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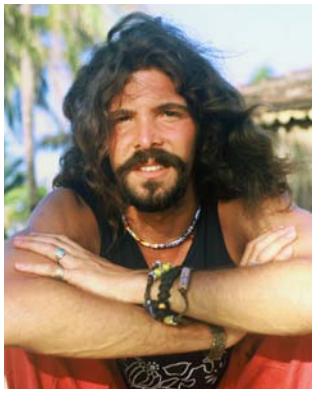
Orthopedics This Week

week in review

picture of success



breaking news

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Brinksmanship in Washington makes it extremely difficult to plan or commit resources. In effect, a new layer of uncertainty has been added to what is already a powerful deleveraging trend in the global economy. Speaking of deleveraging, it won't be over, we think, before 2013 at the earliest.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	14.72%	6.71%	OFIX continues to deliver the best price-to-earnings growth in orthopedics. Still #1.
2	3	Smith & Nephew	22.8	3.26	9% earnings growth on 8% sales growth is the consensus for Q2. Probably gained share last quarter.
3	4	ConMed	9.54	3.27	The key to CNMD is rising profit margins. The Street thinks 9% earnings growth on 3% sales growth in Q2.
4	5	Kensey Nash	34.24	5.04	34% profit margins—after spending 24% of sales on R&D! Yet the Street expects down growth in June quarter. Hmmm…
5	2	Zimmer	27.75	1.83	Big Blue is trading near its 52 week high. Outlook is for 9% earnings growth on 7% sales growth.
6	8	Wright Medical	8.76	5.20	Deal with ArthroCare shows that recent management changes haven't stopped WMGI from taking the initiative.
7	9	Johnson & Johnson	26.33	0.98	For the past 40 years, JNJ has raised its dividend by an average of 15% per year. Current yield is 3.4%.
8	10	Symmetry	7.64	12.33	Most analysts expect SMA to have grown 8% last quarter. We think SMA probably beat that.
9	6	Stryker	25.23	(2.30)	Lower profit margins reported for Q2. Call it corporate heartburn after digesting VITA and BSX's Neuro business.
10	7	Exactech	8.08	2.62	EXAC is a bit of a family business—but one that engenders customer loyalty. But how well will that deliver Q2 sales growth?

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TranS1	TSON	$5.11	$107	13.81%
2	MAKO Surgical	MAKO	$32.51	$1,332	13.35%
3	Symmetry Medical	SMA	$9.84	$358	12.33%
4	RTI Biologics Inc	RTIX	$3.14	$173	10.56%
5	CryoLife	CRY	$5.78	$161	10.31%
6	Orthofix	OFIX	$44.50	$812	6.71%
7	Wright Medical	WMGI	$15.39	$601	5.20%
8	Kensey Nash	KNSY	$25.76	$220	5.04%
9	ArthroCare	ARTC	$34.41	$940	3.33%
10	ConMed	CNMD	$28.12	$796	3.27%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Bacterin Intl Holdings	BONE	$2.45	$93	-19.14%
2	Alphatec Holdings	ATEC	$3.26	$291	-9.94%
3	TiGenix	TIG.BR	$1.25	$114	-8.74%
4	Medtronic	MDT	$37.07	$39,330	-3.20%
5	Stryker	SYK	$56.88	$22,070	-2.30%
6	Tornier N.V.	TRNX	$27.45	$1,072	-1.01%
7	Integra LifeSciences	IART	$47.43	$1,355	-0.15%
8	Johnson & Johnson	JNJ	$66.72	182,889	0.98%
9	Zimmer Holdings	ZMH	$63.29	$12,149	1.83%
10	Synthes	SYST.VX	$179.14	$21,278	2.21%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$37.07	$39,330	11.30
2	Johnson & Johnson	JNJ	$66.72	$182,889	13.64
3	Zimmer Holdings	ZMH	$63.29	$12,149	13.97
4	Kensey Nash	KNSY	$25.76	$220	14.63
5	CryoLife	CRY	$5.78	$161	15.62

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	NuVasive	NUVA	$33.19	$1,317	39.51
2	ArthroCare	ARTC	$34.41	$940	28.92
3	Wright Medical	WMGI	$15.39	$601	23.68
4	Synthes	SYST.VX	$179.14	$21,278	23.42
5	ConMed	CNMD	$28.12	$796	21.47

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	RTI Biologics Inc	RTIX	$3.14	$173	0.96
2	Orthofix	OFIX	$44.50	$812	1.02
3	Kensey Nash	KNSY	$25.76	$220	1.08
4	NuVasive	NUVA	$33.19	$1,317	1.15
5	Exactech	EXAC	$18.43	$241	1.17

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$5.78	$161	2.95
2	Alphatec Holdings	ATEC	$3.26	$291	2.89
3	ConMed	CNMD	$28.12	$796	2.35
4	Johnson & Johnson	JNJ	$66.72	$182,889	2.20
5	ArthroCare	ARTC	$34.41	$940	1.80

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$9.84	$358	0.99
2	RTI Biologics Inc	RTIX	$3.14	$173	1.04
3	ConMed	CNMD	$28.12	$796	1.12
4	Wright Medical	WMGI	$15.39	$601	1.16
5	Exactech	EXAC	$18.43	$241	1.27

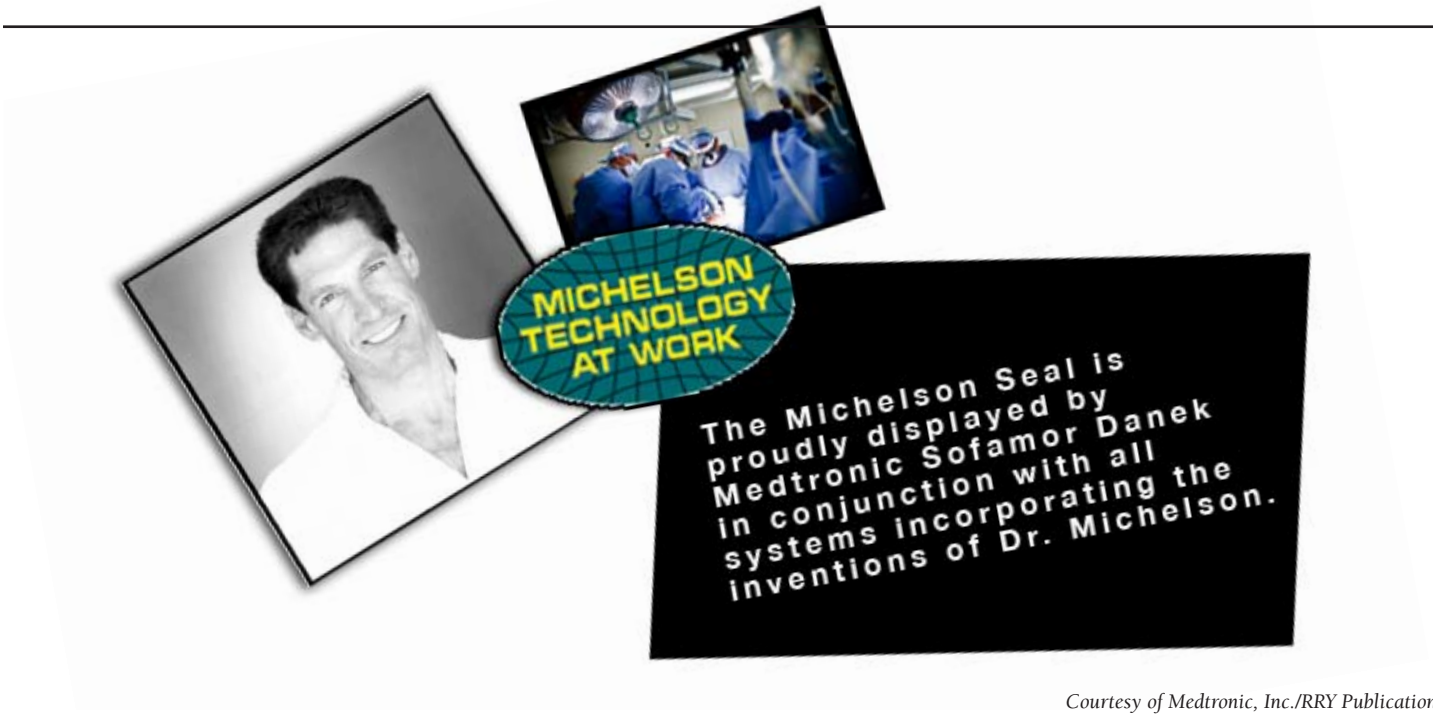
Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$1.25	$114	183.38
2	MAKO Surgical	MAKO	$32.51	$1,332	30.06
3	Synthes	SYST.VX	$179.14	$21,278	5.77
4	Bacterin Intl Holdings	BONE	$2.45	$93	4.99
5	Tornier N.V.	TRNX	$27.45	$1,072	4.71

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

Michelson on Surgeon Industry Relationships

By Walter Eisner



Courtesy of Medtronic, Inc./RRY Publications

In 2010, Bill Hawkins, then head of Medtronic, declared the end of the "Surgeon Champion Era."

The pronouncement came three years after federal prosecutors levied massive fines against the major orthopedic device companies and put in place a new set of rules for companies who pay surgeon/scientists to be consultants or trainers or to receive royalties for inventions manufactured and sold by those companies.

