studied, documented and taught systematically to assure that new surgeons can replicate those results. Stephen Hochschuler said that IITS should step up to define what makes sense and what doesn't make sense from a clinical standpoint.

The IITS being turned over to incoming President Daniel Gastambide, M.D., of France faces the challenge of moving from being revolutionaries to becoming governors. From what we saw, Tony Yeung and the founding band of brothers have succeeded in demonstrating the safety and effectiveness of their craft, and a new generation is ready to step into the mainstream.

company news

Active Implants Raises $10 Million

It's been a couple of busy weeks at Memphis-based Active Implants Corporation, the hip and knee advanced polymer technology start-up led by seasoned pros from a who's who of major orthopedics companies.

A couple of weeks after announcing that it has a new CEO and president, the company announced on June 3 that it has more money and a new board member.

Mike Mainelli, Jr., the new boss and former Stryker executive, said on June 3 that the company has raised $10 million in its Series C Preferred Stock offering. The company will use the money to try and reach its development, clinical, regulatory and early commercialization milestones.

New to the board is Charles Martin, the recent past Chairman and Chief Executive Officer and a current director of Zephyr Associates, a financial services software development firm. He joins Active Chairman Jack R. Blair, a past Group President of Smith & Nephew and former Chairman of DJ Orthopedics, James D. Lackie, founder and President of Lackie Trading, Inc., Amiram Steinberg, founder and key inventor of the AIC polymer technology, and Henry Klyce, founder, president/CEO and Chairman of St. Francis Medical Technologies and founder, president/CEO of Spartek Medical, Inc.

The privately held company is incorporating medical grade polycarbonate urethane technology into orthopedic products through its TriboFit Hip and NUsurface Implant systems. Over the past five years, the company has developed its first product, has had four rounds of fundraising and initiated commercialization of its products in Europe.

The company appears to have the pedigree and funding. Now we'll see if management has developed products the market wants and needs.

—WE (June 4, 2009)

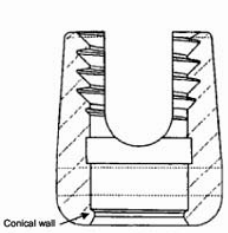
legal & regulatory

Appeals Court Rules on "678" Patent

"Affirmed-in-Part; Reversed-in Part and Remanded."

With those words the U.S. Court of Appeals for the Federal District of New York, sent the DePuy/Medtronic Vertex screw case back to a trial court.

DePuy Spine won a $226.3 million verdict from Medtronic in 2007 for damages related to the patent infringement on its Vertex line of multiaxial screws licensed by Biedermann Motech GmbH (the "678" patent). Those screws are no longer on the market.



Vertex® Model

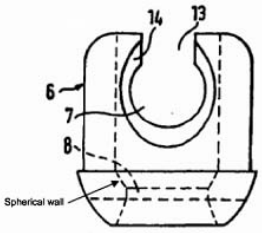


Figure 3 of the '678 Patent

Medtronic appealed that award.

On June 1, Medtronic announced that the Federal Appeals Court eliminated $87.7 million of the award. The court affirmed $149.1 million for lost profits but also reversed a sanctions determination against Medtronic, finding that it was legally incorrect and could not be sustained. The court also found that the jury should not have awarded damages on noninfringing

legal & regulatory

"pull-through" products sold in conjunction with the screws.

Medtronic Spinal and Biologics' business President Steve La Neve said the ruling "has no bearing on our current Vertex Select and OC Systems," which are other spinal systems. DePuy said they were "pleased."

The case will now be remanded to a trial court for calculation of the reduced judgment, which will include amounts both for post-judgment and pre-judgment interest on the damages.

—WE (June 3, 2009)

FDA Through the Keyhole

We've written numerous articles criticizing the FDA for being dysfunctional, inconsistent and secretive in how it handles device approvals.

Now the new team of "HamStein", FDA Commissioner Margaret Hamburg, M.D., and her Principal Deputy Commissioner Joshua Sharfstein, M.D., have announced that they are forming a task force to look for ways to make the agency's decisions about devices, among other things, more transparent.

Said Hamburg on June 2, "While the agency cannot disclose all types of information, I believe the agency can do a better job of providing useful information to the public in a timely manner. The agency can and should communicate with the public in a way that provides more clarity about agency activities and processes, not less."

While the announcement of the task force has been used by the editorial board of *The New York Times* to accuse industry of citing trade secrets in cases where important health and safety information was kept from the public, we believe more clarity and openness might have saved companies like ReGen Biologics time, money, and focus as they attempted to get their Menaflex device through the agency.

Hamburg said that increasing transparency and helping the public understand the reasoning behind FDA decisions was very important to the agency's credibility.

The task force will be chaired by Sharfstein and is scheduled to deliver recommendations to Hamburg within six months.

Sharfstein said the task force wants public input regarding disclosure of clinical trial data and information related to product recalls and approvals. A public meeting has been scheduled for June 24 and another will be held in the fall.

