VOLUME 7, ISSUE 21 | JUNE 28, 2011

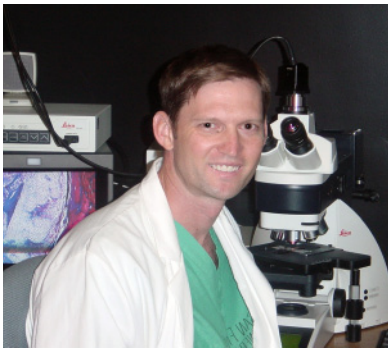
# Orthopedics This Week

## 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:** Last week the FOMC cut its 2011 economic (GDP) forecast from a range of 3.1%–3.3% to a range of 2.7%–2.9%. The FOMC also cut the 2012 forecast from 3.5%–4.2% to a range of 3.3%–3.7%. Keep in mind that government spending accounts for 26% of GDP. That means more headwinds buffeting ortho demand.

| Rank | Last Week | Company | TTM Op Margin | 30-Day Price Change | Comment |
|---|---|---|---|---|---|
| 1 | 1 | Orthofix | 14.72% | 3.37% | The market likes the transition to new CEO Vater. OFIX bucking the overall market malaise. |
| 2 | 3 | Johnson & Johnson | 26.33 | (2.56) | In this market, JNJ's 3.40% dividend is attracting plenty of institutional buyers. |
| 3 | 5 | Kensey Nash | 34.24 | (4.86) | New $35 million credit facility plus $50 million of cash equals formidable war chest. |
| 4 | 9 | Exactech | 8.08 | 2.86 | Expected to grow 9% this year while the industry is growing 3% to 4%. New buyers are finding EXAC. |
| 5 | 2 | NuVasive | 6.84 | (5.27) | NUVA has bounced back impressively and the new product pipeline is strong. But buyers are in profit taking mood. |
| 6 | 4 | Zimmer | 27.75 | (9.80) | Sellers appear to be in charge of ZMH trading. Perhaps this next quarter's report will turn it around. |
| 7 | 7 | Stryker | 25.23 | (7.96) | SYK closes on VITA deal. Getting ready to report Q2—which, if Wall Street is correct, will show 13.50% sales growth. |
| 8 | NR | Medtronic | 28.5 | (4.74) | Back on the Power Rankings by virtue of a higher dividend. Now paying out 31% of profits for a 2.30% yield. |
| 9 | 6 | Smith & Nephew | 22.8 | (8.60) | In the old days, SNN led the industry with the highest dividend payout ratio. No longer. Only 21% of profits go to shareholders. |
| 10 | 10 | Wright Medical | 8.76 | (6.53) | Here's a conundrum. Tornier has half the sales but twice the market cap of WMGI. Hmmm. |

# Robin Young's Orthopedic Universe

## Top Performers Last 30 Days

| | Company | Symbol | Price | Mkt Cap | 30-Day Chg |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $41.77 | $754 | 3.37% |
| 2 | Exactech | EXAC | $18.33 | $240 | 2.86% |
| 3 | Tornier N.V. | TRNX | $27.59 | $1,077 | 0.69% |
| 4 | Orthovita | VITA | $3.83 | $295 | 0.52% |
| 5 | Synthes | SYST.VX | $173.72 | $20,634 | -0.45% |
| 6 | ConMed | CNMD | $27.16 | $769 | -2.55% |
| 7 | Johnson & Johnson | JNJ | $65.06 | $178,339 | -2.56% |
| 8 | ArthroCare | ARTC | $33.39 | $912 | -3.22% |
| 9 | CryoLife | CRY | $5.50 | $154 | -3.68% |
| 10 | RTI Biologics Inc | RTIX | $2.87 | $158 | -4.65% |

## Worst Performers Last 30 Days

| | Company | Symbol | Price | Mkt Cap | 30-Day Chg |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $1.30 | $124 | -19.14% |
| 2 | MAKO Surgical | MAKO | $27.79 | $1,138 | -18.55% |
| 3 | Symmetry Medical | SMA | $8.72 | $317 | -13.49% |
| 4 | Zimmer Holdings | ZMH | $61.50 | $11,806 | -9.80% |
| 5 | Integra LifeSciences | IART | $46.45 | $1,327 | -9.22% |
| 6 | Smith & Nephew | SNN | $51.11 | $9,122 | -8.60% |
| 7 | Alphatec Holdings | ATEC | $3.49 | $311 | -7.92% |
| 8 | Stryker | SYK | $57.38 | $22,264 | -7.69% |
| 9 | Wright Medical | WMGI | $14.46 | $564 | -6.53% |
| 10 | TranS1 | TSON | $4.53 | $95 | -6.21% |

## Lowest Price / Earnings Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | P/E |
|---|---|---|---|---|---|
| 1 | Medtronic | MDT | $38.40 | $41,064 | 11.71 |
| 2 | Johnson & Johnson | JNJ | $65.06 | 178,339 | 13.50 |
| 3 | Zimmer Holdings | ZMH | $61.50 | $11,806 | 13.58 |
| 4 | Kensey Nash | KNSY | $24.68 | $211 | 14.02 |
| 5 | CryoLife | CRY | $5.50 | $154 | 14.86 |

## Highest Price / Earnings Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | P/E |
|---|---|---|---|---|---|
| 1 | NuVasive | NUVA | $32.01 | $1,270 | 38.11 |
| 2 | ArthroCare | ARTC | $33.39 | $912 | 28.06 |
| 3 | Synthes | SYST.VX | $173.72 | $20,634 | 22.71 |
| 4 | Wright Medical | WMGI | $14.46 | $564 | 22.25 |
| 5 | Exactech | EXAC | $18.33 | $240 | 21.31 |

## Lowest P/E to Growth Ratio (Earnings Estimates)

| | Company | Symbol | Price | Mkt Cap | PEG |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $41.77 | $754 | 0.92 |
| 2 | Kensey Nash | KNSY | $24.68 | $211 | 1.05 |
| 3 | Exactech | EXAC | $18.33 | $240 | 1.18 |
| 4 | Symmetry Medical | SMA | $8.72 | $317 | 1.24 |
| 5 | NuVasive | NUVA | $32.01 | $1,270 | 1.25 |

## Highest P/E to Growth Ratio (Earnings Estimates)

| | Company | Symbol | Price | Mkt Cap | PEG |
|---|---|---|---|---|---|
| 1 | Alphatec Holdings | ATEC | $3.49 | $311 | 3.05 |
| 2 | CryoLife | CRY | $5.50 | $154 | 2.71 |
| 3 | ConMed | CNMD | $27.16 | $769 | 2.26 |
| 4 | Johnson & Johnson | JNJ | $65.06 | 178,339 | 2.07 |
| 5 | ArthroCare | ARTC | $33.39 | $912 | 1.76 |

## Lowest Price to Sales Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | PSR |
|---|---|---|---|---|---|
| 1 | Symmetry Medical | SMA | $8.72 | $317 | 0.88 |
| 2 | RTI Biologics Inc | RTIX | $2.87 | $158 | 0.95 |
| 3 | ConMed | CNMD | $27.16 | $769 | 1.08 |
| 4 | Wright Medical | WMGI | $14.46 | $564 | 1.09 |
| 5 | Exactech | EXAC | $18.33 | $240 | 1.26 |

## Highest Price to Sales Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $1.30 | $124 | 199.66 |
| 2 | MAKO Surgical | MAKO | $27.79 | $1,138 | 25.70 |
| 3 | Bacterin Intl Holdings | BONE | $3.04 | $116 | 6.20 |
| 4 | Synthes | SYST.VX | $173.72 | $20,634 | 5.60 |
| 5 | Tornier N.V. | TRNX | $27.59 | $1,077 | 4.74 |

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

# Gary Michelson, M.D., Revisited

By Walter Eisner

*Source: Andrew Huth for RRY Publications LLC*

Seventeen years ago, a spine surgeon called an engineer at Sofamor Danek (now Medtronic Spine and Biologics) and said he had just used their new Orion Cervical Plate. He said it was a nice device, but there were some problems with it. He asked if he could make some suggestions.

The engineer said, "No thanks." He told the surgeon that if he thought he could do a better job, he should do it himself.

## The Gift of Invention

Gary Michelson, M.D. did exactly that. Now, $1.35 billion dollars and 955 patents later, Michelson is on the *Forbes* magazine annual list of the 400 richest Americans. He was listed at No. 290 in 2010, with a net worth estimated at $1.4 billion.

In a 2005 interview with *Orthopedics This Week*, Michelson said he did not want to be a business man. "I wanted to practice medicine. I did not want to get rich from medical devices. That is not why I patented them. I wanted to insulate myself from the business side of things."

Having had the gift of being able to take things apart and put them back together as a kid, inventing was not hard for Michelson. He said the only difficult part in inventing is identifying the problem. Solving it is much easier.