Gary Michelson, M.D., if you count patents filed and payments received, is the single most successful surgeon/inventor/scientist of that era. In his own words, he told *OTW* that in the early '90s, many surgeons who were receiving money from implant suppliers and being called consultants were actually doing almost nothing other than influencing their colleagues to use that same supplier's products.

Recent allegations by peer review journal editors that royalty payments and consulting fees have tainted clinical research have once again brought the issue of the relationship between surgeons and industry to the public conscious.

OTW asked Dr. Michelson, who has received more in corporate payments than any other living surgeon, about these issues of corporate payments to surgeons and the integrity of clinical research and, indeed, the broader state of spine care and orthopedics in the U.S.

Surgeon Champion

OTW: What was a "Surgeon Champion?"

Dr. Michelson: A product champion was to a surgeon what a Michael Jordan was to a basketball fan. They are

Gary Michelson, M.D./Courtesy for the photos, "Courtesy of Seth Casteel"

in a position to directly influence a tremendous amount of sales because they have the minds of the people who are the consumers on behalf of the patients.

When the surgeons wrote so-called monographs, the reader would get the impression that they were the creators of this technology. At the bottom of the monographs they had what was called a 'Pearl.' That was actually the word that was used.

And the 'Pearl' was: "When I do this, I use BMP," or some other product in conjunction with this product.

OTW: Would this include off-label use?

Dr. Michelson: That's not the doctor's concern because there are not the same FDA ramifications of off-label use by a doctor. That is only for a medical device manufacturer or drug manufacturer. But these physicians had financial relationships with those entities. I don't think this will come as big news to anybody in the orthopedic field, but you know Congress has been looking into this for a very long time.

This has become a bit of a game reminiscent of the Spy vs. Spy comic strip from the old *MAD Magazines*. As soon as Congress gets on to one thing, the players just change the game to achieve the same purpose in another way.

The real discussion should be; should doctors be paid for influencing other doctors to use products for medical device companies. I guess that's the right discussion and if all the doctors say yes, that's good and Congress says, that's good, then there's nothing left to discuss. But where there is a lack of transparency, where it happens in the dark, that is suspect and then the question is, 'Is that really ethical?'

A Transparent Relationship

OTW: Devices aren't like drugs. You're not going to develop those in the lab. So, there is a requirement for a marriage between the physician and the industry engineer. How do you properly structure an ethical and transparent relationship there?

Dr. Michelson: It's an intriguing question. There are all different things that lead to invention. If you read Land, the man who invented the Polaroid process, he said the difficult part was simply to define the problem and then the solution is much easier.

The surgeon is in the best position to recognize how the state of the art is insufficient. He's very aware of what it does, but is also in a position to understand what is still needed. So, perhaps he comes up with what he thinks is a solution to what he needs and he goes to a device manufacturer and says, 'You're in this area, here's the problem. How can this be solved?' In that situation, maybe he really is working as a consultant.

In which case, his remuneration should probably be proportionate to his contribution. So, maybe the surgeon makes an average of $300 an hour or $500 an hour when you take his total hours work versus income.

You know, under the old model that was going on in the early '90s, people were just getting a lot of money being called consultants and doing almost nothing except influencing other surgeons to use the products.

And either the medical device company, be it spine or hips or anything else, was simply buying the purchasing value of that particular surgeon because he used a lot of stuff. Or, what's worse, that person was in a position to influence a lot of other doctors to magnify the benefit back to the device manufacturer.

And then, the person in that position wasn't saying, 'Listen, I'm hawking or I'm shilling for such and such a medical device company.' This was happening even under rules of various medical societies and journals, where he, as a physician, was required at a minimum, to disclose his financial ties and the sheer magnitude of their remuneration to a manufacturer. The bad actors had those undisclosed relationships.

Fraud

OTW: Some of the most vocal critics of surgeon consulting fees have claimed that this lack of transparency was tantamount to fraud.

Dr. Michelson: If one were to look at the definition of 'fraud,' you would find that is where a person is induced to make a purchase where the seller either makes statements that he knows to be false; or, withholds from the purchaser important information, which had he known, he would not have made the purchase.

The physicians who had the financial relationships with the maker of these products, which were either undisclosed or the magnitude of the financial value of those relationships were undisclosed, and who misled other physicians (the intermediary purchasing decision-maker on behalf of the patient) such that they were induced to purchase those products, are in my opinion guilty of fraud.

While this statement may seem incendiary, it is not. There are a lot of conditional prepositions (ifs) in that statement, such that if the shoe does not fit, then no one needs to be offended. If, on the other hand, someone wants to stand up and say that statement applies to me so I am offended, then I stand by the statement.

OTW: Where are the problems?

Dr. Michelson: The number one problem and I don't mean in terms of importance, but just in order is, transparency.

Number two, were they even being honest? If they were to say, 'Look, I do have a relationship with company X. I get money and this is what this product does. Here are the good parts or the bad parts,' then at least they are being honest. I think what's now causing the fall-out in the recent BMP issue, is the question about whether the researcher paper's authors and physician promoters were being honest. They were representing that they were academicians when they were being salespeople.

If what someone is doing is shilling for people who are giving them a lot of money for doing it, that's probably a crime. And if it's not, it should be.

Not One Piece of Evidence

OTW: When then federal prosecutor Christopher Christie reached the deferred prosecution agreements with device companies, he said he had evidence that surgeons were taking money to use the product. To this day, not one piece of evidence has been made public nor has one surgeon has been prosecuted.

Dr. Michelson: That's because I think government has looked at this as if the surgeons were the Johns. We are going to take the hookers off the street rather than going after the Johns. It wasn't for lack of evidence.

So they had a day of 'mea culpas.' They had admissions where the companies just said 'Yeah we did that, we had to do that because it was the playing field.' In the end the companies were not denying it and not saying that never happened.

Then they said, 'We're for new governance, we'll go forward, we'll clean up our act.'

That was up to government whether to go after the physicians. But apparently they figured they could clean up the situation and move on. That was their decision.

OTW: When Christie testified in front of Congress, he said had he brought prosecutions forward, the big device companies would've fallen because they would all have lost their Medicare and Medicaid certification.

Dr. Michelson: The Medicare business is particularly important to those companies whose primary source of income are total joints because that's the demographic of people who are getting total knees and total hips, they are the people covered by Medicare.

Restoring Trust

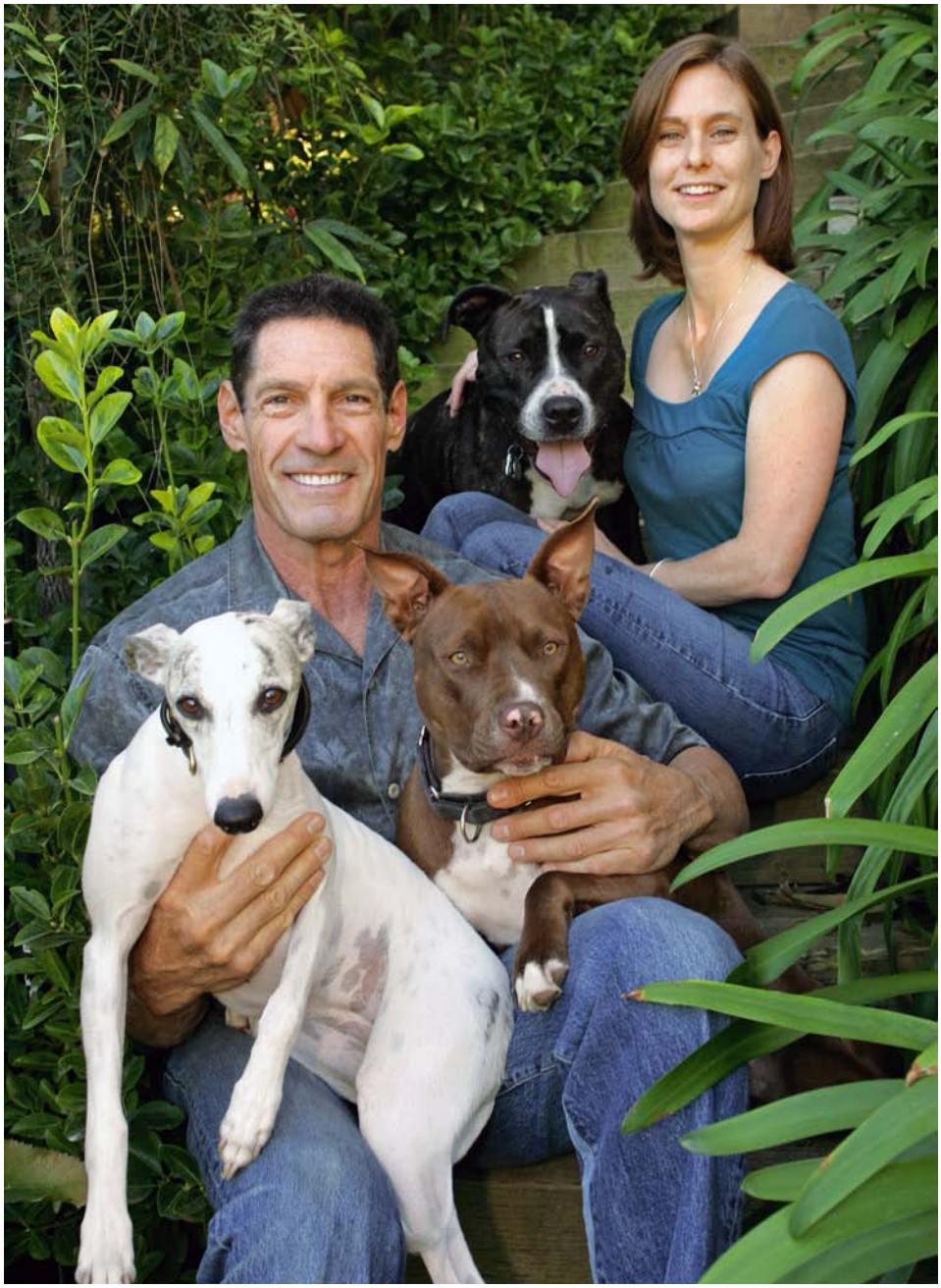
OTW: Do you have any thoughts on how research, particularly involving the FDA, can be more trustworthy?