The FDA Transparency Task Force will:

- Seek public input on issues related to transparency;
- Recommend ways that the agency can better explain its operations compatible with the appropriate protection of confidential information;
- Identify information the FDA should provide about specific agency operations and activities, including enforcement actions and product approvals;
- Identify problems and barriers, both internal and external, to providing useful and understandable information about FDA activities and decision-making to the public;
- Identify appropriate tools and new technologies for informing the public;

legal & regulatory

- Recommend changes to the FDA's current operations, including internal policies and guidance, to improve the agency's ability to provide information to the public in a timely and effective manner;
- Recommend legislative or regulatory changes, if appropriate, to improve the FDA's ability to provide information to the public; and
- Submit a written report to the commissioner on the Transparency Task Force's findings and recommendations.

We think this is a good first step towards helping restore a little credibility to the agency's decisions and make it easier for industry to navigate their products through the agency's approval process.

—WE (June 3, 2009)

biologics

England's Stem Cell Money Shot

England got a stimulus package of its own this week, but it's not for failing banks; this award is going to the scientific community. Scientists at four universities received almost £4 million (currently about $6,459,000) to fund research and development for new ways to heal broken bones, including stem cell therapies and tissue engineering. The research projects will especially focus on orthopedic problems associated with aging.

The funding comes from the Biotechnology and Biological Sciences Research Council (BBSRC), a funding agency sponsored by the UK government which annually awards about £450 million to a wide range of research projects. The lead researchers from the four universities are Professor Alicia El Haj, University of Keele, Professor Kevin Shakesheff, University of Nottingham, Professor Molly Stevens, Imperial College London, and Professor Richard Oreffo, University of Southampton.

Although these four scientists come from four different universities, the award will actually fund a collaborative study combining the researchers' own specialties. According to the BBSRC, "Over the next five years, the scientists will combine

The Queen's Tower at the Imperial College London

biologics

their expertise in skeletal stem cells, scaffolds and materials chemistry to identify the key growth factors, matrix proteins and physical conditions that will enhance tissue regeneration and ultimately lead to more effective skeletal repair strategies."

Professor Oreffo, the lead researcher of the study, said, "We believe a paradigm shift in approach is required if we are to lead internationally in regenerative medicine. Our findings of how stem cells, scaffolds and the physical environment can be combined to induce new bone and cartilage will be used to augment and accelerate bone repair. This will allow us to develop new regimes for cartilage and bone regeneration ultimately leading to more effective treatments."

After President Obama lifted the ban on federally funding embryonic stem cell research, many scientists in the UK worried about losing researchers to the U.S. The NIH (National Institutes of Health) is hard at work drafting new guidelines for human stem cell research, and the California Institute for Regenerative Medicine has already awarded funding for new, promising stem cell research projects in the U.S.

This award from the BBSRC, however, brings fresh enthusiasm and attention to stem cell research in the UK. It also represents a whole different approach to funding research projects. Rather than pitting these four scientists against each other in competition for one grant, the award brings them together in a collaborative effort. It remains to be seen whether or not this "paradigm shift in approach" will bring about new stem cell therapies or new methods of tissue engineering, but bringing four leading scientists together, rather than splitting them into separate projects, is certainly a good start.

—DK (May 29, 2009)

New Bone-Forming Stem Cells: GSCs

The study began as a search for root causes of infertility but instead made a wholly different discovery: a new and unique population of stem cells. Gonadal Stem Cells (GSCs), to be exact, isolated from adult human testis. These cells can differentiate into both bone (osteogenic) and cartilage (chondrogenic) cells, and orthopedists could potentially use this discovery to help heal broken bones and damaged joints.

The discovery came from the international collaborative efforts of DaVinci Biosciences LLC, the University of Utah, the Southern California Center for Regenerative Medicine and the Omni Hospital in Ecuador, and the findings were published in *Biochemical and Biophysical Research Communications,* an international, peer-reviewed journal.

Much of the research on stem cells in the orthopedic field centers on bone marrow mesenchymal stem cells (BMSCs). BMSCs can take a little extra coercion to differentiate into bone forming cells, but according to Dr. Rafael Gonzalez, Director of Research & Development at DaVinci Biosciences, "GSCs have a great propensity to differentiate into bone and cartilage cells, and we can easily obtain GSCs from small biopsies of the testis. There is no need for feeder cells or animal cells to grow the population; we can expand and produce a large amount of GSCs from just a small starting biopsy."