For instance, during one surgery he thought to himself, "I cannot leave this piece of bone behind, it's too big…I never invented something in the abstract and then wondered what it will be useful for," said Michelson.

That led him to develop a small set of instruments which were the right size and right shape for treating different spurs and osteophites. He eventually made a deal with Sofamor Danek to develop his patented devices.

## The Lawsuit

However, in 2001 the company filed a lawsuit against him for allegedly attempting to license his inventions to competing spinal implant companies.

He countersued Medtronic and accused the firm of failing to aggressively develop his inventions and pay him royalties.

A jury awarded Michelson $510 million in punitive and compensatory damages. Eventually, in order to settle all claims, he agreed to accept $1.35 billion and sell the company a range of inventions and technologies

Michelson's experience and settlement will be seen by some as a watershed moment in the relationship between spine surgeons and device companies. A new health care economic environment is pushing payers to demand that products be safer, more effective and cost effective than previous products.

## Customer Needs

"Companies that are the most successful are driven not by their research and development department, not by their marketing people," noted Michelson, "they are driven by their customers' needs. That's what drives the process."

When Michelson started his career in Philadelphia, a physician told him that a spine surgeon was like a carpenter building a house. Every time he has a bent nail he throws it in a bucket. In the end all he had was a bag a bent nails. "If you want be a spine surgeon, the results are so bad, every few years you will have to pick up and move to a new state. The people who get better you never see again, the people who did not get better are your bent nails," warned the physician.

"Back then," said Michelson, "those were the largest operations orthopedic surgeons performed. Yet they had the least gratifying results. When you operated on somebody for a back condition, if it did not go well, then they never went back to work. These were devastating disabilities."

He continued, "We saw trauma—people who broke their neck or backs. But much more common were degenerative conditions of the spine. Up until the 1800s, people had a life expectancy of 30 years. We have managed to triple that and a lot of people's backs began to wear out in their 40s, yet we live in a society where people are reaching the peak of their productivity as workers when they are in their 40s."

## Value of Inventions

Michelson believes his inventions have allowed a spine surgeon of ordinary skill to have the same results as the highly skilled surgeon.

He takes greatest pride in the technology that directly impacts patients. "The first thing that comes to mind is the interbody spinal fusion technology. I think what made this successful is that the methods and instruments made the 'sweet spot' so big that you did not have to be a flawless carpenter to make the procedure work. A spinal surgeon with moderate skill can achieve a great result with this procedure over and over again."

The instruments have a number of redundant safety features which Michelson says anticipate mistakes and keep them from happening and make it possible for the ordinary spinal surgeon to do the procedure.

Michelson's inventions shifted the relative economic value from the carpenter to the tools and instruments and device companies saw their revenues rise while surgeons saw stagnating or declining reimbursements.

## They Shoot Horses Don't They

Outcomes are what have driven the retired surgeon. Dealing with humans, for example, is very much different than dealing with horses said Michelson.

"When you do an operation on a horse to stabilize its spine and it fails one out of seven times, you have a paralyzed horse and you shoot it. You saved six horses and shot one. That is a good result because you were going to shot all seven horses." But it's different with humans. "One out a hundred makes it a useless procedure. You cannot have a procedure where 99 of them go great and the 100th one you paralyze."

## The Multi-Lock System

The most successful product from a patient standpoint, according to Michelson, has been the cervical plating system. "The patent that covers this product is called multi-lock. The multi-lock system revolutionized cervical spine surgery. The plate allows doctors to put in a plurality of bone screws to fix the plate to the spine and then lock all those screws at once rather than one at a time. The lock is preinstalled in the plate so the lock goes in before the screws go in. This has really revolutionized cervical plating," said Michelson.

In thinking about motion preservation for the spine, Michelson said the laws of nature, whether its gravity or the way the joints work, never change. "If someone were to tell you the back is different, it's not like the knee; it's not like the hip-they're just dead wrong."

While each body part has its own characteristics, Michelson says they all have to obey the same basic principles. "We have principles of arthroplasty that have evolved and developed through more failures then ever should have occurred."

*Source: Andrew Huth for RRY Publications LLC*

## Lessons From Hips and Knees

Michelson said that 25 years ago when the industry was having total hips stem wars, one company would say that the cross section of the stem should look like a diamond and another would say it should like another geometric design.

The only stems which really worked, according to Michelson, were the ones the surgeon made when he cleaned out the femoral canal, poured in some latex, and pulled it out. It had a shape which wasn't geometric, it was biologic. It corresponded to the true shape of the femoral canal. "When you make a stem by using that latex mold you get a femur which does the best over time."

They did the same thing with total knees.

"When I was a resident, total hips were surviving maybe 15 years and total knees were surviving only about 5 years. The instruments for total knees were insignificant."

Michelson noted that when instruments were invented to protect the vital structures surrounding the knee, the survival of total knees became comparable to total hips. The key was the development of methods and instruments such that it was safe, easy and reproducible for the surgeon.

In the total knee war, Michelson said it was the instruments which ultimately sold the product. The company whose instruments let the ordinary surgeon get a great result easily got the sale. It was better for the doctor and better for the patient.

"Ultimately, it will be the surgical methods and the instruments which drive the sales of the artificial disc implants."

## Michelson Today

Michelson stopped practicing in the beginning of the year 2001 because being an inventor was a full time job.

Today, Michelson devotes his time to a variety of causes ranging from animal

welfare, medical research, online textbooks and buying up parts of the tropical rain forest in Central America.

He also formed the Medical Research Foundation trust. He's using the first $200 million from the sale of the new technology to Medtronic to fund the foundation. He'd like to hear proposals from people who are on the cutting edge. "Not the people who already are the leaders who need no help getting funded. We would like to get into something on the ground floor, for example genetic engineering, or fetal stem cell research; something that has the potential to make a tremendous breakthrough in medicine." ◆

# This Article Will Save You $500,000

By Robin Young

But only if your hospital or clinic needs a health information system that integrates seamlessly with your electronic health record system.

Still interested? Then you need to hear about VistA—the Veterans Health Information Systems and Technology Architecture that is available for FREE.

It is also very popular with its physician and administrative users.

VistA is a collection of about 100 integrated software modules that run the largest single medical system in the United States—the VA (Department of Veterans Affairs). With VistA, the VA provides care to over 4 million veterans, employs 180,000 medical personnel and operates 163 hospitals, more than 800 clinics, and 135 nursing homes.

This is a robust system. It is probably the most widely used electronic health record (EHR) and health information systems in the world. Nearly half of all U.S. hospitals that have a full implementation of an EHR are VA hospitals using VistA.

And you can get it for free.

*U.S. Department of Veterans Affairs*

## Brief History

The VA has had automated data processing systems, including extensive clinical and administrative capabilities, within its medical facilities since before 1985. That system was initially named the Decentralized Hospital Computer Program (DHCP) information system and it was the recipient of the Computerworld Smithsonian Award for best use of Information Technology in Medicine in 1995.

From that august start, billions of dollars were invested in upgrading DHCP to support both ambulatory and inpatient care and the result, which again is FREE and available to any hospital or clinic or nursing home in the U.S is VistA. The most significant change from DHCP and the one that has its users so impressed is the Computerized Patient Record System (CPRS) which is a wonderfully intuitive graphical user interface for physicians and nurses. In addition to CPRS, VistA includes, hang on to your hats, a computerized order entry system, a bar code reader medication administration system, an electronic prescribing system and, yes!, a clinical guideline system.

The CPRS piece allows physicians and nurses to review and update a patient's electronic medical record including: the ability to place orders for medications, special procedures, X-rays, nursing interventions, diets, and laboratory tests. CPRS is very flexible and will allow for a wide variety of settings

so the entire spectrum of health care workers can access a consistent, ***event-driven***, Windows-style interface which is presented to a broad spectrum of health care workers.

## Benefits

The VistA electronic medical records system improves efficiency by about 6% per year in most hospitals, clinics or nursing homes. The monthly cost of administering VistA is more than offset by eliminating the cost of even a few unnecessary tests or admissions.

For example, with VistA the VA achieved a pharmacy prescription accuracy rate of 99.997%, and the VA outperforms most public sector hospitals on a variety of other key performance criteria. All due to VistA.

Another example. The VA, because of VistA, is one of only THREE hospital systems in the U.S. that have reached HIMSS stage 7, the highest level of electronic health record integration. To put this in perspective, only 1 of 42 US hospitals have reached HIMSS stage 6.