Dr. Michelson: Maybe what is needed is for the academicians who are involved in this and the FDA to sit down and figure out some other way to do this. Maybe there needs to be a third party

that says, 'Okay, we'll go out and conduct the research.' But that third party is getting paid regardless of the result of the research.

But you know, of course, what happens now simply does not work. That's the problem. ◆

Note: Over the next few weeks, OTW will bring readers more of our interview with Dr. Michelson as he discusses the state of the science of orthopedics and his work with patent reform, medical research, animal advocacy, rainforest preservation and the 20 Million Minds Foundation to bring free textbooks to college students.



Dr. Michelson with Aimee Gilbreath, Executive Director of Found Animals/Courtesy for the photos, "Courtesy of Seth Casteel"

The Carver Boys: Going Somewhere

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

"You can't imagine what you don't see," says Dr. Claudia Thomas, the first Black female orthopedic surgeon in the United States. Think about that. If in your youth you saw no one in your immediate environment who had achieved some measure of success, how would you even begin to think that there were options open to you? Combine that with the pressures of "the street" and it's clear that many of today's young people have little hope of exploring their full potential.

I have had the pleasure of interviewing roughly 400 orthopedic surgeons in the past six years. There is not one who achieved success without having had someone who believed in them and stuck with them. Perhaps it was a physician—someone in the family or someone who fixed your leg—but more often it was another type of respected individual who coached you to focus on your studies, grab hold of a goal, and not let go.

Dr. Thomas, winner of the 2008 Diversity Award from the American Academy of Orthopaedic Surgeons (AAOS), grabbed hold of a challenge several years ago and isn't letting go anytime soon. Dr. Thomas sits on the board of the J. Robert Gladden Orthopaedic Society (JRGOS), a group whose mission is to increase diversity in the field. She states, "In 2007 my colleagues and I on the JRGOS Board were discussing the educational pipeline for African Americans, and came to the conclusion that it was especially difficult for males. We saw that the number of African American males in medical school had decreased. But especially alarming was that they weren't just dropping out of school, they seemed to be dropping out of life."

The Carver - Tri-County Orthopaedic Center students

As she reflected on this, Dr. Thomas knew that each day when she opened her private practice and looked forward to rewarding experiences, not far off there were young children who started their days with a slim chance of having their days—or their lives—turn out

"Dr. Mitchell had sent the students a questionnaire asking things such as, 'What do you think you will be when you grow up?' (most said 'rap star' or 'professional athlete'). We could see that our job was to give them some perspective and be very frank that, 'Hey, that is not going to happen.'"

well. "We saw that it was at the middle school level that we were losing African American males to the streets and to the penal system. When the Gladden Society suggested that its members mentor a group of middle schoolers I couldn't not get involved."

Dr. Thomas took this message back to her partners, who were equally enthused about the chance to alter the trajectory of young lives. "My four partners are all African American males. One of them, Dr. Isaac Mitchell, is originally from Compton, California—gangland—and was particularly taken with the idea of helping young boys create a path that leads away from 'the streets.' He identified the school, Carver Middle School in Leesburg, Florida, and set things in motion."

"Talented, but at risk." That was the specific type of child with whom they thought they could succeed. Dr. Thomas says, "The principal of Carver identified 30 African American boys in grades 6-9 who had potential but were not of such excellence that it was a given that they would go on to greatness. In the fall of 2007 my four partners and I had our first meeting with the students and delivered a strong message that we were successful and that they had a better chance of being like us than being like 'Mike.'"

With the "know your audience" rule in mind, the organized Dr. Mitchell had already learned a bit about the boys before that first meeting. Dr. Thomas says, "Dr. Mitchell had sent the students a questionnaire asking things such as, 'What do you think you will be when you grow up?' (most said 'rap star' or 'professional athlete'). We could see that our job was to give them some perspective and be very frank that, 'Hey, that is not going to happen.'"

Knowing that they needed concrete, live examples of what happens in the real world, Dr. Thomas and her colleagues pulled in others who have 'walked the walk.' "It's difficult to tell a 12 year old that he should banish his dreams of becoming a football star. So one of my partners, Dr. Kerina came in and told them, 'My son made it all the way to the draft pick and then was cut for no apparent reason. This kind of thing happens all of the time. It is better to set your sights on being a different kind of professional.'

"Last year I brought in my neighbor, an African American gentleman who had played with the New York Giants and the New England Patriots. The children were surprised to hear that he was now

"Not only did the students' grades improve, but so did their behavior and attendance. By being challenged and monitored by these doctors, the students have become more goal oriented and aware of what they need to do in order to excel. We now have students who are aspiring to be doctors, and seem to truly understand that this can be a reality for them."

Dr. Thomas with a student on the Zimmer bus.

head of the FBI for Central Florida. As he passed around his badge he continued with the message of, 'Sports is not a given for anyone, and it's not forever.' The boys were in awe of him."

Then it was time for the students to get a hands-on sense of how Dr. Thomas and her colleagues spend their days… and how they might follow in their footsteps. "Zimmer brought its mobile OR to the school, and the kids had a chance to use saws and perform mock surgery. Their expressions as they sawed through the artificial bones were amazing, as in, 'Hey, look what I did!' Their little faces just lit up."

A local hospital also opened its doors to the curious youngsters. Dr. Thomas notes, "That day, the students got to do mock arthroscopy where they used the arthroscope inside of an artificial knee. They looked at the monitor and saw how their hands were directing the arthroscope and the cutting instrument. I told them, 'This is better than any video game you've ever played.'"

Then these successful professionals took the students somewhere in the hopes that they would never return. "My partners took the boys to a local prison. These kids often romanticize prison, and many of them walked in with a street swagger. But after witnessing the ugly reality, and having horrible comments directed at them, they were looking over their shoulders as they hurried out of the prison later on."

Let's bring in the perspective of Dr. Isaac Mitchell. "I always knew that this program would be important, but at first I thought that it would be very painful to see children who were growing up much like I did—limited financial resources, tough neighborhood, etc. Now I am thrilled and gratified to see that they are so proud when they do something well. And it is truly heartening to see their faces light up when they are exposed to things that many of us with money take for granted. This may be going to a pro sports game with great seats, or going to a restaurant and ordering whatever you want without studying the prices at length.

"Probably the best single experience to date was taking these boys to a Magic/Lakers game. We went to dinner, then headed to the arena, where we had incredible seats. At the game they were screaming so much and in such high pitches…the principal said that they were bragging about it for weeks."

So is it working? Are these tireless mentors "getting through" to the Carver boys? Dr. Mitchell: "Some of them really seem to 'get it,' i.e., no grades=no opportunities. We attempt to instill a sense of pride in them, in part by ensuring that the rewards they receive are publicly presented. That way, they get to show everyone how 'cool' it is to be smart."

Dr. Thomas, known for her loving toughness, adds, "The boys' grade point average has gone from 2.2 to 2.9 over the last four years. We have established a message that Cs are unacceptable and

"Dr. Mitchell: "This program is low cost/high reward. We must all remember how we got where we are now…someone somewhere helped us. Now we must carry the torch.""

Students on the Zimmer bus.

Bs mean that you didn't try. When the boys get As they are rewarded with tickets to professional basketball or baseball games, as well as gift certificates."

And those who get a D grade? "We call their parents and try to impress upon them the importance of taking this opportunity for us to all be on the same page for their child. We even offer to buy the child's video games so that they won't have that as a distraction."

Someone else who is working to open windows in the children's minds—and keep them open—is A. Denise Kinsey, the Achievement Liaison at Carver Middle School. Commenting on the value of this program, Kinsey states, "The majority of the participants did not know or had never met a Black doctor. With this program, the children interact personally with the doctors, and have even visited the physicians' homes. The majority of the participants are from single family households headed by women. Aside from introducing the boys to the outstanding Dr. Thomas, this program has given the students several positive Black male role models."

Kinsey has seen a number of concrete and promising changes in the boys during this program. "Not only did the students' grades improve, but so did their behavior and attendance. By being challenged and monitored by these doctors, the students have become more goal oriented and aware of what they need to do in order to excel. We now have students who are aspiring to be doctors, and seem to truly understand that this can be a reality for them."

The lessons are vast and timeless. Helping others makes for a better society overall. Kinsey says, "The students have learned the real meaning of the saying, 'I am my brother's keeper.' They have bonded and realize that they too must give back. Several are now Peer Tutors, and volunteer their time to tutor students who need additional extra help."

Dr. Thomas challenges her orthopedic peers, saying, "This is our responsibility…this is your responsibility. We cannot abandon these children who are left without fathers, without role models, and without hope."