Previous studies have isolated pluripotent cells (cells able to differentiate into any cell type) from germ-line stem cells within the human testis, but these cells come with the same negative side effects of embryonic stem cell transplants: the propensity to form tumors. Since

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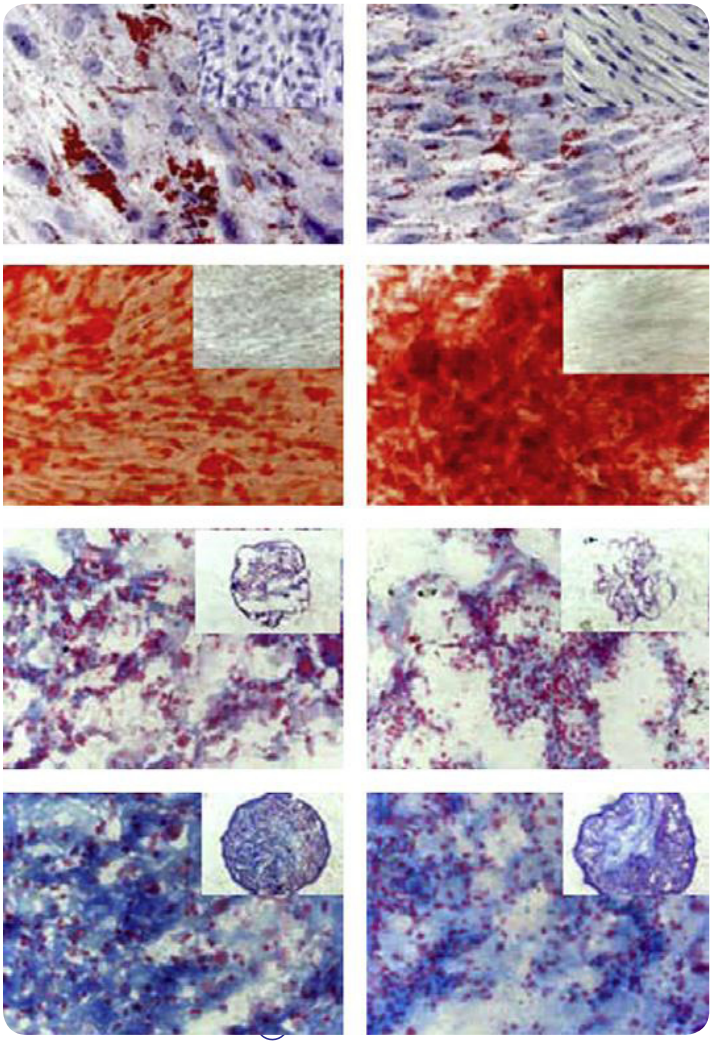

Caption: Image of GSCs differentiating into fat cells (top row), bone cells (second row) and cartilage cells (bottom two rows)

Source: "A putative mesenchymal stem cells population isolated from adult human testes" from Biochemical and Biophysical Research Communications by Rafael Gonzalez

GSCs are not germ-line stem cells, they avoid this potential complication which often halts promising research.

Dr. Gonzalez told *OTW* that the next step in the research will be transplanting GSCs into diseased animal models. The research team will also test and develop delivery systems for the GSCs. They hope that this new line of stem cells will be especially useful in healing complicated bone fractures, such as atrophic nonunions. If the animal tests are successful, the research team will then move ahead to human trials. In March of this year, DaVinci Biosciences announced the successful human trials of bone marrow derived stem cell transplants into patients with spinal cord injuries. In the not-too-distant future, these researchers may continue their streak of successful trials with GSCs and further unlock the potential of the body's own cells to heal itself.

—DK (June 5, 2009)

large joints

To the Park! Tai Chi & Arthritis

Kinder, softer martial art good for the joints…A new study, headed up by Amanda Hall of The George Institute in Sydney, Australia, examines the effectiveness of Tai Chi in decreasing pain and disability and improving physical function and quality of life in people with chronic musculoskeletal pain. The study, published in the June issue of *Arthritis Care & Research,* suggests that Tai Chi not only helps decrease the pain of arthritis, but improves overall physical health, level of tension, and satisfaction with health status.

The researchers conducted a systematic review and meta-analysis, examining seven eligible randomized controlled trials that used Tai Chi as the main intervention for patients with musculoskeletal pain.

As indicated in the news release, the authors state, "The fact that Tai Chi is inexpensive, convenient, and enjoyable and conveys other psychological and social benefits supports the use this type of intervention for pain conditions such as arthritis."

They also noted, "It is of importance to note that the results reported in this systematic review are indicative of the effect of Tai Chi versus minimal

large joints

intervention (usual health care or health education) or wait list control."

Teasing out the particular effects of Tai Chi would require a placebo-controlled trial, something not yet undertaken.

—EH (June 1, 2009)

BMD and Focal Erosions

Behind bone breakdown… Research to date has shown that after five years of struggling with rheumatoid arthritis (RA), up to 50% of patients show evidence of focal erosions. A new study examines the relationship between this, and the fact that RA doubles the risk of osteoporosis and fractures, seeking to increase understanding of the underlying pathophysiology of RA-related bone disease.

The study, published in the June issue of *Arthritis & Rheumatism*, was headed up by Daniel H. Solomon of Brigham and Women's Hospital in Boston. Researchers took data from 163 postmenopausal women with RA, none of whom were taking osteoporosis medications. Participants underwent bone density scans of the hip and spine, as well as X-rays of the hand to determine if they had bone erosions.