## VistA in Private Hospitals and Clinics

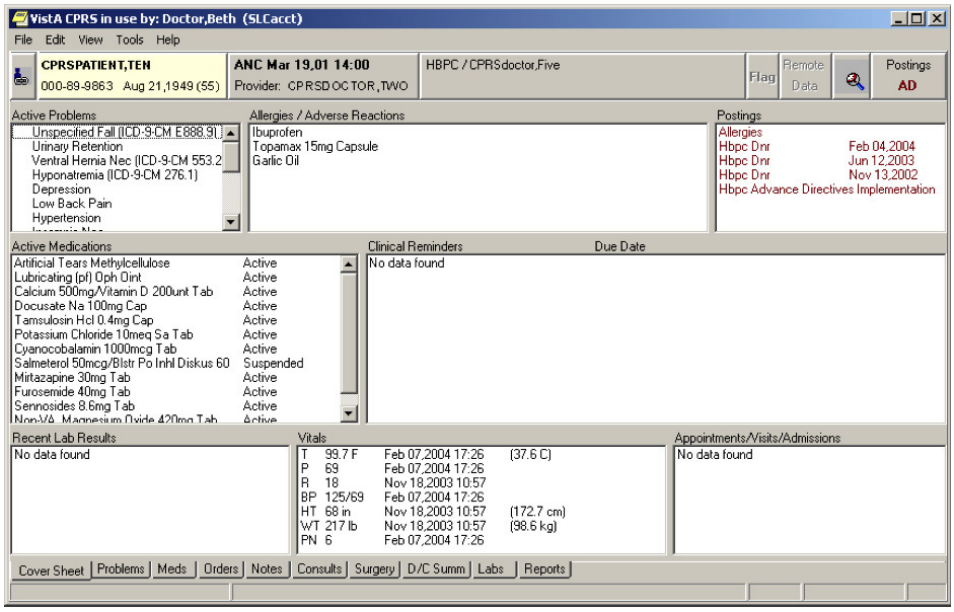
Under the Freedom of Information Act (FOIA), the VistA system, the CPRS interface, and unlimited ongoing updates (500–600 patches per year) are available to any hospital, clinic or nursing home for free. To make it even easier for non-governmental health care providers to have a world class information system, Pacific Telehealth & Technology Hui produced a version of VistA ( the Hui 7), which runs on GT.M in a Linus operating system environment.

Several independent software developers including Blue Cliff, DSS, Inc., Medsprere and Sequence Manager's Software have adapted VistA so that it will work in the whole variety of health care practices including: individual practices, small and large clinics, all kinds of hospitals and even regional health care confederations which are trying to achieve co-ordination between far-flung facilities. Universities like UC Davis or Texas Tech have implemented such modified VistA systems. In one case, VistA was even adapted for a large veterinary practice.

The icing on the cake, we think, is that VistA can be linked in with any health care databases which was not initially used by the VA system, including billing software, lab databases, and image databases (radiology, for example).

VistA is now at work in non-VA health care facilities in Texas, Arizona, Florida, Hawaii, New Jersey, Oklahoma, West Virginia, California, New York, and Washington, D.C.

In one state, hospital administrators implemented VistA EHR network in a multiple hospital network for one-tenth the price of a commercial EHR network. Specifically, to hire the team to implement and train, this particular hospital network spent about $9 million versus $90 million which



*U.S. Department of Veterans Affairs*

was quoted for a commercial system. Interestingly enough, BOTH the VistA and the commercial system used the MUMPS database.

## Downloading VistA

Because of the FOIA, the VistA system is public domain software and available to any hospital, clinic or nursing home directly from the VA website or through a growing network of distributors. "Astronaut" is an automated VistA installer suite which installs VistA in less than 30 minutes. Installation instructions for the Astronaut VistA Installer Suite can be found at http://astronautvista.com/astronaut-help/how-to/how-to-install-astronaut-vista-server-and-client. The software engineers at Astronaut have done many bug fixes, upgrades and enhancements which makes VistA eminently usable and suitable for non-governmental use.

## VistA's Details

VistA was developed using the M or MUMPS language/database. It runs on an open source MUMPS database engine, called GT.M. An engine for Linux and Unix computers was also developed. Publicly available VistA distributions are now often bundled with the GT.M database in an integrated package. This makes the installation of VistA very easy. In addition, the free and open source nature of GT.M allows for redundant and cost-effective failsafe database implementations, which has really increased the reliability of the system in complex hospital or clinic networks.

M2Web is an open source web gateway to MUMPS for use with VistA.

Finally, a free open source module from M/Gateway called MGWSI is available to act as a gateway between GT.M, Cache, or M21 MUMPS databases and programming tools such as PHP, ASP.NET, or Java. How cool is that? With these tools, any user can build a great, robust and intuitive web-based interface for VistA.

## Personal Health Records With VistA

The VHA (Veterns Health Adminitration) has an ongoing pilot project, known as HealtheVet (HeV) that is creating the next generation of VistA. This new interface will allow every patient (or veteran in the case of the VA) to access, and create a copy of, their health records online. Every patient will be able to port their health records to institutions outside their home health system as well as keep a personal copy of their health records..

## VistA Imaging

VistA Imaging is the module that talks to PACS (radiology imaging) systems and integrates such images as EKGs, pathology slides, and scanned documents into the overall VistA electronic medical records system.

## VistA as a Portal to a National Healthcare Network

The federal government has mandated that all citizens will have an electronic medical record by 2014. That mandate will require standardized health care data transmission. Enter VistA Web. This is a set of protocols that is being used by the VHA to transfer data between hospitals and clinics so that a single patient record may be viewed by health care providers in any of the 128 VA sites running VistA today.

In addition to VistA Web, the VHA also created the Clinical Data Repository/

Health Data Repository (CHDR) which lets data flow between the Department of Defense's Clinical Data Repository (CDR) & the VA's Health Data Repository (HDR). We're talking two-way, real time, flow of pharmacy, allergy, demographic and laboratory data. Coming soon is an upgrade which will add in drug/drug interaction and allergy checking.

Because VistA has proven to be so user friendly and flexible, it has all of the drivers to be the portal for an eventual national health care data network. Already, VistA can standardize text based information exchange using a protocol called HL7 (Health Level 7) which was approved by the American National Standards Institute and DICOM.

Finally, if your hospital or clinic already has a commercial off-the-shelf system, VistA has the ability to interface with them as well. VistA can talk to other EHRs using a standardized information exchange protocols. In 2009, VistA's managers build an EHR communication link between the VA (using VistA) and Kaiser Permanente (using Epic) using NHIN Connect. When the VA and Kaiser collaboration is done, it will have combined two of the largest medical record systems in the U.S.—which will be exchanging health data across both systems.

VistA—some of the best things in life are free. ◆

# Research for Life: The Airlift Research Foundation

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

For most Americans, watching the heart wrenching films, *Saving Private Ryan* or *Full Metal Jacket* is the closest we will ever get to war. We won't hear the screams or be witness to the terror felt by a young man or woman who has been hit by an IED in the sands of Iraq…who looks down and sees that his leg is ripped open and his arm isn't much better…who lies there with a thousand thoughts flying through his mind: "Am I going to die? Will I ever see my family again? If I make it, will I lose my leg?"

Six thousand miles away, a cadre of dedicated engineers—a brain trust, really—work in labs around the U.S. to help ensure that when soldiers ask those questions, they have the kind of answers that any of us would want.

Susan Lephart, Ph.D., is the president of the Airlift Research Foundation, a public charity formed in 2008 by The Aircast Foundation to improve the care of wounded warriors. "At the outset, Aircast provided grants to young investigators to foster their careers; the foundation invested $3.6 million and the researchers managed to bring in $39 million in additional extramural funding."

*Photos provided by Airlift Research Foundation*

Explains Dr. Lephart, "Aircast was impressed by the outside support and wanted to build on that to make a more significant impact. They initially considered focusing the research to improve the care of amputees coming from Iraq and Afghanistan, but then learned that 82% of those returning suffered from significant extremity trauma, while only 6% were amputees. It became clear that the injuries created by IEDs were so significant that we were dealing with a different type of trauma. While modern body armor has greatly improved the survival rate of our troops, it still leaves the extremities vulnerable."

In 2008 the Aircast Foundation put all of these ideas into a new, non profit entity–the Airlift Research Foundation. Dr. Lephart: "The goal of Airlift is to fund research that is specific to extremity trauma so that we could hopefully

**"The reviewers and scientific board members engage in rigorous discussions and take significant time with each application. Whether or not someone is granted funding, they will receive substantial constructive feedback."**

*LT (RET) Edwin Salau is on the left and Sgt. (RET) Andrew Butterworth is on the right.*

have a larger reach. It was obvious that while the government was doing its best, there was just not enough money to fund the amount and type of research that is needed. The Airlift mission is threefold: fund orthopedic research, increase public awareness of traumatic war injuries, and work with other groups whose goals are similar to our own."