Dr. Mitchell: "This program is low cost/high reward. We must all remember how we got where we are now…someone somewhere helped us. Now we must carry the torch." ◆

Note: The Carver Middle School students will be touring a Zimmer plant in August 2011. Stay tuned to learn how their trip turns out!

Is Orthopedic Research Falling Short?

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

To effect concrete changes in the *clinical* realm, surgeons increasingly require data from high level studies such as randomized clinical trials (RCTs). But, for a multitude of reasons, RCT studies are too few and too far between. With the storm of controversy erupting over past studies of such products as Infuse, is research into orthopedic products or procedures failing to meet the demands of a modern, multifaceted practice?

The first in a series of three articles was recently published in the *Journal of Bone and Joint Surgery (JBJS)*, and it attempted to answer an increasingly critical question—*what is standing in the way of RCT research?*

Wikimedia Commons and Tatpong Tulyanon

Dr. James Wright, an orthopedic surgeon with The Hospital for Sick Children in Toronto, was the article's lead author. He explains, "The American Academy of Orthopaedic Surgeons (AAOS) and the Orthopaedic Research Society (ORS), with the support of *JBJS* and NIH [National Institutes of Health] held a symposium that tackled issues such as, 'What is the appropriate research agenda for orthopedic surgery?' and, 'What are the key issues that are facilitating or impeding high level research?' and 'How can we improve the quality of orthopedic clinical trials?' Although an increasing number of orthopedic surgeons are behind the idea that there is a substantial role for more and better RCTs, how we should proceed is not completely clear."

Dr. Wright worked with Jeffrey Katz, M.D., Director of the Orthopaedics and Arthritis Center for Outcomes Research at Brigham and Women's Hospital (BWH), and Elena Losina, Ph.D., Associate Professor of Orthopedic Surgery at BWH. Dr. Wright says, "In this particular article we highlight the cultural and practical barriers to research, and we address what key infrastructure is needed to support randomized trials in orthopedics."

It may seem odd to discuss culture—a "soft" science—in relation to "hard" data, but, says Dr. Wright, culture is exactly what may be holding back the world of orthopedic research. "By 'culture' we mean how orthopedic surgeons address and resolve clinical questions, respond to clinical controversies, the degree to which they are enthused about participating in randomized trials, and their responses to the results of randomized clinical trials."

Beware the Case Series

Donning a cultural anthropologist hat, Dr. Wright explains, "Cultural changes emanate from altering events such that people can have new experiences that let them think about things different-

"Evidence based medicine is not only the principle of using the best evidence available…it's acknowledging when we don't have the "evidence"."

ly. Surgeons have largely functioned in isolation with their own strategies, something which has manifested itself in an excess of case series (which by lacking a control group limits the ability to answer the question, 'What is the best treatment option?'). The case series served us well for years, but it is useful for grabbing the low hanging fruit in the field. When the benefit of a new treatment or technique is so overwhelmingly obvious we don't need a RCT."

If you ask any orthopedist if he or she is a lifelong learner, you are likely to receive a "yes" in response. But is that always the case? To learn something new, you must be able to let go of the old. Dr. Wright: "Those of us promoting evidence-based orthopedics often hear, 'I don't need to do a RCT. My case series approach works just fine.' But what they are overlooking is that as differences between treatment outcomes become smaller, then there are other factors to explain why one treatment may be better than another. That is a high hanging fruit and so you need a better method. That better method is controlled studies such as RCTs."

We all use the past to interpret the present and create the future. Surgeons, says Dr. Wright, are no different. "The personal experience of orthopedic surgeons has understandably been held in high regard—it has also resulted in the overabundance of case series. The problem is that this type of study only creates more uncertainty with regard to surgical success and other issues…not to mention that if you get 10 experts in a room you could well have 10 expert opinions."

Medical education involves learning, alright, but not so much about learning to be comfortable with not knowing. Dr. Wright: "It is harder to embark on a major surgical intervention if you can't say with certainty that you are proceeding in the right manner. But alas, the surgical personality is to go forward with complete assurance. While the healthy approach is one of equipoise, namely, comfort with recommending more than one treatment option, it is often regarded as a sign of weakness.

"Explain that the trials improve care, and with improved care comes more satisfied patients…patients who will return to your institution. Highlight the ways that a trial is in line with the hospital's strategic directions. Furthermore, those who are motivated to do research are some of the most thoughtful individuals in the field. Let them know that their hospital could attract the cream of the crop if it were known for being supportive of these large research endeavors."

My message to my colleagues who will listen is, "Evidence based medicine is not only the principle of using the best evidence available…it's acknowledging when we don't have the 'evidence'."

But how to change human nature or, more specifically, surgeon nature? "One of the strategies was to bring opinion leaders to this symposium, have them begin the conversation, and then have them take these issues back to their institutions. Indeed, many participants made a personal commitment to continue the conversation at their institution, letting their colleagues know how important high level research is."

Wikimedia Commons and VIC CVUT

Raise Journal Standards

A key issue says Dr. Wright, is the extent to which peer review journals will raise their standards. "We must get the journals on board. Fortunately, Dr. James Heckman, whose was editor of *JBJS* at the time, came to the symposium and shared his ideas on the importance of evidence-based medicine. Journals are in a position where they can only publish the best material they receive; on the other hand, they can signal the kind of material that they are looking for. My goal is to reach the point where journals say, 'We will no longer accept case series' or at least, 'We will publish a case series only under XYZ conditions.'"

As things so often do, this—on some level—relates to the human ego. "No one likes to be wrong," states Dr. Wright, "and the fact is that when you present the results of trials they are controversial to a great extent because a wide swath of the audience is wrong. For example, several years ago the results of a high profile clinical trial were published in the *New England Journal of Medicine* showing that the use of arthroscopy was not useful for most patients with knee arthritis. That is obviously not going to be a popular outcome with a lot of orthopedists."

Money, Money, Money

And other deterrents to high level research? First of all, you can't do what you don't understand. "Due to time and budgetary constraints, the majority of residency programs devote little time to training students in research methodology. And because of reimbursement issues, there is often a financial penalty for those who do become surgeon-researchers. Also, the fact is that being the principle investigator on a randomized trial is going to take between one to three days of your time per week. As it stands now, it's a lot of time and effort for what may be seen as not a lot of reward."

Especially, says Dr. Wright, if the institution views clinical trials as a headache. "Your hospital may not support your work by giving you time and/or research assistance, thus making a difficult process even more challenging. A wise hospital administrator will take the long view, and realize that clinical trials end up saving money because clinicians then do the right things the first time around."

And if you've landed a meeting with the hospital CEO? Dr. Wright advises, "Try to help them see that conducting a high level clinical trial only enhances the reputation of the institution. Explain that the trials improve care, and with improved care comes more satisfied patients…patients who will return to your institution. Highlight the ways that a trial is in line with the hospital's strategic directions. Furthermore, those who are motivated to do research are some of the most thoughtful individuals in the field. Let them know that their hospital could attract the cream of the crop if it were known for being supportive of these large research endeavors."

"Even if you have institutional support, running a trial is a huge undertaking,

complete with patient enrollment problems and issues related to maintaining morale and organization at different sites. It is truly frustrating if the other investigators involved don't obtain enough patients, don't follow-up on all patients, or deviate from the protocol."

The Intrepid Commitment to RCT Research

So as it is now, only the most intrepid surgeon-researchers will swim in these waters. Dr. Wright: "There are several strategies that can be used to lessen the burden on those who are willing to conduct clinical trials. First of all, the trials can be designed in a way to streamline logistics. For example, many aspects of routine clinical care are components of the required information and processes for an RCT…by harmonizing clinical care with an RCT both processes can be made more efficient. Secondly, institutions need to step up to the plate and provide a level of financial compensation for research that is commensurate with that of clinical activity. Ultimately, the solutions will come from the specialty societies whose members will eventually say, 'enough is enough.'"

Dr. Wright: "If we do not find and implement concrete solutions to these issues, surgeons will continue to look at clinical trials and think, 'This is unreasonably difficult. I'm going to stick to surgery.'"

And without high quality research, where we will be? Undoubtedly, going backward. ◆

company

AAOS Honored at White House

You might say that it was serious play at the White House on July 19 when a special ceremony was held to honor the American Academy of Orthopaedic Surgeons (AAOS). Representatives from the Academy accepted the U.S. Department of the Interior's prestigious National Volunteer Award—Non-Profit Organization in the 2011 Take Pride in America Awards. Interior Secretary Ken Salazar awarded the AAOS as an "outstanding non-profit organization" for the medical society's one-day playground build in San Diego, which was built on February 15, 2011. This is the first time a medical association has won a Take Pride in America Award.

"The Spring Valley Family Fitness and Fun Park is the legacy we were honored to leave at our 2011 Annual Meeting. In just seven hours we created a safe place for three generations to get fit and have fun together. On behalf of the Academy's 36,000 members, I would like to thank the U.S. Department of the Interior for recognizing the Academy and our partner, KABOOM! with this award," said AAOS second vice president, Joshua Jacobs, M.D., in the July 19, 2011 news release.

For the Spring Valley park build, 600 volunteers, including orthopedic surgeons, medical professionals, donors, community members and representatives from KABOOM!, came together to dig, paint and construct a park on a vacant piece of land next to the Spring Valley Youth and East Communities Center.

The Family Fitness and Fun Park contains features above and beyond an average park. This project transformed the grounds into a 6,100 square-foot community gathering spot designed to accommodate people of all ages and abilities, which is critical to the continued use of any public facility. This park features two separate playgrounds designed for different ages, and a quarter-mile walking/running trail and seven exercise stations.