The findings included a correlation between hip bone mineral density (BMD) and bone erosion; the relationship was not statistically significant after adjusting for clinical factors such as age, BMI and use of oral glucocorticoids used to treat RA. The relationship did appear stronger, however, in patients with early RA.

As indicated in the news release, the authors stated, "Our findings suggest that the relationship between focal erosions and generalized osteoporosis

Hand radiograph of a patient with rheumatoid arthritis. Imaged is the hand of a patient with advanced rheumatoid arthritis with severe destruction of the joint architecture. Asterisks indicate bone erosion.

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is complicated and modified by many aspects of RA and other factors." They point out that with longer disease duration, other variables such as the use of disease-modifying antirheumatic drugs (DMARDs), disease activity and markers of inflammation may dilute the relationship between focal erosions and hip BMD.

Regarding the stronger relationship found between hip BMD and erosions than with spine BMD, the authors offer several possible explanations. One is the possibility that the inflammation underlying RA affects the hip more than the spine; another is that the effects are more apparent at the hip, which may more closely relate to joint mobility and overall functional status.

While there have been other studies looking at the bone manifestations of RA, the current study is one of the only ones that has focused on the relationship between two skeletal manifestations of the disease. The authors note that none of the patients were taking glucocorticoids or osteoporosis medications but may have in the past, which could affect the results. Supplemental vitamin D use may also have had an unforeseen effect.

"It may be that the presumed association between erosions and BMD is most relevant with regard to patients with severe or early untreated RA," the authors conclude. This could become more of an issue given that bone-directed treatments are more often becoming part of RA treatment protocols. For example, data from trials of a monoclonal antibody directed at a molecule important in bone metabolism suggest that it may be effective at improving BMD and reducing progression of erosion. Since focal erosions and osteoporosis may be manifestations of a similar inflammatory response, further studies may clarify important roles of inflammation in both of these processes in RA.

—EH (June 1, 2009)

United/Oxford and Hospital for Joint Diseases Sign Agreement

Coming together in good faith can mean good results for all involved. Such is the case with the recently announced multi-year agreement between UnitedHealthcare, a UnitedHealth Group company, and the physicians of the Hospital for Joint Diseases (HJD) at NYU Langone Medical Center.

UnitedHealthcare and its Oxford Health Plan and Medicare plan can now benefit from in-network access to more than 40 orthopedists affiliated with the Hospital for Joint Diseases, a designated UnitedHealth Premium Specialty Center for Surgical Spine and Total Joint Replacement. This brings UnitedHealthcare and Oxford's provider network to more than 38,000 physicians and 200 hospitals statewide.

"This new agreement doubles the number of our physicians participating with UnitedHealthcare on an in-network basis," said Joseph Zuckerman, M.D., in the news release. Dr. Zuckerman, the Walter A.L. Thompson Professor of Orthopedic Surgery and Chairman of the Department of Orthopedic Surgery at the Hospital for Joint Diseases, added: "We are excited about our expanded relationship with UnitedHealthcare and look forward to continuing to serve its health plan customers."

"Our agreement with the physicians at the Hospital of Joint Diseases, a

large joints

facility that focuses on evidence-based quality standards for care, will expand access to quality, affordable health care for our customers," said Dr. Sanford Cohen, Chief Medical Officer of UnitedHealthcare's northeast region. "We believe that productive, collaborative relationships between physicians, hospitals and payors are an important step in ensuring more people have convenient access to quality, cost-efficient care and in modernizing our nation's health care system."

Regarding the impetus for the agreement, Dr. Zuckerman told *OTW,* "UnitedHealthcare/Oxford Health Plans, now one company, is a major player in the New York metropolitan area. Their goal is to improve patient access to the highest level of care, in this case, orthopedic treatment. Our objective is for patients to have access to the outstanding care by our faculty at NYUHospital for Joint Diseases. The realization that our goals dovetailed led to a series of meetings. There was an existing contract in place, with a number of our faculty already participating. The new agreement, which took approximately six months to negotiate, resulted in a system that increased the number of participating physicians…in all different orthopaedic specialty areas"

Commenting on the teamwork involved, Dr. Zuckerman added, "We were able to come to a successful agreement because there was a significant level of hospital/physician cooperation."

To ensure things stay on track, says Dr. Zuckerman, there will be data collection. He told *OTW,* "Given that the goals were to increase patient access, as well as increase patient flow to HJD, we will track these numbers. There will most likely be a quarterly assessment of how many UnitedHealthcare/Oxford Health patients undergo surgery, as compared with those numbers prior to the agreement."

—EH (June 1, 2009)

Got RA? Get Hydrangea Root

Hope blooms anew in Boston. Researchers from the program in Cellular and Molecular Medicine and the Immune Disease Institute at Children's Hospital Boston (PCMM/IDI), along with investigators from the Harvard School of Dental Medicine, have found that a drug derived from the hydrangea root may be helpful in treating autoimmune diseases such as rheumatoid arthritis. The study was published in the June 5 edition of *Science*.