So who are the dedicated recipients of the Airlift foundation grants? They are the late night, goggle wearing young investigators…they are the ones who bring hope to those in pain whose minds are churning with a thousand questions. Dr. Lephart: "Each year, Airlift provides two $200,000 grants for young investigators (either young as in just beginning their careers or as in just beginning a specific research agenda) to embark on proof of concept work that will ideally be funded by NIH [National Institutes of Health] or the Department of Defense (DOD) at a later date. When selecting the grantees, our bottom line is that the project should be able to be translational and have the potential to improve clinical care by exhibiting some marketability within five years. Thus far we have had two grant cycles; I'm excited to say that one of those projects may be approved by the FDA next year, while another two have led to patents."

Dr. Christopher Born, the chief of Orthopedic Trauma at Brown University, is one of the research grantees. According to Dr. Lephart; "Dr. Born developed an intramedullary nail (IM) that has a special coating to fight infection. This is especially helpful in Iraq and Afghanistan where soldiers who have lost a significant portion of a femur can have an IM nail that will likely *not* result in what so often happens, i.e., the nail is rejected or the patient requires several follow on surgeries because of infection. The texture of the coating that Dr. Born uses is also revolutionary, and appears to increase healing. They are now looking at expanded ways of using the coating and other ways to manufacture the nail so that it may be used in lesser developed countries. The reach is just huge, and we hope they will receive FDA approval in the foreseeable future."

Down at the University of Texas Health Science Center, another Airlift grantee, Peter Yang, Ph.D., developed something with so much potential that the DOD has opened its arms. Dr. Lephart explains, "Dr. Yang has created scaffolds that are weight bearing, which is significant because that makes quite a difference with large bone defects. There are patents on his work, and he has garnered close to $4 million in additional funding from the DOD and NIH. Fortunately, this work will benefit our troops as well as the general populace."

With scaffolds occupying such an important place in the healing process, it's not surprising that another Airlift grant recipient is pursuing excellence in this arena. "Yufeng Dong, M.D., Ph.D. of the University of Rochester Medical Center, is working with skeletal stem cells that are harvested from the injured patient. He is making a scaffold for large segmental bone loss, something that is novel because most times scaffolds are made using synthetic grafts or stem cells from outside the body. This work is so new and so applicable to the types of bone defects we are seeing in Iraq and Afghanistan that he will likely receive follow on funding."

According to Dr. Lephart, the race to market just might be won by a young

investigator at Harvard. "Tianhong Dai, Ph.D., has created a fascinating product. He is using light-based therapy—UV-C light—which is highly antibacterial, with the goal of putting it into a portable format. This 'flashlight' device could be carried by paramedics who need to treat a wound quickly and cut down on the bacteria. On the battlefield and in regular life, we are seeing that because of the overuse of antibiotics so many patients are resistant to these drugs…it is really the time for something noninvasive."

So how do the stewards of the Airlift Foundation ensure that its precious resources go only to the most promising research? "We have a preliminary application deadline of July 1, something that enables us to determine if a project is in line with our mission and has scientific merit. This is also best for the applicants as we don't want them to go through the rigors of a full application without knowing that they are fundable. Full applications are then due September 1, with the review process beginning in October. The reviewers and scientific board members engage in rigorous discussions and take significant time with each application. Whether or not someone is granted funding, they will receive substantial constructive feedback."

As for what those guarding the funds look for, Dr. Lephart states, "It is important that applicants have had the appropriate type of mentoring. While the science and clinical translatability are the most important aspects of the project, we also look at the institution and how much support they are willing to provide. Also, we want to know if the researcher has the right team in place. Finally, we assess the relevancy of the work to the task of assisting military personnel."



Highlighting the organization's unusual position, Dr. Lephart notes, "We have a unique opportunity because as a public charity we can function differently than the government or a for-profit organization. Airlift can be more nimble, for example, being in more direct communication with the applicants and grantees. And our review process is both arduous and pure, which is challenging

**"Airlift can be more nimble, for example, being in more direct communication with the applicants and grantees. And our review process is both arduous and pure, which is challenging because orthopedics is a small community. We have to work hard to keep the process unbiased, but we feel that we have been able to do it."**

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Aside from the financial elephant in the room—the need for funding—what are the organization's growth pains? "Building our board has been a little slow because the members are very well respected individuals who are quite active outside of Airlift. But our board members are not just names on a letterhead…they have significant responsibilities to help us raise funds and national awareness."

"In five years I would like us to be a sustainable organization with our percentages as low as possible relative to operations and programming. I would like to be able to provide more grants and add a second program that will fund senior investigators pursuing a new line of research."

First Lieutenant Ed Salau is an Airlift board member and a wounded warrior. In his view, the key to Airlift is its ability to understand the unique nature of these war wounds from Iraq and Afghanistan. "Those at Airlift know that more than 80% of war injuries are extremity trauma and that research is vital to improving patients' quality of life during and after recovery. The fact that Airlift is raising that awareness among the general public is key to improved treatments for soldiers and civilians alike."

Salau continues; "It is personal for me because my fellow service members need the scientific, medical improvements each grant recipient promises. Airlift is its own quietest cheerleader. America needs to know what our young researchers are accomplishing."

Bernard Morrey, M.D., emeritus chairman and professor of the Department of Orthopedics of Mayo Clinic/Mayo Foundation, is chair of the Scientific Advisory Board for Airlift, adds, "Airlift fills a void in the research world, and provides for the rapid translation of important work to real life. The review process has a proven track record that can ably handle conflicts of interest and other hurdles that might impede this important work."

Dr. Morrey, a former president of the American Academy of Orthopaedic Surgeons summed up the Airlift Foundation story best when he said, "I believe that we need to reach outside of the orthopedic community as well. So often, it seems that there are misunderstandings within our field about various groups that appear to be doing the same type of work. In sum, I am proud to offer my experience to help these very deserving wounded soldiers and young investigators." ◆

*If any of our readers would like to receive more information about the Airlift Research Foundation please visit their website: www.airliftrf.org or email Dr. Susan Lephart: SLephart@airliftrf.org*

company

## NuVasive to Raise $325 Million

NuVasive, Inc. is planning to raising $325 million through the issuance of convertible Senior Notes due in 2017.

The company announced on June 21 that it wants to use the money for, "general corporate purposes and to repurchase up to $230 million of its 2.25% Convertible Senior Notes" due March 2013. The company noted it may also use the proceeds for "possible strategic acquisitions" or investments in companies, technologies, products or assets. The company said it has no current commitments or agreements for such investments.

Note holders will be able to convert the notes into cash and/or common stock. NuVasive shareholders will have to approve an increase in the total number of authorized shares to repay the note holders if they choose to take stock.

BMO Capital Analyst Joanne Wuensch said there are several good things about the news.

First, it removes the refinancing overhang of the 2013 notes. Second, the move shores up the company's cash position, which stood at $226 million at the end of the first quarter of 2011.

Wuensch said NuVasive could be on the hook for potential milestone payments from the Progentix acquisition. Those milestones include up to $45 million to purchase the remainder of the company and $25 million more in sales milestones. The company also has $33 million in contingent considerations for the Cervitech acquisition. Then there's the $60+ million in escrow and attorney fees related to the Neurovision name dispute.

Wuensch also commented even though the company said it hasn't inked any potential transactions, she suspects acquisitions are on the table, namely biologics or another spine technology. She also said the funds may used to accelerate the company's overseas build-out, which is expected to reach 8% of 2011 revenue.

BofA Merrill Lynch and Goldman, Sachs & Co. are acting as joint book-running managers for the offering.

—*WE (June 22, 2011)*


*Kevin Rosseel and morgueFile.com/NuVasive, Inc.*

## Back Pain Company Raises $30 Million

Spinal Modulation, Inc., a developer of an implantable spinal cord stimulator system has just completed a $30 million Series D financing to fund U.S. and international clinical trials. Spinal Modulation's product is, essentially, a pacemaker that delivers programmable amounts of electricity to a patient's spinal cord and, in the process, relieves back pain. The device uses wires connected to an electrode which


*Spinal Modulation, Inc.*

is implanted into the back or belly of the patient. The electrodes are positioned on the spinal cord, according to company spokesman Dimas Jimenez. Jimenez estimates the world-wide market for pain-modulating devices of this

sort could eventually rise to somewhere in the neighborhood of $1.5 billion dollars. Nice neighborhood.

The system is presently in clinical trials in Europe and Australia. If all goes as planned, Spinal Modulation's management hopes to receive permission to sell in Europe this year and to begin a clinical trial in the United States in 2012.

Investors in Spinal Modulation include Medtronic, Inc. DeNovo Ventures, ePlanet /DFJ, InCube Ventures, Johnson & Johnson Development Corporation (JJDC), Kleiner Perkins Caufield & Byers, MedVenture Associates, and Raffles Venture Partners.