Sandy Gordon, director of public relations for AAOS, told *OTW,* "It was such an honor to be there and witness the Academy and our members receive the Take Pride in America Award. For 12 years we have been leaving a legacy of safe and accessible playgrounds in every host city of our annual meeting. And hundreds of orthopedic surgeons, our very generous industry partners, and members of the community built this in one day and gave this park to a community desperately in need. I am so proud to be a part of this program and especially proud that the hundreds of our members who get out there and build every year received such meaningful recognition."

—EH (July 20, 2011)

American Academy of Orthopaedic Surgeons

Stryker Parties On in Second Quarter

It may have been Stryker Corporations's CPCEO (Chairman, President and CEO) Stephen MacMillan's birthday when he announced second quarter results on July 19 in an analyst call, but investors dumped on his party as the company reported a 16.3% rise in revenue to $2.05 billion for the second quarter. The company's stock dropped a couple of bucks on the news.

Such an increase would normally be seen as good news, but costs from two recent acquisitions (Orthovita and Memometal Technologies S.A.), caused the quarter's net profit to slip 3.1%. No good deed goes unpunished.

Revenue at Stryker has risen the past four quarters. Revenue increased 12% to $2.02 billion in the first quarter. The figure rose 8.8% in the fourth quarter of the last fiscal year from the year earlier and climbed 6.9% in the third quarter of the last fiscal year from the year-ago quarter.

On a reported basis, Stryker's sales rose 10.8% in hips, 3.6% in knees, 11.3% in trauma and 7.5% in spine.

Gaining Share

Mizuho analyst Mike Matson said that while orthopedics markets continue to tread water, Stryker is gaining share and is benefiting from strong 15% Medical Surgical growth. He cited the company's organic growth in the Reconstructive segment and Spine business, which rose 2% and 3%, respectively, on a constant currency basis over the first quarter of the year.

Stryker Corp. 2Q11	Sales ($ in millions)	% Change
Total Reported Sales	$2,045.0	16.3%
Reconstructive	$916.0	7.4%
Hips	$312.4	10.8%
Knees	$328.5	3.6%
Trauma/Extremities	$219.3	11.3%
Med Surg	$773.0	15.0%
Neurotech/Spine	$356.0	52.6%
Spine	$169.0	7.5%

Source: Mike Matson, Mizuho Securities

Photo manipulation by RRY Publications. Source: Stryker Corp. and Morguefile

Matson estimates that the recon market, based on reports from Biomet, DePuy and Stryker, grew, on a constant currency basis, by 1% in the second quarter. He also estimates that, on a constant currency basis, global knee growth was 0% and global hip growth was 1% for the quarter. He notes, on a constant currency basis, Stryker's hip growth of 4% indicates market share gains while its knee growth of -1% indicates market share losses. Analysts attributed the hip results to movement away from competitors' metal-on-metal products.

Hips and Knees

The company said its X3 Modular Dual Mobility Mobile Bearing Hip System, launched February 2011, and its ADM X3 Mobile Bearing Hip System have given it a presence in the large head market and are building momentum, to the point where there may be supply constraints.

It was Macmillan's' birthday party, but the CPCEO wasn't crying. He was particularly enthusiastic about the prospects for picking up some market share in knees with the FDA's green light of the company's ShapeMatch Cutting Guides (OtisMed) in May. He said the company was starting to hurt and was at a breaking point after the last American Academy of Orthopaedic Surgeons meeting because they didn't have a custom cutting product for existing customers. He says they lost some surgeons to competitors but expects to get them back slowly.

Stryker ended the quarter with net cash of about $1.7 billion. Acquisitions, share buybacks, and dividends continue to be the primary uses of cash.

—WE (July 20, 2011)

DePuy 2Q11: Steady as She Goes

DePuy maintained consistent results and held a steady course for the second quarter while it waits for Synthes to join the family.

Sales rose 7.2% to $1,469 million for the quarter. Currency added 5.5% to the revenue line.

Mike Matson, senior analyst at Mizuho Securities, said DePuy's reconstructive sales growth was in line with the first quarter. Reported hip sales rose by 2% and knees sales grew 1%. Spine sales were up 4%. Matson said the relative stability is a positive for spine-oriented firms and may indicate that Biomet's 10% slowdown in the second quarter was not representative of market growth.

Management attributed the decline in hip sales to lower demand for the company's metal-on-metal products and price pressures and reported an increase in the reserve associated with its ASR hip recall; primarily due to patient-related costs versus litigation expense (the total amount reserved has not been disclosed). New hip products during the quarter include the ReClaim Revision Femoral Hip System (launched in the U.S. and Europe) and the Gription Acetabular Augment System—both of which, said BMO Capital analyst Joanne Wuensch, should allow the company to tap the faster-growing revision segment of the market.

During the quarter, the FDA approved DePuy's Pinnacle CoMplete Acetabular Hip System, the first ceramic-on-metal hip implant available in the U.S.

Wuensch suspects that, similar to last quarter, Zimmer and Stryker were hip market share gainers in the quarter. She also noted while management believes that it is holding its own in the knee market globally, she suspects that Smith & Nephew continues to be a share gainer in the knee segment.

Wells Fargo analyst Larry Biegelsen said while the macro economic slowdown continues to depress procedure volume, the rate of decline of the orthopedic segment growth may be easing.

DePuy. 2Q11	Sales ($ in millions)	% Change
Total Reported Sales	$1,469.0	7%
Hips	$314.0	2%
Knees	$364.0	1%
Spine	$276.0	4%

Source: Larry Biegelsen, Wells Fargo

DePuy's parent, Johnson & Johnson, announced on July 19 that reported sales were up 8.3% to $16.6 billion for the quarter.

—WE (July 19, 2011)

US Navy/Wikimedia.org

large joints

"The Pill" and Bone Density

A little pill that can become, well, a pill. Researchers from Group Health Research Institute (GHRI) in Seattle, Washington have found that birth control pills may reduce a woman's bone density. The study, published online July 13 in *The Journal of Clinical Endocrinology and Metabolism*, indicated that impacts on bone were small, depended on the woman's age and the pill's hormone dose, and did not appear until about two years of use. The research focused on 14 to 18-year-old teenagers, and aimed to examine how bone density could change when someone stops using the pill.

GHRI Senior Investigator Delia Scholes, Ph.D., led the study. "The teen years are when women most actively gain bone, so we thought it was important to look at that age group," said Dr. Scholes in the July 19, 2011 news release. "We found that oral contraceptive (OC) use had a small negative impact on bone gain at these ages, but took time to appear, and depended on hormone dose." The researchers measured hip, spine, and whole-body bone densities in 301 teenagers aged 14 to 18, and in 305 women aged 19 to 30. The bone densities of 389 participants using OCs were compared to 217 similar women who were not using this method, looking at both teens and young adults, and the two most commonly prescribed estrogen doses in pills.

After two years, teens who used 30 to 35 microgram pills showed about 1% less gain in bone density at both the spine and whole body sites than teens who did not use hormonal contraceptives. For young adult women, users and non-users of oral contraceptives showed no differences in bone density at any site. Any differences in bone density between users and nonusers of OCs were less than 2%, and were seen only after two or more years of use, and only at some measured sites. At 12 to 24 months after stopping, teens who took 30 to 35 microgram pills still showed smaller bone density gains at the spine than teens who did not use oral contraceptives. At 12 to 24 months after stopping, young adult women who used either pill dose showed small bone density losses at the spine compared to small gains in women who did not take oral contraceptives.

Wikimedia Commons and Ceridwen

Dr. Scholes told *OTW*, "We were surprised to see that the small differences in bone density between OC users and non-users didn't go away after oral contraceptives were discontinued, at least not in the time we had to follow our participants. Ours is the first report to assess bone changes after stopping use, so it's a good area for further inquiry."

Dr. Scholes also commented to *OTW*, "We would love to design a study to examine longer-term bone changes after discontinuation of pill use. Looking at how long-term premenopausal pill use affects future fracture risk is also needed. It would also be great to know more about how pill use impacts internal hormones and chemical markers of bone gain and loss, looking at the pill estrogen dose, age, and changes after pill discontinuation."

—EH (July 22, 2011)

Young Athletes and Hip Deformity

Young folks out there might want to go easier on the dribbling, passing, and layups…According to a new study from the University of Bern in Switzerland, vigorous sports activities like basketball during childhood and adolescence can cause abnormal development of the femur in young athletes, resulting in a deformed hip with reduced rotation and pain during movement. This, says Dr. Klaus Siebenrock, may explain why athletes are more likely to develop osteoarthritis than more sedentary individuals. This research is published online in Springer's journal *Clinical Orthopaedics and Related Research.*

Dr. Siebenrock and colleagues found that, in those studied, osteoarthritis of the hip was more prevalent in high-level athletes than in those who do not take part in regular sports. It is also linked to higher intensity activities and greater physical loading of the hip. He noted other investigations have found that male athletes, particularly those who play soccer and handball, and take part in competitive track and field activities involving running and jumping, are at greater risk of early osteoarthritis of the hip.

The research team compared the prevalence of cam-type hip deformity in high-intensity athletes during childhood and adolescence and age-matched controls. (This is a condition characterized by abnormal bone development on the head of the femur affecting contact between the femur and the hip socket.) They looked at the physical condition and range of movement of 72 hips in 37 male professional basketball players and 76 hips in 38 control participants who had not participated in high-level sports.