"Um…tasty"

large joints

Across several ponds—in China—folks have been using hydrangea root for centuries. It seems, says the news release, that a small-molecule compound known as halofuginone inhibits the development of Th17 cells, immune cells recently recognized as important players in autoimmune disease. And, it does so without altering other kinds of T cells involved in normal immune function. Additionally, a mouse model of autoimmunity showed that halofuginone reduces disease pathology.

In a ballet of biochemistry, the researchers found that halofuginone prevented the development of Th17 cells in both mice and humans, halted the disease process they trigger, and was selective in its effects. Also, say the investigators, it has the potential to be taken orally. "This is really the first description of a small molecule that interferes with autoimmune pathology but is not a general immune suppressant," says Mark Sundrud, Ph.D., in the news release. Dr. Sundrud, affiliated with PCMM/IDI, is the study's first author.

Th17 cells, recognized as the culprit in a number of autoimmune disorders, are genetically distinct from the other major categories of T-cells. When the researchers cultured mouse CD4+ T-cells along with cytokines that normally induce Th17 development, there was a pronounced decrease in Th17 cells—but not in Th1, Th2 or T regulatory cells—when halofuginone was added. Similarly, in cultured human CD4+ T-cells, halofuginone selectively suppressed production of IL-17, the principal cytokine made by Th17 cells.

Microarray studies of the halofuginone-treated cells allowed the researchers to examine patterns of gene expression in response to the drug. They found that many genes involved in stress responses were turned on, and they eventually learned that halofuginone acts by activating a biochemical pathway known as the "amino acid starvation response," or AAR, which typically protects cells when amino acids are at low levels. When excess amino acids were added to cultured T-cells exposed to halofuginone, the AAR didn't switch on, and Th17 cells were able to develop. Conversely, the researchers were able to inhibit Th17 differentiation simply by depleting amino acids, thereby inducing the AAR.

The researchers hypothesize that AAR prevents Th17 cells from forming because it (AAR) acts an energy-saver, slowing down a cell's building activities to conserve amino acids. "When a cell senses amino acid deprivation, it tries to conserve amino acids by preventing specific types of responses that are energetically expensive," said Dr. Sundrud in the news release. "In inflamed tissues, a lot of cells are producing a lot of protein, so it would make sense that a cell with amino acid deprivation would want to block signals that promote inflammation."

But halofuginone, or some yet-to-be developed derivative compound, could potentially be used to address any autoimmune or inflammatory disease related to Th17 cells by activating the AAR, the researchers said.

"Remarkably, halofuginone evokes the AAR in all cells but selectively inhibits T-cell inflammatory responses," said Anjana Rao, Ph.D., in the news release. Dr. Rao, also of the PCMM/IDI, was a senior investigator on the study. He added, "This recalls the actions of cyclosporin A and FK506, two other immunosuppressive drugs that block the activity of calcineurin. Calcineurin is present in all cells, but selectively prevents the rejection of heart, lung, liver and bone marrow transplants when given to patients. These drugs

large joints

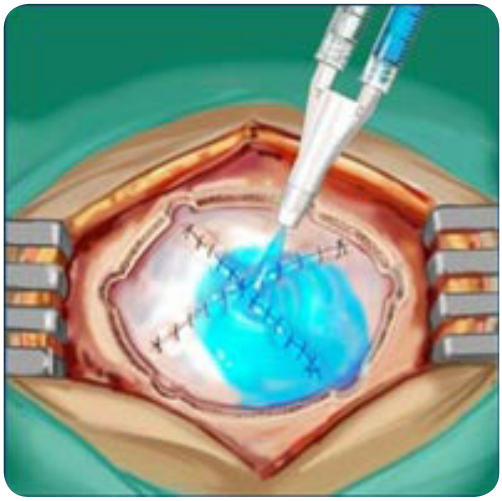
revolutionized transplant medicine when they were introduced over 20 years ago, and halofuginone may herald a revolution in the treatment of certain types of autoimmune/ inflammatory diseases."

—EH (June 4, 2009)

spine

DuraSeal Goes Spinal

Covidien's DuraSeal Sealant has been recommended for use in spinal surgeries. The sealant has already been approved for use in cranial surgeries.



The recommendation came in May from an FDA advisory panel on a unanimous vote. The panel told the agency that FDA approval should come with a requirement that Covidien collect more data for at least three month. Some panelists had concerns because there was no clear difference in fluid leakage 90 days after surgery, even though the data showed the sealant worked better than alternative methods during surgery itself.

The synthetic polymer provides a watertight seal when sprayed onto the surgical site in addition to traditional sutures. Leakage of cerebral spinal fluid in brain and spinal surgeries can cause complications such as infections. Surgical sutures alone can leave small gaps. Currently, surgeons use additional stitches, soft tissue patches or unapproved glues to try to further prevent leaks.