David Wood, president and CEO of Spinal Modulation, said, "We are encouraged by the early clinical results with our fully implantable system and look forward to providing physicians new options to care for their patients suffering from chronic pain."

Mir Imran, Spinal Modulation's founder and chairman, commented, "Spinal Modulation has made significant progress in the development of the company's technology. I am confident that the company's commitment to excellence in clinical research will lead to additional tools for the treatment of chronic pain."

Spinal Modulation, headquartered in Menlo Park, California, is an early stage, privately held medical device company developing the next generation spinal cord stimulator system for the treatment of chronic pain. Spinal Modulation has completed development of its first fully implantable spinal cord stimulation system for the treatment of chronic pain.

*—BY (June 20, 2011)*

## Cayenne Medical Aligns With Parametrics

Cayenne Medical, Inc., a private sports medicine device company, has entered into a co-marketing partnership with Parametrics Medical, a provider of bone and tissue allografts designed to provide surgeons with tailored knee ligament reconstruction options. Cayenne Medical specializes in soft tissue reconstruction.

Cayenne Medical CEO David Springer said, "Through this strategic partnership with Parametrics Medical, Cayenne now offers surgeons a comprehensive menu of safe and effective allograft options that compliment Cayenne's knee implant solutions."

"We are pleased to be working with Cayenne Medical to partner our high quality allograft service with their innovative knee ligament repair systems," said Dan Leary, Vice President and General Manager of Parametrics Medical." This relationship is highly synergistic, providing surgeons with the optimal tools and technologies to fit the specific needs of their patients."

Surgeons use allografts in knee ligament reconstruction procedures frequently—approximately 40% of the time and, of course, according to each surgeon's preference or the specific anatomical requirements of their patients. This new alliance will allow Cayenne Medical sales representatives to cater to the specific graft needs of each surgeon, whether he or she is performing a bone-patellar tendon-bone ACL reconstruction using the iFix PEEK Interference System or a soft tissue allograft reconstruction using Cayenne's AperFix II System.

Cayenne Medical, of Scottsdale, Arizona, is a privately held medical device company, founded in 2005. Cayenne's corporate focus and objective is to transform traditional arthroscopic procedures by providing surgeons with advanced technologies which incorporate minimally invasive techniques.

Parametrics Medical, with regional offices in Kalamazoo, Michigan and Austin, Texas, has national contracts with several tissue banks throughout the United States—all of which are certified by the American Association of Tissue Banks and registered with the Food and Drug Administration .The company offers irradiated grafts, non-irradiated grafts, SuperCritical CO2 non-irradiated grafts, as well as various other bone allografts including those that are freeze-dried, frozen, fresh, or cryopreserved.

*—BY (June 20, 2011)*


*Cayenne Medical and Parametrics Medical*

legal

## Infuse Payments Under Investigation

Senator Chuck Grassley is after Infuse again. This time it's bipartisan as the Chairman of the Senate Finance Committee, Democrat Max Baucus, joined Grassley in demanding documents and information about the product and payments to physicians by Medtronic.

In a June 21 letter to Medtronic's new chairman and CEO, Omar Ishrak, the Senators cite a recent study that "found that men treated with Infuse developed a condition that causes temporary or permanent sterility at a far higher rate than men who received a bone graft." This link to sterility, they claim, was not reported in the original Medtronic-funded study.

The Senators also referenced a Medtronic-funded study published in 2004 that they said found that 75% of bone morphogenetic protein 2 (BMP-2) patients experienced ectopic bone growth, where potentially harmful bone growth occurs outside of the fusion area. "The authors, who had financial ties to Medtronic, concluded that 'although not desirable,' the ectopic bone growth did not appear to have an ill effect on the patients."

They note a separate 2008 study conducted by physicians without financial ties to Medtronic, found "neurological impairment occurred" in five patients who had the same ectopic bone formation.

In addition to Medtronic, the Senators also have University of Wisconsin orthopedic surgeon, Tom Zdeblick, M.D., in their sights, noting he has received "more than $23 million in various royalty payments from Medtronic since 2002."

*Senators Max Baucus and Charles Grassley*

In addition, they point out that, "Zdeblick is also the editor of the journal where two of the Infuse papers that failed to mention the link [to sterility] were published."

Finally, the Senators are "concerned that other severe side effects of Infuse and similar bone growth products developed by Medtronic may have been unreported or under-reported in clinical literature. Reports have linked Infuse to potentially fatal swelling in the neck and throat, and radiating leg pain. Concerns have also been expressed about a potential link to cancer.

Given these concerns, the Senators are asking Medtronic to provide the Committee with a large number of documents, including:

"All documents and communications pertaining to adverse postoperative events and/or medical complications relating to the use of recombinant human bone morphogenetic protein 2 (rhBMP-2) treatments, and a detailed account of payments that Medtronic made to all Infuse clinical investigators."

Medtronic spokeswoman Mary Beth Thorsgaard reportedly noted that complications cited in the letter are listed on the product's warning label. In regard to cancer concerns, she said 44 clinical trials involving Infuse observed cancer rates that were not statistically different between the patients treated with the product and those who were not.

The Senators "look forward" to hearing from Medtronic by no later than July 11, 2011.

*—WE (June 24, 2011)*

trauma

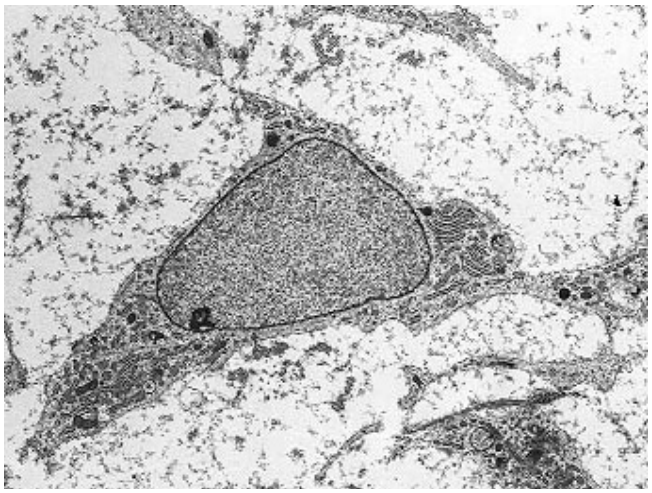
## Stem Cell Grout for Surgery

Orthopedic surgeons at the University of California, Davis, are testing (as part of a clinical trial) a stem-cell grout that—if successful—could be used to treat patients whose fractured bones fail to fully heal. The surgeons are using a specialized syringe and new cell separation equipment to take stem-cell-rich bone marrow from the pelvises of patients. Called bone marrow aspiration, the surgical team considers it a less-invasive procedure than the current practice of surgically removing bone and bone marrow from the pelvis to obtain the stem cells needed to repair non-healing bones.

The process produces a concentrated solution of bone-forming cells—including stem cells—which the surgeons mix with tiny pieces of donor bone to create the grout-like mixture that serves as the framework for new bone formation. Surgeons pack the mixture into the fracture area before suturing the incision site closed.

"We are offering a promising new alternative for augmenting bone regeneration," said Mark A. Lee, associate professor of orthopedic surgery and principal investigator of the study. "Surgically removing bone and marrow from a patient's hip can involve considerable pain and a long recovery. We're hoping to avoid these problems while remaining at least as effective."

For most people who have suffered a fracture in one of their long bones recovery normally takes from three to six months for the broken ends of the bone to grow back together. Although most fractures respond well to surgery, some cases defy the best efforts of surgeons and do not fully heal, leaving a gap between the broken ends and causing serious complications.



*Wikimedia Commons and Robert M. Hunt*

According to the American Academy of Orthopaedic Surgeons, about six million individuals suffer fractures each year in North America. In about 5% to 10% of cases, patients suffer either delayed healing or fractures that do not heal. The problem is especially troubling for the elderly, many of whom suffer from osteoporosis, a condition in which bones become weak and break more easily.

"Bone marrow aspiration for treating non-healing fractures could potentially become an extremely important option as our population ages and we expect to see more broken bones," said Lee, who also is exploring whether the bone marrow cell mixture can be delivered to the fracture site through a minimally invasive incision rather than open surgery. "This study will help us determine the optimum therapy and technique for non-healing fractures, and we hope that this gentler approach really helps people get back on their feet faster."

"Dr. Lee's clinical trial is the culmination of five years of collaboration with a high-tech firm, the UC Davis School of Veterinary Medicine and our Department of Orthopaedics," said Jan Nolta, director of the UC Davis Institute for Regenerative Cures. "It is a great model for bringing together industry, academics and medicine to rapidly develop and test important new technology to improve clinical care for patients." Lee and his colleagues are working with Rancho Cordova-based ThermoGenesis and Texas-based Celling Technologies.