They found evidence of deformity of the head of the femur, leading to abnormal contact between the femur and the hip socket, in men and adolescents who played in an elite basketball club since they were eight years old. As a result, internal hip rotation was reduced and hip movements were more likely to be painful. These differences became more pronounced after closure of the femoral growth plate during late adolescence. Overall, the athletes were ten times more likely to have impaired hip function than the controls.

Dr. Siebenrock told *OTW*, "We were surprised to learn that obviously the cam-type deformity may be triggered by high level sports activity during the growth period. Future research will have to focus on children in order to improve early detection of growth abnormalities, reflect about physical activities on a highly competitive level during childhood and, develop methods for prevention."

—EH (July 22, 2011)

Wikimedia Commons and Jon Ridinger

Bilateral Knee Replacements A Hazard

Replacing the knees in both legs at once may reduce hospital costs and save recovery time for the patient—but may also cause problems. The disturbing fact is that bilateral knee replacements are associated with greater morbidity and mortality than are unilateral knee replacements.

According to a recent study by researchers at New York's Hospital for Special Surgery (HSS), patients who have congestive heart failure or pulmonary hypertension face an increased risk for major complications if they undergo bilateral knee replacements.

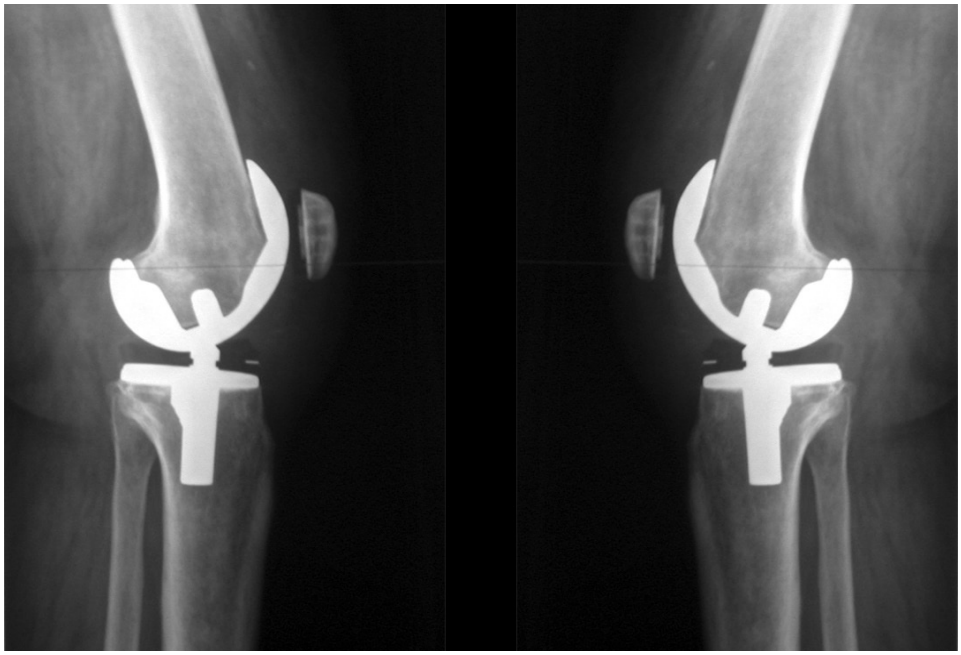
"What we sought to do for the first time with this study, was to provide evidence-based risk stratification for who should be considered at high risk for morbidity and mortality when undergoing bilateral knee replacement surgery," said Stavros Memtsoudis, M.D., Ph.D., Hospital for Special Surgery, who led the study.

To find out which patients are more at risk, researchers turned to the Nationwide Inpatient Survey, sponsored by the Agency for Healthcare Research and Quality (AHRQ). They analyzed data between 1998 and 2007 and found that more than 200,000 bilateral total knee arthroplasties (TKAs) were performed during this time frame. The incidence of major in-hospital complications and mortality was 9.5%.

Patients undergoing bilateral TKA were 5.5 times more likely to have adverse outcomes if they had congestive heart failure and four times more likely to have worse outcomes if they had pulmonary hypertension. Additionally, patients were almost twice as likely to have complications if they were older than 75 years of age compared to individuals below the age of 65 years. Men had a 50% greater risk of complications than women.

"Age by itself will be a risk factor in any kind of surgery...patients with extremes in age should be carefully evaluated before consideration for bilateral procedures." said Memtsoudis. He added that the role of male gender is unclear, but could involve factors not accounted for in the analysis, such as hormonal differences.

What should be clear from the study, Memtsoudis explained, is that patients with congestive heart failure and pulmonary hypertension as well as significant other comorbidities are not good candidates for this bilateral surgery. "During orthopedic surgery, bone particles and marrow enter the bloodstream and lodge in the pulmonary vasculature and other organs thus impacting on blood flow through the lung and other systems. While these events stress the heart, they rarely cause any clinically noticeable effects in otherwise healthy patients. However, people who have a history of heart failure are already at a disadvantage."



Wikimedia Commons and fpjacquot

The HSS researchers say national guidelines should be developed regarding bilateral knee replacement surgery." What we are providing with this study is the first step towards an evidence-based approach to risk stratifying patients," Memtsoudis said.

Almost 600,000 knee replacements are performed each year in the United States. The study, which was funded by the Department of Anesthesiology at HSS, the AHRQ Center for Education and Research in Therapeutics, and the National Institutes of Health, appears online ahead of print in the journal *Anesthesia & Analgesia.*

—BY (July 18, 2011)

No Shadows With Cordless Lights

Surgeons need to be able to see what they are doing. The technicians at Engineered Medical Solutions of Phillipsburg, New Jersey, believe they have solved the problem of what to do when illumination is not adequate or a surgeon's head blocks the light during a procedure. They developed a cordless light source that provides brilliant illumination of the deepest surgical site.

Engineers created the Scintillant Surgical Light (SSL) in conjunction with a urogynecologic surgeon who needed better light to perform pelvic floor reconstructions. The product they developed, with an ergonomic handle, comes in three configurations. One is a flexible light wand that is available pre-assembled to a Yankauer tip suction for light and aspiration. The second is a flat low-profile general purpose tissue retractor. A third modification of the light wand comes with two adjustable straps to attach it to various surgical instruments and suction devices. Packaged for one-time use, the battery-powered Scintillant Surgical Light is sterile and untethered, providing focused intense LED white light wherever extra illumination is needed.

Unlike some traditional surgical lighting that gets hot, the battery-powered SSL which utilizes the latest LED technology to produce cool white light, will not burn tissue that comes in contact with it.

—BY (July 18, 2011)

Engineered Medical Solutions

extremities

Ankle Surgery No Weight Loss Panacea

If you expect ankle fusion or total ankle replacement to lead to weight loss—forget it.

"Overweight and obese patients do not typically lose weight despite significant reductions in pain and disability after successful ankle surgery," Murray J. Penner, M.D., said about a study he presented at the July 2011 Annual Meeting of the American Orthopedic Foot and Ankle Society.

Wikimedia Commons

Penner and his team chose 145 patients who underwent ankle replacement or fusion from the Vancouver Prospective Ankle Reconstruction database. The criteria for inclusion were one-year minimum follow-up, successful surgical outcome defined by improved Ankle Osteoarthritis Scale (AOS) and no revision surgery. The investigators also selected patients with a BMI (body mass index) between 25.1 and 29.9, obese patients with a BMI between 30.0 and 34.9 and morbidly obese patients with a BMI of 35.0.

The team excluded patients with diabetes, neuropathy, or major medical comorbidities which would limit the participants' ability to function. They

also excluded patients with cardiovascular, respiratory, cerebrovascular or neuromuscular impairments and patients with cognitive or psychiatric disease or debilitating hip, knee or spine arthritis.

The study ended up with 87 men and 58 women with a mean age of 61.5 years and a mean BMI of 29.2. Ninety patients underwent total ankle replacement and 55 patients underwent ankle fusion.

The team compared preoperative BMI to postoperative BMI at 6 months, 1 year, 2 years and 5 years. Penner said that patients with improved SF-36 or AOS scores postoperatively had no significant change in BMI when compared with preoperative BMIs.

"Physicians and patients should not assume weight loss will naturally follow successful ankle reconstruction," Penner said.

—BY (July 20, 2011)

To Avoid Ankle Injury—Lace-Up!

How do you avoid an ankle injury if you are a basketball player? Wear lace-up ankle braces. That is the message from a new study from the University of Wisconsin (UW) School of Medicine and Public Health which showed that high-school basketball players who wore stabilizing lace-up ankle braces had 68% fewer injuries than athletes who did not.

The study, presented at the July 2011 annual meeting of the American Orthopaedic Society for Sports Medicine, is the first of its kind to examine the efficacy of lace-up ankle braces to prevent both first-time and recurrent ankle injuries in young basketball players.

The researchers gathered data on a total of 1,460 male and female basketball players from 46 high schools across Wisconsin during the 2009-10 basketball season. The players were randomly assigned to be part of a group that used braces (740 students) or a control group that did not (720 students). Players in the control group sustained 78 acute ankle injuries, while players who wore the brace got only 27 similar injuries during the same amount of exposures. (An exposure is defined as any coach-directed competition, practice, or conditioning session.)