"There are currently no approved products for this indication," said Xavier Lefebvre, Clinical Vice President for Covidien's device unit.

Panel member and spine surgeon Michael Yaszemski, M.D., reportedly said at the panel meeting, "The key point here is (this is) an aid for the surgeon at the point when he or she is having trouble closing a surgical opening."

However, Dr. Peter Lurie, deputy director of consumer advocacy group Public Citizen's Health Research Group, reportedly told the panel that not enough patients had been studied. "We're approving this for patients not for doctors...We need to see rigorously controlled data, and these data are not it," said Lurie.

The company looked at 158 patients, with 102 given DuraSeal and 56 treated with other methods, according to the FDA.

In the end, the panelists sided with approving expansion for use of the sealant as long as the additional data was collected. The FDA provided no timetable for when they will make their decision.

—WE (June 3, 2009)

Low Back Pain Recommendations From APS

The American Pain Society (APS) has issued new clinical practices guidelines for low back pain.

These recommendations are sure to fuel the fire of the ongoing debate between pain management specialists and spine surgeons.

The new guidelines, which include eight recommendations, were published in the May issue of Spine and emphasize the use of non-invasive treatments over interventional procedures and shared decision-making between the patient and their physician. This seems to confirm the findings of the SPORT study which demonstrated higher patient satisfaction when patients were more involved decisions about their options for treatments.

"These recommendations are based on a more complete body of evidence than was available even just several years ago, consequently, we believe these recommendations will give physicians more confidence when treating patients with persistent back pain," said Roger Chou, M.D.,

spine

lead author, director of the APS' Clinical Practice Guideline Program, and associate professor of medicine (general internal medicine), Oregon Evidence-based Practice Center, Oregon Health & Science University. "Unfortunately, randomized trials are still limited for a number of commonly used interventional procedures to generate evidence-based recommendations, and our review also highlights the need for more research."

To develop the guideline, a multi-disciplinary APS panel, joined by experts on interventional therapies, reviewed 3,348 abstracts and analyzed 161 relevant clinical trials.

Based on the data the panel gathered, the APS now recommends:

1. Against the use of provocative discography (injection of fluid into the disc in order to determine if it is the source of back pain) for patients with chronic nonradicular low back pain

2. The consideration of intensive interdisciplinary rehabilitation with a cognitive/behavioral emphasis for patients with nonradicular low back pain who do not respond to usual, non-interdisciplinary therapies

3. Against facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injections for patients with patients with persistent nonradicular low back pain, and insufficient evidence to guide use of other interventional therapies

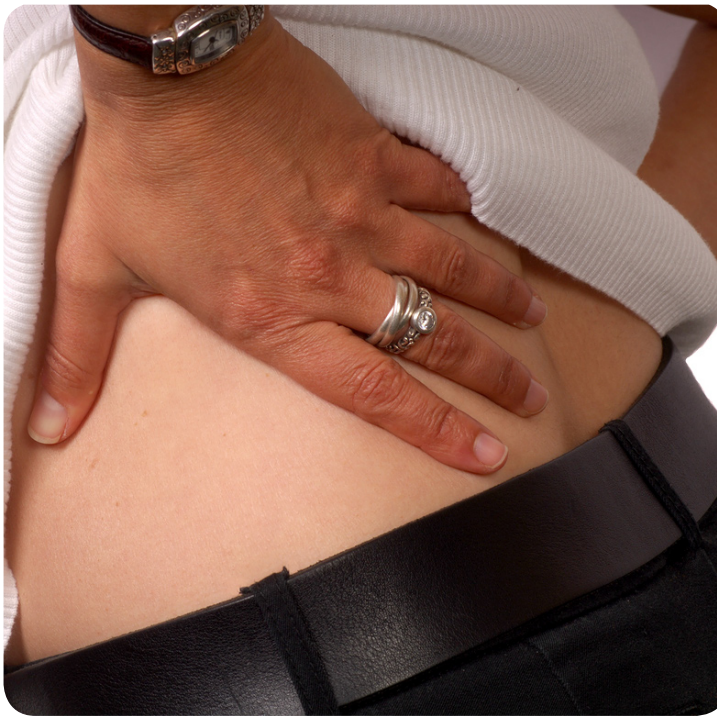
4. A discussion of risks and benefits of surgery and the use of shared decision-making with reference to rehabilitation as a similarly effective option for patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms

5. Insufficient evidence to guide recommendations for vertebral disc replacement

6. A discussion of the risks and benefits of epidural steroid injections and shared decision-making, including specific review of evidence of lack of long-term benefit for patients with persistent radiculopathy due to herniated lumbar disc

7. A discussion of the risks and benefits of surgery and use of shared decision-making that references moderate benefits that decrease over time for patients with persistent and disabling radiculopathy due to herniated lumbar disc or persistent and disabling leg pain

8. Discussion of risks and benefits of spinal cord stimulation and shared decision-making, including reference to the high rate of complications following stimulator placement for patients with persistent and disabling radicular pain following surgery for herniated disc and no evidence of a persistently compressed nerve root



Low-back pain is the fifth most common reason for doctor's visits and accounts for more than $26 billion in direct health care costs nationwide each year.