*—BY (June 20, 2011)*

large joints

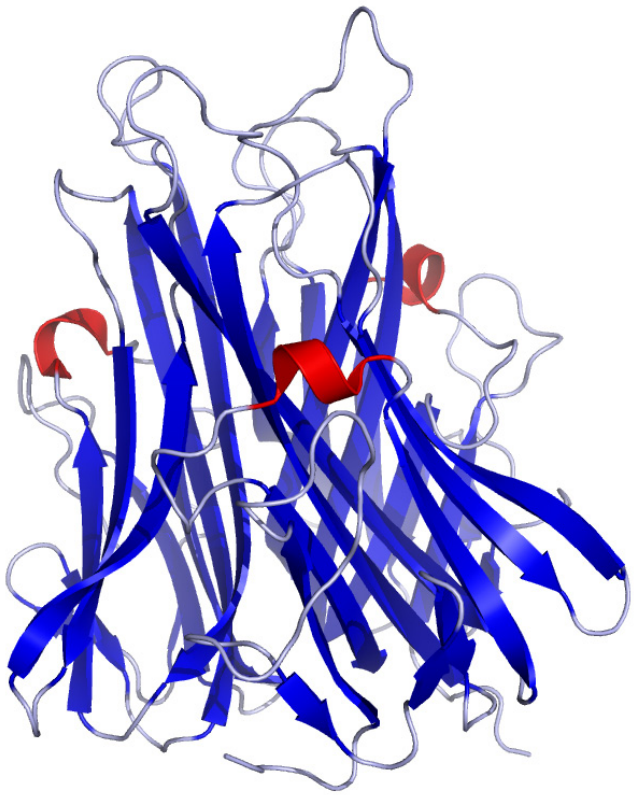
## RA, Tumor Necrosis Factor, Diabetes

Good news for those who have excess sugar in their blood AND joint pain…Researchers at Brigham and Women's Hospital (BWH) have found that among patients with RA or psoriasis, the risk for developing diabetes was lower for those patients who started TNF inhibitor or hydroxychloroquine.

"While there may be other mechanisms at play in these medications aside from their effect on inflammation, we observed a reduced risk for diabetes in patients with RA or psoriasis who were treated with tumor necrosis factor (TNF) inhibitors or hydroxycholoriquine when compared with patients who began treatment on other non-biologic DMARDs," said Daniel Solomon, MD, MPH, in a June 21, 2011 news release. Dr. Solomon is the lead author of the study and a researcher in the Division of Rheumatology and the Division of Pharmacoepidemiology at BWH.

Researchers evaluated data gathered from 13,905 patients with RA or psoriasis with 22,493 new instances of treatment initiation. The patients were categorized based on four categories of commonly used DMARD regimens: non-biologic DMARDs, TNF inhibitors, methotrexate and hydroxychloroquine. The researchers found 267 newly diagnosed cases of diabetes:

- 55 cases among 3,993 patients treated with non-biologic DMARDs
- 80 cases among 4,623 patients treated with TNF inhibitors
- 82 cases among 8,195 patients treated with methotrexate
- 50 cases among 5,682 patients treated with hydroxychloroquine



*Wikimedia Commons and Ramin Herati*

Researchers report that the rate of newly diagnosed diabetes was highest in individuals who were treated with nonbiologic DMARDs and lowest for TNF inhibitor users. Additionally, when adjusting for other risk factors for diabetes, researchers found a reduced relative risk of diabetes in patients treated with TNF inhibitors and hydroxychloroquine compared with other non-biologic DMARDs.

Dr. Solomon added, "Our study shows an association between these two DMARDS (TNF inhibitors and hydroxychloroquine) and reduced diabetes risk, but we cannot be sure that the association is causal—that the medications are the cause of the reduced risk. Currently we are working on an NIH-sponsored [National Institutes of Health] randomized clinical trial using hydroxychloroquine in RA patients to assess for its effects on glucose and insulin. If this and other randomized clinical trials show the same relationships, then physicians may want to consider assessing their patients not only for the management of their RA or psoriasis, but also for insulin resistance."

Regarding details about the NIH-sponsored clinical trial, Dr. Solomon told OTW, "We are enrolling patients with rheumatoid arthritis into a double blind cross-over study of hydroxychloroquine and assessing insulin sensitivity. We are nearly fully enrolled and hope to have results in about one year."

*—EH (June 26, 2011)*

# First Ceramic-on-Metal Hip Approved in U.S.

*Pinnacle CoMplete Acetabular Hip System/DePuy Orthopaedics, Inc.*

The FDA approved the first ceramic-on-metal hip implant in the U.S. on June 13.

And the proud parent of the implant named the Pinnacle CoMplete Acetabular Hip System? DePuy Orthopaedics, Inc.

This comes as welcomed news to the company that just announced the hiring of a new leader, Andrew Ekdahl, and is protecting itself on all fronts from lawsuits over its recalled metal-on-metal ASR hip system.

"Orthopedic surgeons and their patients now have an additional option for total hip replacement," said Christy Foreman, director of the Office of Device Evaluation in the FDA's Center for Devices and Radiological Health.

Previous total hip replacement systems cleared or approved by FDA have used different combinations of metal, ceramic, and polyethylene. The Pinnacle CoMplete Acetabular Hip System is the first to combine a ceramic ball and a metal socket.

The hip system, "offers durability and stability, along with enhanced low-wear characteristics, that will provide surgeons with an important new option for patients with severe osteoarthritis," said Randy Kilburn, DePuy Orthopaedics' vice president, U.S. Marketing. "This addition to the Pinnacle platform, when available, will provide surgeons with the freedom to choose the bearing combination, whether it is metal-on-metal, metal-on-polyethylene, ceramic-on-polyethylene, ceramic-on-ceramic, or ceramic-on-metal, that best meets the patient's individual needs."

A company press release stated the Pinnacle Cup has been available for more than 10 years, and has become "one of the most widely used and clinically successful modular acetabular cup systems for hip replacement." A multi-center clinical study conducted by orthopedic surgeons showed that 96.1% of the cups are still in use eight years after surgery (Kaplan-Meier survivorship results. Abstract submitted for 2011 American Association of Hip and Knee Surgeons Meeting).

The FDA said its approval is based on a two-year, randomized clinical trial, which found no clinical difference between 194 patients who received the new ceramic-on-metal system and 196 patients in a control group who received a metal-on-metal hip implant. Two patients who received the system required a second surgery to replace their new implant compared with three patients who required a second surgery in the control group.

**Postmarket Study**

As a condition of FDA approval, the company will conduct a 10-year postmarket study, monitoring patients for adverse events and metal ion concentrations in their blood. According to the Approval Letter, the study will enroll a total of 250 subjects; approximately 100 subjects recruited from the IDE (Investigational Device Exemption) clinical study and approximately 150 new subjects will be recruited.

This is the second orthopedic related device approved by the FDA so far in 2011. The previous approval was for Tokyo-based Seikagaku Corporation's Gel-One, a hyaluronate hydrogel.

*—WE (June 17, 2011)*

extremities

# More Good News for STAR

The communications gurus at Musculoskeletal Clinical Regulatory Advisers (MCRA), LLC have hit another home run. Effective March 8, 2011, health plans managed by QualChoice Health Plans of Little Rock, Arkansas—which covers almost 50,000 members in that state—will reimburse SBi's STAR total ankle replacement system.

Tasked by Small Bone Innovations, Inc. (SBi) to get the good word out about STAR, in 2009 MCRA launched a program to communicate clinically proven benefits, comparative effectiveness and overall cost benefits of the STAR ankle. They are a roaring success, says SBi, with nearly all insurers revising their policies to provide coverage for total ankle replacement.

With this move by QualChoice, the second largest health insurer in Arkansas, the procedure is now accessible by 95% or more than 260 million Americans enrolled in either private or government-funded health plans such as Medicare. QualChoice offers a comprehensive line of health benefits and ancillary products on both a fully insured and self-insured basis.



The STAR ankle is the only total ankle replacement system ever to be cleared through the FDA's Premarket Approval (PMA) process. In the PMA process, the STAR ankle's safety and effectiveness was compared with ankle fusion in a multi-center, multi-year, Investigational Device Exemption (IDE) study. The STAR gleamed, and was found to be superior in efficacy and comparable in safety to fusion. The IDE and other study results also demonstrated that the STAR ankle has better pain relief, greater clinical success, less blood loss and a shorter operating time than fusion.

STAR Total Ankle Replacement System Source: SB

Commenting in the June 14, 2011 news release was Jesse B. Burks, DPM, a reconstructive foot and ankle surgeon in Little Rock, Arkansas: "For years the only option for people with severe ankle arthritis was fusion. Nobody likes the idea of having a stiff ankle. The big thing with the STAR ankle is its ability to actually mimic the anatomical function of a good ankle joint resulting in a real step forward in treating this painful condition."