"The research suggests that wearing lace-up ankle braces is a cost-effective injury-prevention strategy for adolescent basketball players," said Tim McGuine, UW sports medicine researcher, athletic trainer and lead author. "Basketball has one of the highest rates for ankle injuries, and this study illustrates how a simple brace can help keep an athlete on the court."

—BY (July 18, 2011)

Wikimedia Commons and U.S. Navy Mass Communication Specialist 3rd Class Matthew Jackson

Wright Medical to Distribute ArthroCare Suture Technology

Wright Medical Group, Inc., the Arlington, Tennessee-based manufacturer of extremity and large joint reconstruction implants and instruments has agreed to distribute ArthroCare Corporation's knotless suturing technology, according to July 13 press releases from the companies. ArthroCare, which has built its business on its minimally invasive patented Coblation technology, has an extensive presence in the orthopedic sports medicine segment. ArthroCare will supply Wright with a line of products for soft tissue fixation of the food and ankle which Wright will distribute exclusively to foot and ankle surgeons worldwide.

ArthroCare's patented Opus technology allows surgeons to affix tendons and ligaments to bony structures efficiently and reproducibly, without the need to tie knots. The company's fixation technology is widely used in the rotator cuff repair market and has been used clinically since 2001 in more than 100,000 procedures worldwide.

Bob Fencl, senior director of Foot and Ankle Marketing at Wright, commented, "We are extremely pleased to enter this agreement with ArthroCare. Soft tissue repair is a cornerstone of foot and ankle surgery, and this agreement allows Wright to deliver another innovative technology to our customers."

Wright Medical specializes in the design, manufacture and marketing of devices and biologic products for extremity, hip and knee repair and reconstruction. The company has been in business for 60 years and markets its products in over 60 countries worldwide.

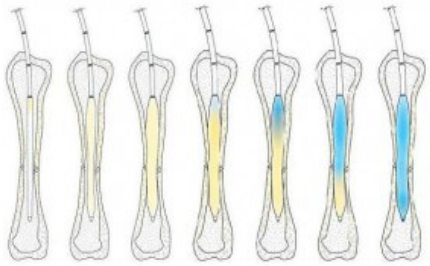
—BY (July 19, 2011)

Courtesy ArthroCare Inc. and Wright Medical Group, Inc.

trauma

Bones Repaired From the Inside

In a surgical first, a German surgeon has repaired the broken fibula of an 80–year-old woman from inside the bone. As Dr. Thomas Gausepohl explained, "With the IlluminOss system, I was able to stabilize the fibula using a small incision without disturbing the ankle joint or the skin surrounding the fracture. Only a thin layer of skin and soft tissue covers the distal fibula, and the classic technique of plating with screws often results in patient complaints of plate prominence, pain, and skin irritation."



IlluminOss Medical Inc.

The IlluminOss system is manufactured by IlluminOss Medical, Inc. a privately held medical device company in East Providence, Rhode Island, which develops minimally invasive orthopedic systems for the stabilization and treatment of bone fractures. Gausepohl inserted the company's device into the patient's bone through a tiny hole. With inflation, the implant formed in place, conforming to the inside of the bone to provide axial and rotational stability.

Dr. Gausepohl said that he was able to treat the patient in less than 40 minutes and was "totally satisfied with the result." After closing the tiny skin incision, the patient had mobility without the need for heavy external plaster casts. "The minimally invasive approach provided by the IlluminOss System reduc-

es injury to surrounding skin, muscle and soft tissues," he said. "My continued and expanded use of the technology reinforces my belief that this is the beginning of a new era in fracture repair and fixation. Customized, minimally invasively formed implants will be the future of orthopedics."

The IlluminOss Photodynamic Bone Stabilization System treats fractures through a small entry into the bone. The flexible balloon catheter is inserted into the bone and placed across the fracture site. A proprietary liquid monomer is then infused through the catheter, expanding the balloon that assists in the alignment of the fractured bone. A special light source is then used to illuminate the monomer inside the balloon, converting it into a hardened polymer implant. The result is a customized orthopedic implant that, the company states, provides strength and stabilization to the bone during the healing process.

The firm has CE Mark approval for the use of its product in low load bearing bones in the metacarpal, radius, ulna, distal radius, olecranon, clavicle and fibula. Scott Rader, president and CEO of IlluminOss Medical, said, "This case demonstrates the power of IlluminOss' patented platform to treat clinical applications throughout the anatomy. Utilizing a simple, safe, minimally invasive implant that conforms to the patient, we are proving the versatility of the IlluminOss Photodynamic system that will dramatically advance fracture treatment and provide improved patient care."

The system has been in use in Europe and Latin America for two and a half years. It is not yet been cleared for use in the U.S. but has an IDE investigational permit.

—BY (July 18, 2011)

spine

Spinal Disc Repair Patent Issued

SpinalCyte, LLC

On July 7, SpinalCyte, LLC, a four-year-old biologics company based in Houston, Texas, announced that it had received a U.S. Patent for a unique process to re-grow the spinal disc titled "Methods and Compositions for Repair of Cartilage Using an in Vivo Bioreactor."

The allowed claims include the use of human dermal fibroblasts from the patient's own body to re-grow the nucleus of the spinal disc in vivo. SpinalCyte has simulated the environment of the spinal disc. Under intermittent hydrostatic pressure, the dermal cells have successfully differentiated into cartilage type cells necessary to re-grow the nucleus pulposus.

Per the press release: "The nucleus pulposus is a gelatinous material that acts as a cushion or shock absorber to the spinal column. It functions to distribute hydraulic pressure in all directions within each disc under compressive loads. The nucleus pulposus consists of chondrocytes, collagenfibrils, and proteoglycan aggrecans."

Previously the company had announced that it had received a Chinese patent for the same process.

Lower back pain, a condition strongly associated with the degeneration of the intervertebral discs, afflicts an estimated 10 million people annually in the U.S. Lower back pain is also associated with sciatica and disc herniation or prolapse. Disc degeneration alters disc height and the mechanics of the rest of the spinal column, adversely affecting other spinal structures such as muscles and ligaments. In the long term, the degeneration of the discs can lead to spinal stenosis, a major cause of pain and disability in the elderly. Surgeons perform over 700,000 procedures each year to treat degenerative disc disease.

"This milestone is a major achievement and strengthens our position in this emerging technology," said Pete O'Heeron, CEO. "We are excited about the future for this type of technology and the benefit it will ultimately bring the patient by re-growing their disc, using their own cells."

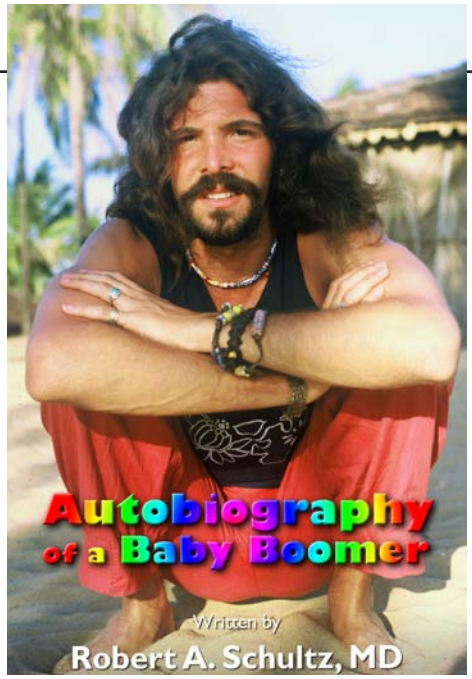
The goal of SpinalCyte is to develop a nucleus regrowth technology using autologous dermal cells harvested from the patient. To date, the company has been funded entirely by angel investors.

—BY (July 18, 2011)

THE PICTURE OF SUCCESS

Dr. Robert Schultz

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



Dr. Robert Schultz

Twenty-three-year-old Robert Schultz sat in a squalid prison cell thousands of miles away from home…all he could think was, "I'm going to die in a Turkish prison and I could have been a doctor." Like many other young people of his generation, he considered a career in medicine as something overly conventional that lacked real meaning. "Surely," thought Schultz, "there is something better out there."

Robert Schultz, who eventually built a successful private practice, came to see that the "something better" didn't involve a guru in India or a wise man from Marrakech…it was right inside him (even in his native Fair Lawn, New Jersey). It was living with an attitude of being in the present moment and accomplishing something every day. It was about living up to his own expectations of himself.

Dr. Schultz is the author of *Street Smarts for the Practicing Physician* and Surgeon, a forthright primer on how to avoid the pitfalls of private practice. "There are numerous ways we can 'get in trouble' as private practitioners, such as selecting the wrong partner, failing to eliminate disruptive patients from the practice, and not providing a sense of safety and belonging to our patients. My goal in writing this was to give some hard facts and practical solutions to these types of issues."

While he wrote the book as sort of a retirement gift to the profession, Dr. Schultz admits, "You can't expect that people will fully understand a situation because they read about something. In order to 'get it' you must live it."

Medical—and life—experience is nothing that Robert Schultz lacks. Like a bachelor who is not quite ready to settle down, a young Robert Schultz criss-crossed the world, running away from the acceptance letter he had received from Cornell Medical School. "I went abroad the summer after college and felt myself being drawn to the exciting people I met who were in search of nirvana. I was distancing myself from medicine as the summer went on, and then fell in love with a French girl with a drug problem. I'll never forget sitting in café in Marrakesh thinking, 'In three weeks I'm going to medical school, the most conventional thing I could do.' I tried to ignore this…then summer ended and I returned to the U.S. and headed for Cornell."