—WE (June 3, 2009)

The Picture of Success: Dr. Thomas Byrd

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

You might think that someone who works with "loose bodies" is a plastic surgeon. In the case of Dr. Thomas Byrd, founder of the Nashville Sports Medicine and Orthopaedic Center, however, the work lies more in the realm of failing hips and knees.

Thomas Byrd was born in Nashville, Tennessee, to a mother whose time was consumed with taking care of six children, all one year apart, along with a father who was a busy general surgeon. "Interestingly, my father rarely gave advice, preferring to lead by example. While a medical career was never my plan, over the years I developed an interest in chemistry and biology, and, not sure which direction to take, went to college. I am now proud to be the third generation of doctors to serve the Nashville community."

After highlighting many a math and physics textbook during his undergraduate years at the University of Miami, Thomas Byrd set out for medical school. "I entered the Vanderbilt School of Medicine in 1978. In my third year I began clinical rotations and then quickly decided on orthopedics. The hands-on nature of the field was appealing, as was the obvious intellectual stimulation. Not to mention the fact that all the orthopedists I came into contact with were a good bunch of folks who were quite animated."

Deciding to stay where he could get a hot biscuit on a Sunday morning, Dr. Byrd took up higher level orthopedic study in Kentucky. "I began my residency at the University of Louisville (UL) in 1982. It was a good fit for me to remain in the south, and the Louisville program was known for being very hands-on, something that I knew would accelerate my understanding of orthopedic concepts. 'Two sides to every coin' comes to mind when reflecting on that time. While we were given a great deal of autonomy, it was pretty stressful because the challenging problems of patients with no recourse were being thrown at us day and night… often without a lot of supervision."

"The facility's greatest strength," says Dr. Byrd, "was its trauma program. In fact, UL had a trauma center before there were even level one trauma centers. Helping me navigate these waters was Dr. Walter Badenhausen, an accomplished sports medicine doctor who worked with the University of Louisville athletic programs. A quiet and dignified hand surgeon, Dr. Badenhausen also had a busy pediatric practice. It was amazing to see this Abe Lincoln looking guy enter a room and all of the kids rush up to hug him. Perhaps most impressive was his consistent demeanor. He never assumed a different persona—he was who he was. As for how he influenced my career, Dr. Badenhausen had an extremely unpretentious nature that somehow struck a chord in me. Here was this accomplished surgeon who was able to achieve so much and didn't have a big ego."

And in a way, Dr. Byrd's greatest strength was his father. "Unquestionably, my father was my most significant mentor. In addition to being available for me 24/7, he was an inspiration because of his service to our country, and because of the experiences he endured. As a medical officer in World War II he oversaw 'Normandy' and lost 75% of his officers in the first 24 hours. In the course of discussing my trauma experience in general surgery work with him one day, my father said, 'I saw all the trauma I ever needed to see in the first 24 hours at Normandy beach.'"

Dr. Byrd knew that to become distinguished, one must distinguish oneself. "During my intern year the chief resident landed a sports medicine fellowship with the renowned Dr. Jim Andrews, whose facility sounded like an excellent place for training. After determining that there was little separating me from anyone else looking at such a program, starting in my first summer of residency I took every vacation at Dr. Andrews' clinic. By the last year of residency I

had secured a place in his fellowship program, where I would come into contact with world famous athletes… as well as the lady who bakes pies down the street."

"Aside from imparting his exceptional surgical skills, Dr. Andrews also taught me that you must treat athletes as regular people. Whenever he walked into a room, whether the patient was a famous athlete or someone who had never been on CNN, at that moment in time that person had his undivided attention. Dr. Andrews may not have taught me every procedure I do, but he graced me with the tools that set the stage for all of my accomplishments."

A brief sojourn "up East" in 1989 would broaden Dr. Byrd's thinking as far as how healthcare delivery can be structured. "Because I knew that many people come limping in to see a sports medicine doctor, I spent six months focusing on total joints at New England Baptist Hospital in Boston where I got an opportunity to see how the healthcare system works in a different environment. Boston has more of a traditional educational format with more hierarchy, whereas Birmingham is more geared to private practice—and, even though it's the south, the wheels of change turned a little faster than in Boston."

He continues, "I then returned to my Nashvillian roots and went into private practice where I focused on sports medicine and arthroscopy. Like most orthopedists who do arthroscopy and sports medicine, I spent a lot of time on knees and shoulders. As time went on and my desire to do something novel increased, I turned more toward elbow and hip arthroscopy."