—*EH (June 20, 2011)*

Watch Video

reimbursement

## Physician Alignment Top ACO Obstacle

A recent survey conducted by AMN Healthcare asked hospital executives and physicians about their potential participation in Accountable Care Organizations (ACOs).

The survey, completed by 882 hospital administrators and physicians, found that physician alignment is the most serious obstacle they are facing in forming ACOs.

The survey also found:

- 58% of responsers indicated their facilities are either in the process of forming ACOs or are considering doing so
- 42% said their facilities will not form ACOs in the foreseeable future

The following obstacles were reported by those moving toward ACOs:

- 42% physician alignment
- 38% lack of capital
- 31% lack of integrated IT systems and
- 25% lack of evidence-based treatment protocol data.

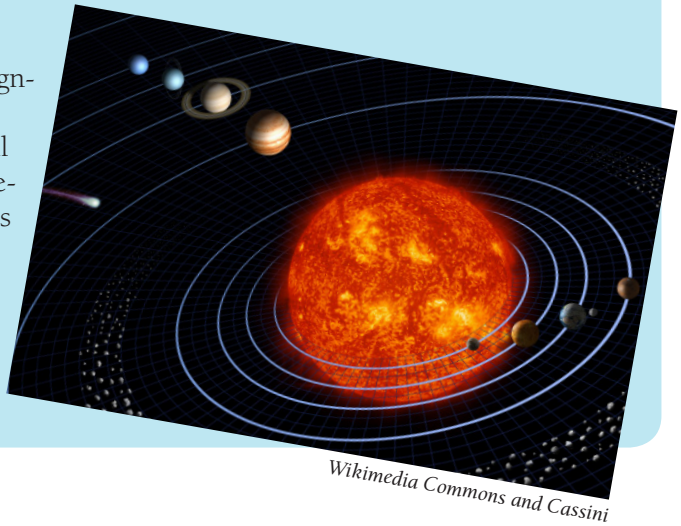
Those not moving towards ACOs reported the following reasons for their hesitancy:

- 40% physician alignment
- 31% lack of capital
- 26% lack of integrated IT system
- 23% lack of evidence-based treatment protocol data

Susan Salka, AMN's president and CEO said, "While capital and data are essential to forming ACOs, the success of this emerging model turns on people. Health facility leaders and physicians must align their interests, communicate and cooperate for this model to work."

According to the company, AMN Healthcare is the largest healthcare staffing and workforce organization in the U.S.

*—WE (June 22, 2011)*



*Wikimedia Commons and Cassini*

people

## Lifetime Award for Joseph Lane, M.D.

Champagne was probably popped… Joseph M. Lane, M.D., chief of the Metabolic Bone Disease Service and medical director of the Osteoporosis Prevention Center at Hospital for Special Surgery (HSS) was recently feted at a grand gala where he received a Lifetime Achievement Award from HSS. Dr. Lane's research helped identify the possible link between long-term use of osteoporosis medications and increased risk for certain types of bone fractures.

*Hospital for Special Surgery*

Dr. Lane began his tenure at Hospital for Special Surgery in 1975 and went on to become professor at Weill Cornell Medical College and an adjunct professor at the Columbia University College of Physicians and Surgeons. He is also associate director of the Orthopaedic Trauma Service at Hospital for Special Surgery.

Dr. Lane's clinical research has focused on bone and soft tissue tumors, adult spine and hip trauma, spinal surgery and osteoporosis. He has received many

NIH [National Institutes of Health] career and R01 grants, Orthopaedic Research and Education Foundation (OREF) grants, and foundation awards and has authored more than 300 published articles and chapters.

"By identifying the possible link between long-term bisphosphonate use and certain types of unusual bone fractures as part of his ongoing studies, Dr. Lane continues to keep the hospital on the forefront of bone research," said Thomas P. Sculco, M.D., in the June 16, 2011 news release. Dr. Sculco, surgeon-in-chief at Hospital for Special Surgery, said, "Dr. Lane is one of the great teachers and research minds in orthopedic surgery."

"I am truly humbled by this award," added Dr. Lane. "The hospital has provided unwavering support as I have grown in my career, and I am eternally grateful for that. I look forward to continuing to work with my brilliant colleagues and to helping patients regain the mobility needed to maintain their active lifestyles."

Dr. Lane graduated Magna Cum Laude from Columbia College in 1961 and received a medical degree from Harvard Medical School in 1965. He then went on to the Hospital of the University of Pennsylvania, where he completed his internship in 1967, fellowship in 1970, and residency in 1973, during which he was awarded the Kappa Delta Award from the American Academy of Orthopaedic Surgeons for his research on inhibiting scar formation.

When asked about one of his favorite memories from the lab, Dr. Lane told *OTW*, "We had reported a new type of hip fracture related to prolonged bisphosphonate use. Working with Adele Boskey, Ph.D., we uncovered the fact that even thick bone becomes weak when it ages and loses the ability to renew itself. As a consequence of this discovery we have developed the clinical concept of a 'bone holiday' that means stopping the osteoporosis drugs and allowing the bone to rejuvenate itself."

*—EH (June 23, 2011)*

## LDR's Lavigne Wins Entrepreneur Honor

Christophe Lavigne, the cofounder, president and CEO of Austin, Texas-based LDR, has been named a 2011 Ernst & Young Entrepreneur of the Year award winner for the Central Texas Region.

The company, founded in 2000 by Lavigne, Hervé Dinville and Patrick Richard in Troyes, France, makes spinal implants for both non-fusion and fusion applications.

*Christophe Lavigne*

The Ernst & Young award recognizes entrepreneurs, "who demonstrate excellence and extraordinary success in areas such as innovation, financial performance and personal commitment to their businesses and communities."

Lavigne was recognized for his dedication and leadership combined with LDR's ongoing success, global expansion, and growing contribution to improved patient care.

"I am honored and humbled to have received the Entrepreneur of the Year award. Since LDR's founding with my two partners in 2000, our work has been exclusively focused on improving the treatment and clinical outcomes for patients suffering from spinal disorders. It is very satisfying today to be realizing our goals. LDR operates in more than 25 countries worldwide and earlier this year we surpassed 10,000 implantations with our VerteBRIDGE Plating Technology platform," commented Lavigne.

He added, "In fact, our continued strong U.S. and international growth will necessitate a relocation and expansion of our Austin facilities by early 2012. And finally, we are very pleased to be in the FDA PMA [premarket approval] review process for both our single- and two-level Mobi-C Cervical Artificial Disc IDE [investigational device exemption] trials."

*—WE (June 22, 2011)*

spine

## Vexim: Two New Implants

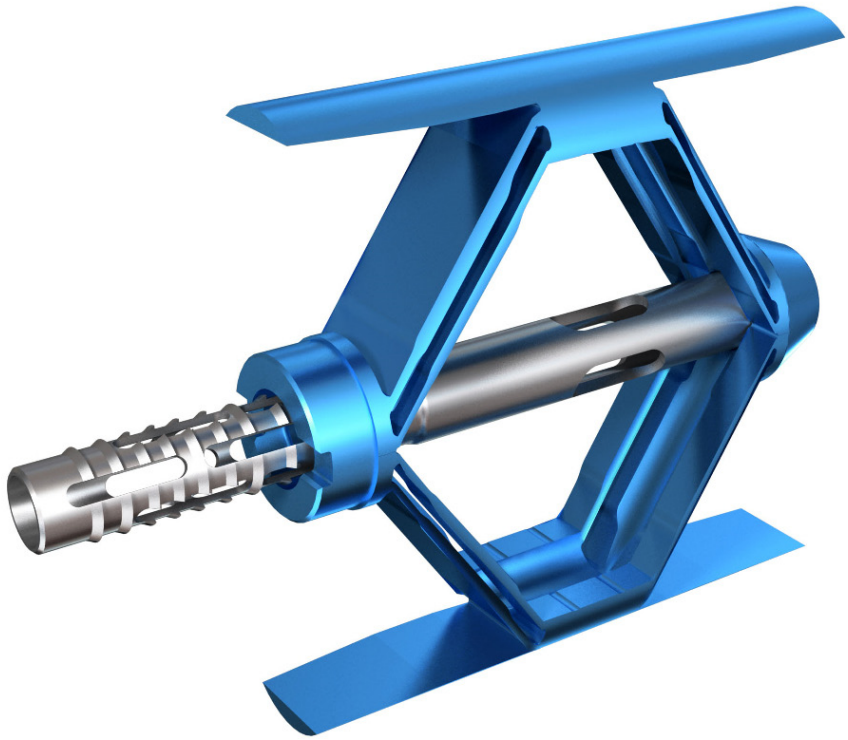
A certain minimally invasive (MI) French company now has maximum coverage of the spine…Vexim, an enterprise specializing in the MI anatomical treatment of vertebral compression fractures, has just added two new implant sizes to its SpineJack range of implants. The new sizes (measuring 6.5 mm and 4.2 mm in diameter) will be added to the standard 5 mm size, meaning, says the company, that the SpineJack can to be used to treat almost all vertebral fractures of the spine.