These days, Dr. Schultz can be found at Duke University, reviewing cases with residents and fellows. He has found the excitement within the conventional. And to a great degree, it was all of that

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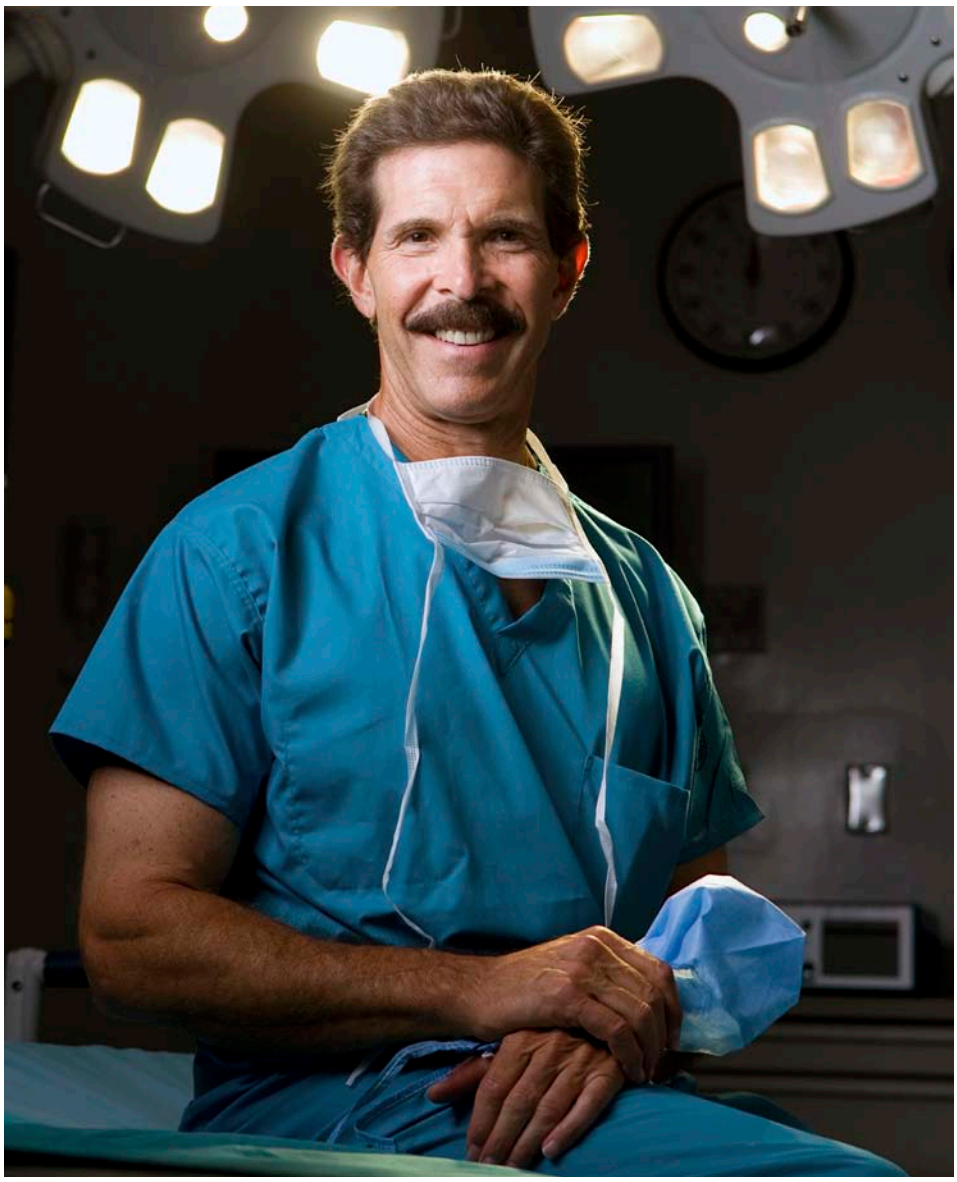
searching as a younger man that created a doctor who knows how to find things. "Much of the value and allure of our work lies in the subtly of getting the diagnosis right. A surgeon must be a detective, and must be patient enough to get the details of the patient's complaint. When a resident says, 'Can I run this by you?' and tosses up an X-ray, I say, 'Wait. Tell me about the patient.' While the OR is exciting, if you're doing the wrong operation then what is the point?!"

This sense of thoroughness and doing the right thing has always been with Robert Schultz. "I remember walking out of Mass General one evening, crying and wiping my eyes on my shirt. I had logged 500 knee arthroscopies alongside attendings, and that day I had been alone. It was a simple torn medial meniscus but I kept scuffing up the surface cartilage—in part because I was using a cumbersome forearm camera. I thought, 'I can't do this. I am going to hurt people.' Shortly thereafter handheld cameras were available, which changed everything."

But back to his first, ambivalent days as a medical student. Whereas he would later experience real jail cells, Dr. Schultz says that walking in the doors at Cornell felt very much like confinement. "One day, a surgeon in a significant position of responsibility said to me, 'I am entrenched here, and I have a family. I envy you. Go take a year off. And if you tell anyone what I said I'm denying it.'"

Robert Schultz's parents, who were happy because "at least" he wasn't quitting medical school, took him to the airport. "My folks thought I wasn't thinking clearly, and we had a fight at the gate. I wouldn't see them for four years."



Dr. Robert Schultz

What now seems like a conventional, stereotypical path for "seekers," i.e., heading East, was novel in the '70s. "I wandered around India, but couldn't find a guru. After awhile, it felt like I was just 'hanging out'—and I was lonely. I was beginning to realize that travel is totally self-indulgent…I wasn't responsible to anyone but myself."

Ironically, when asked about the career experience that most changed him, Dr. Schultz notes something that involves responsibility…failure. "I have had outcomes that were not to my liking or to the patient's satisfaction. It's best not to beat oneself up, however…we can only look for self-acceptance. Think about the feedback you get when you do something right. Then your thoughts and/or actions change for the better because you have made yourself live up to the part of you that is noble."

Some of what Dr. Schultz learned about patient care emanated from his time as

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an apprentice to a Filipino faith healer. "I spent time working with Bobby Deleon, who served those living on the garbage heaps of Manila. He was the judge, jury, doctor, and peacemaker of this realm, and it was a revelation to see how he worked. I witnessed the power of creating an ambiance where you give the patient confidence in you, and are extremely attuned to them and invested in their care."

Years later, it was a sobbing OR nurse who led Dr. Schultz to see that he needed to work on his own ambiance creating skills. "I used to get really upset with incompetence in the OR, and I would go to a corner, face the wall, and try to regroup. One day a nursing supervisor came into the OR and told me to 'Calm down.' My response? 'Get out! You're part of the problem!' I later found her crying, and she said, 'People don't want to work with you.' She took me into another OR that had a hole in the wall. She said, 'Dr. X threw a mallet through the wall once and he will not repair the hole. He wants it to be a reminder not to 'lose it.' Ever since, before I walk into the OR I say a mantra—'I know things are going to go wrong today, but I refuse to act like an asshole."

Dr. Schultz homes in on his point that while he can try to teach others, it is the residents' and fellows' daily experiences that will make the biggest impressions on them. "During a recent case I told the resident, 'The only way you'll have an unhappy patient is if you get an infected nonunion.' I told him not to leave the wound open while he tries to make things perfect. He said, 'I know you're frustrated with me because I'm working slowly.' I responded, 'It's not that. It's that the principle of moving along is not that important to you. When you have had the experience of a patient with an infected nonunion you will feel differently.' I can't *give* someone that experience…I just don't have that much control over their development."

There are several experiences that he wouldn't want to give anyone. Namely, jail. During his peregrinations, Robert Schultz experienced the ambiance of foreign prisons on several occasions.

"My friends and I were in Turkey and came upon an accident scene. We took two injured people to a hospital where the local authorities concluded that I had caused the accident. When I was released it was a freedom like no other—and yes, I was thinking that medical school didn't look like so bad."

Not that an Afghan prison is much better. "I was driving a van near Kabul when a kid slammed into the side. My friends and I took him to a hospital and took the cop who had witnessed the event. I was still thrown in jail, however, because the guy on the bike was the brother of the local commandant. This man told my friend that I would get out of jail when his brother's leg healed. I got out sooner that that, but my passport was held for three months…they wanted to make sure that leg was going to heal."

My goodness, he should write a book. "I didn't think my life story was so special, but then I got nostalgic. That, coupled with the fact that my children were asking about my youth, led me to write *Autobiography of a Baby Boomer.* Philosophizing is a turnoff, so I just had fun with it, and wrote it in a way that the reader would get lost in this era."

So how and why did he finally get back to Cornell? "Once my parents heard that I was going to get involved in a shrimp boat business in the Philippines they had had enough. They flew over, said, 'You're throwing away an outstanding opportunity.' I let their words sink in for several months and then I was on a flight home."

"I don't regret a thing. If I had not taken that time, I would not be as satisfied with my life. You must at least try to pursue your dreams."

The unconventional-conventional Dr. Schultz says, "My wife and I have raised three kids, all of whom have good values and good judgment. Yes, I play the doctor's game—golf. I also meditate every day. I had heart surgery last year and nearly died. From that I learned two things: first, if this is my last day I'm OK with that…that was comforting. Also, I am still here so each day is really a gift." ◆

To read more about Dr. Robert Schultz's experiences, please visit www.autobiographyofababyboomer.com

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