Dr. Byrd's quest for originality would result in hope for the hopeless. "The area that has set me apart more than anything has been my role in developing techniques for arthroscopic surgery of the hip. In 1990 my partner had a young teenager with loose bodies in his hip, and asked if I would attempt to remove the fragments arthroscopically instead of doing an open surgery. We did so and it worked exceptionally well."

"Based on that experience we realized that we could remove loose bodies arthroscopically. Things limped along, with one or two such patients a year being referred to me. After awhile, our physical therapist approached me, saying, 'I think my brother has loose bodies in his hip.' The imaging didn't show much, so we considered the possibility that there were radiolucent loose bodies. I did an arthroscopic surgery in the hip, where I found a bucket handle tear of the labrum (a large displaced fragment entrapped in the joint). We removed the fragment and after 14 years this guy's symptoms were gone. We now knew that there were other things going on in the hip that could be addressed arthroscopically."

He continues, "We then began receiving a lot of referrals for patients who had been experiencing unexplained hip pain for a prolonged period of time, and for whom conservative treatment had failed. Time and again we went in with an arthroscope and were able to identify the damage in the joint. As we began recognizing these problems, we started to nudge the radiologist to get better at detecting them. It was becoming obvious that most problems went unrecognized and untreated for several years."

"And keep in mind that the evolution of hip arthroscopy is different than that of knee arthroscopy. With the knee most things we address have evolved from open techniques and gradually evolved to less invasive methods. In the hip, most things that we addressed evolved from no treatment at all. In the past we weren't doing big open operations on otherwise healthy joints. Most problems in the hip went unrecognized and patients were simply resigned to living within the constraints of their symptoms. Athletes are especially prone to these problems and have many times been forced to give up their careers."

Dr. Byrd didn't need an arthroscope to see into the future. He knew that each of these cases—as data points—would one day tell a more complete story. "The two smartest things I ever did were number

one, marry my wife, and number two, begin keeping track of this data early on. We now have 16 years of data on approximately 4,000 patients. There has been a lot of pathology recognized in the last six or seven years that we didn't recognize existed in the early '90s. Prospective data collection doesn't capture that, obviously. Fortunately we have videos and X-rays on all patients so we can go back and look at data on, for example, impingement, something that was not recognized in the '90s. As you can imagine, this is an enormous undertaking."

Also a visionary in the visualization realm, Dr. Byrd saw room for improvement in the offerings of the day. Not pleased with what was available at the time, in the early '90s he developed a technique called the "Supine Approach to Hip Arthroscopy." Dr. Byrd: "This approach involves positioning the patient in a way that provides adequate joint space for safe access and visualization of the joint. The basic principles we described all those years ago are sound, and thus the original technique has changed very little. As technology has advanced, we've built on the basic principles and introduced other methods to access the joint. The basic procedure is to use a distraction device, or a standard fracture table, and apply distraction force to the hip joint and separate the joint surface 8 to 10 millimeters for safe entry. We use three arthroscopic portals for access to the central part of the hip joint, even managing to address pathology surrounding the hip area."

Even after making these advances in hip arthroscopy, Dr. Byrd knows that there is still work to be done. "I am excited that there is such a groundswell of interest in hip arthroscopy and joint preservation strategies. There are so many talented and innovative people who are turning their attention toward this area. For awhile there were only a handful of us doing this…to the point where we could recite each other's presentations. Now, there is more understanding of and interest in hip joint pathology.

When hip arthroscopy began we didn't know certain problems existed. Now we are much better poised to dig deeper and determine why these problems exist."

This devotee of the arthroscope wants his trainees to approach this tool with a dash or two of caution. Dr. Byrd: "When working with visiting fellows, I am mindful that their philosophy and approach is probably pretty well established by the time I begin to work with them. The most important thing I can impart is how to perform these procedures as safely as possible and how to undertake the appropriate patient selection. We know that the results of our procedures are more dependent on proper patient selection than on how successfully you do the procedure."

"It is essential to ensure the patient has the type of pathology that can be successfully addressed with arthroscopy. For example, someone with advanced arthritis is unlikely to benefit from arthroscopic intervention but may be an excellent candidate for hip replacement. It is also vital to ensure that the patient has reasonable expectations of what the procedure can accomplish. If you have someone whose lifestyle and daily activities have been hindered for years because of hip pathology they may really benefit from arthroscopy but they should understand that they're not going to return to running marathons."

Regarding the "first smart thing" Dr. Byrd did, he and his wife Donna are celebrating 30 years of marriage in 2009. "Donna and our two wonderful daughters, Allison and Ellen, have always taken wonderful vacations and enjoy being out on the water. Fishing is always one of my favorite parts of the trip. Actually, for 31 years we have been going to the Caribbean with the same group of boating enthusiasts. We head down, enjoy the crystal blue waters, go free diving, spear fishing, and deep sea fishing. It's all very relaxing."

Dr. Thomas Byrd…collecting data, compiling evidence, and rounding up grouper.

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