The SpineJack is a titanium implant (5 mm in diameter and 25 mm in length) that covers 80% of spinal column fractures (vertebrae TH10 to L5). It is inserted into a patient's vertebra via a transpedicular, minimally invasive approach (just one or two 5 mm skin incisions). A specialized set of instruments is used to prepare the vertebra for the X-ray-guided insertion of one or two implants, depending on the anatomical configuration of the fracture and the degree of reconstruction required. Once this step has been completed, bone cement is injected into the restored vertebra in order to secure the vertebral structure and relieve the patient's pain. A trained surgeon needs only 25 to 35 minutes to complete the whole procedure. The patient can expect a very significant reduction in pain immediately after the operation and will generally be discharged from hospital 24 hours later.

Vexim's President and CEO Bruce de la Grange told *OTW*, "We started out with one size (5 mm in diameter) which could be inserted through the trabecular canal. This was a fine cylinder that resembles a car jack when opened and expands to 17 mm in height. We were only covering 80% of the indications with this 5 mm size implant however. Certain countries have people who are bigger boned, while others have a population that has smaller bones. We wanted to be able to address both of these issues with the two new sizes to enable Vexim to cover nearly all indications in all markets."

de la Grange also commented to *OTW*, "The challenge in producing the larger size was to make the implant big enough to meet patient needs but still be able go through the pedicle. The challenge of developing the smaller implant was how to make the implant capable of doing the same mechanical job (lifting up the endplates of a fractured vertebra and keeping them in place while cement is injected through the implant). Fortunately, Mr. Edouard Arrubarrena, our executive director, spent 35 years in the aeronautical world and is an expert in precision mechanical development and with his R & D team solutions to both challenges were found."

*—EH (June 22, 2011)*

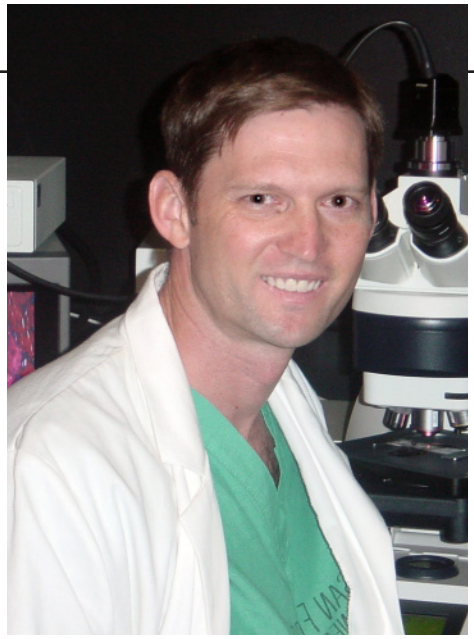


*Vexim*

# THE PICTURE OF SUCCESS

## Dr. Ted Miclau, Part I

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



*Dr. Ted Miclau*

When those in charge at the Orthopaedic Research Society (ORS) were reviewing potential presidents for 2012, they saw one extraordinary, seasoned researcher who could bring an expanded vision to the organization. They saw Dr. Ted Miclau.

"He holds coveted research grants." But so do other orthopedists.

"He has built a research lab." So have other orthopedists.

"He cares." Don't we all?

What makes Ted Miclau stand out is a combination of unusual achievements in the research and administrative realms, an exceptional understanding and compassion for those who are in need, and the fact that he routinely puts those emotions into action in a ***sustainable*** way.

No lab rat, Dr. Miclau's true milieu is not the sterile, orderly world of flasks, beakers, cadavers and esoteric scientific inquiry. While his high quality research follows all the appropriate protocols, his background reveals a familiarity and indeed a comfort with real life…with the unkempt, irrational, often messy world of people, culture, poverty, and aspiration. Undoubtedly, he is a better physician for having lived it.

Dr. Ted Miclau, the next president of the ORS and a professor in the Department of Orthopaedic Surgery at the University of California, San Francisco (UCSF) School of Medicine, grew up knowing the difficulties inherent in navigating another culture, dealing with divorce, and barely having enough to live on.

A young Ted Miclau grew up in Puerto Rico and held a number of odd jobs—in some cases, truly odd—in order to buy his own clothes and otherwise help support the family. Dr. Miclau: "My parents moved the family to Puerto Rico in the '70s, but then divorced. My mother stayed and raised my brother and me, but most of the time we didn't have two nickels to rub together. I did what I could to make money, from babysitting chickens, to unloading cargo on the docks of San Juan, to working the cash register at my father's discotheque. All along I was learning the value of hard work and adversity."

This grit runs deep in Dr. Miclau's family. "At the age of 16, my paternal grandfather took a boat from Romania, landed in Patagonia, and worked his way up to the U.S. in a variety of different jobs, including railroad gangs. Once he reached Chicago he met my grandmother, and opened several businesses, including a nightclub…a nightclub that Al Capone frequented and wanted 'a piece of.' He left that dangerous situation and went to Cleveland, where

**"I grew up a minority in Puerto Rico, and learned what it was like to be different, including what it was like to be helped last in a store. I know what it feels like to not be considered important. Not only do I never want my patients to feel like that, I never want the opinions of my orthopedic colleagues to feel undervalued."**

he started new businesses. Overall, he made and lost his fortune twice, but still died a millionaire. This is a great American Dream story, and a recurrent theme in my family…work hard and never give up."

But if he ever did flirt with the idea of giving up, it may have been during the "birthing" process of the Orthopaedic Trauma Institute (OTI). Dr. Miclau explains, "The concept of the OTI, a collaboration with UCSF and San Francisco General Hospital (SFGH), started in 2002 when I set out to develop a comprehensive center with an academic focus on trauma. My goal was to develop an entity that would add something to UCSF (rather than compete with its existing programs), as well as serve the mission of SFGH. The hospital is owned by the city, which contracts the university for its physicians and support staff, and its day-to-day activities involve an interesting mix of city and county and state university regulations and politics. In navigating these waters during the building of a completely new entity, I definitely honed—and taxed—my diplomatic skills."



Dr. Miclau's diplomacy skills were not learned from a book or a weekend course on how to communicate. They were born of witnessing and participating in real life. "When my parents divorced, my mother worked full-time, sometimes having to drive over an hour-and-a-half to get to her job. We still had very little. She was an exceptional female role model, working as an American female in a male-dominated Latin American world, and she set an incredible example for me. This level of respect has now carried over to my interactions with female professionals, which I believe helps me have a healthy, mutually supportive working relationship with them."

Ted Miclau knows that if you're going to make progress as a leader, then you had better feel comfortable loosening your grip on your perspective in order to see things from the other person's perspective. "Puerto Rico in the '70s was a time of strong (and sometimes violent) anti-American sentiment. I grew up a minority in Puerto Rico, and learned what it was like to be different, including what it was like to be helped last in a store. I know what it feels like to not be considered important. Not only do I never want my patients to feel like that, I never want the opinions of my orthopedic colleagues to feel undervalued."

And if the person across from him is experiencing something that he or she is not expressing, there is a good chance that Dr. Miclau will know. "As an undergraduate at Yale I majored in psychobiology, and my thesis involved using a facial recognition system that helped me interpret the emotions of patients with breast cancer and Tourette's syndrome through their facial expressions. As a physician, this is a particularly useful skill. For example, if a patient is reluctant to question me about something, I can pick up on that…and then I can draw them out and have a more full discussion, something that inevitably contributes to a successful treatment. If the situation involves a colleague, this knowledge helps me to move closer to understanding his or her way of thinking."

Which brings us back to the uphill battle of the OTI…"Just getting the building renovated was an exercise in diplomacy and fundraising. There was no available money from the university, and the city didn't have the funds, so we did it all using other resources. To date, we have invested $6 million into the project—and this is in a county hospital with a poor payer mix. About one-third of our funding came from our reserves (doctors reinvesting back into their workplace), one-third came from extramural funding, and one-third came from creative negotiations with companies from which we needed equipment. Furthermore, we developed a new model for a surgical training facility that included collaboration with industry partners. I'm proud to say that we have now trained over 5,000 surgeons from all over the globe."

So how did this "surgeon's surgeon" develop an interest in the medical arena at all? Via dogs and cats. "I worked for a veterinarian during high school in Puerto Rico. I did clerical work, cleaned cages, and restrained the animals for immunizations. Along the

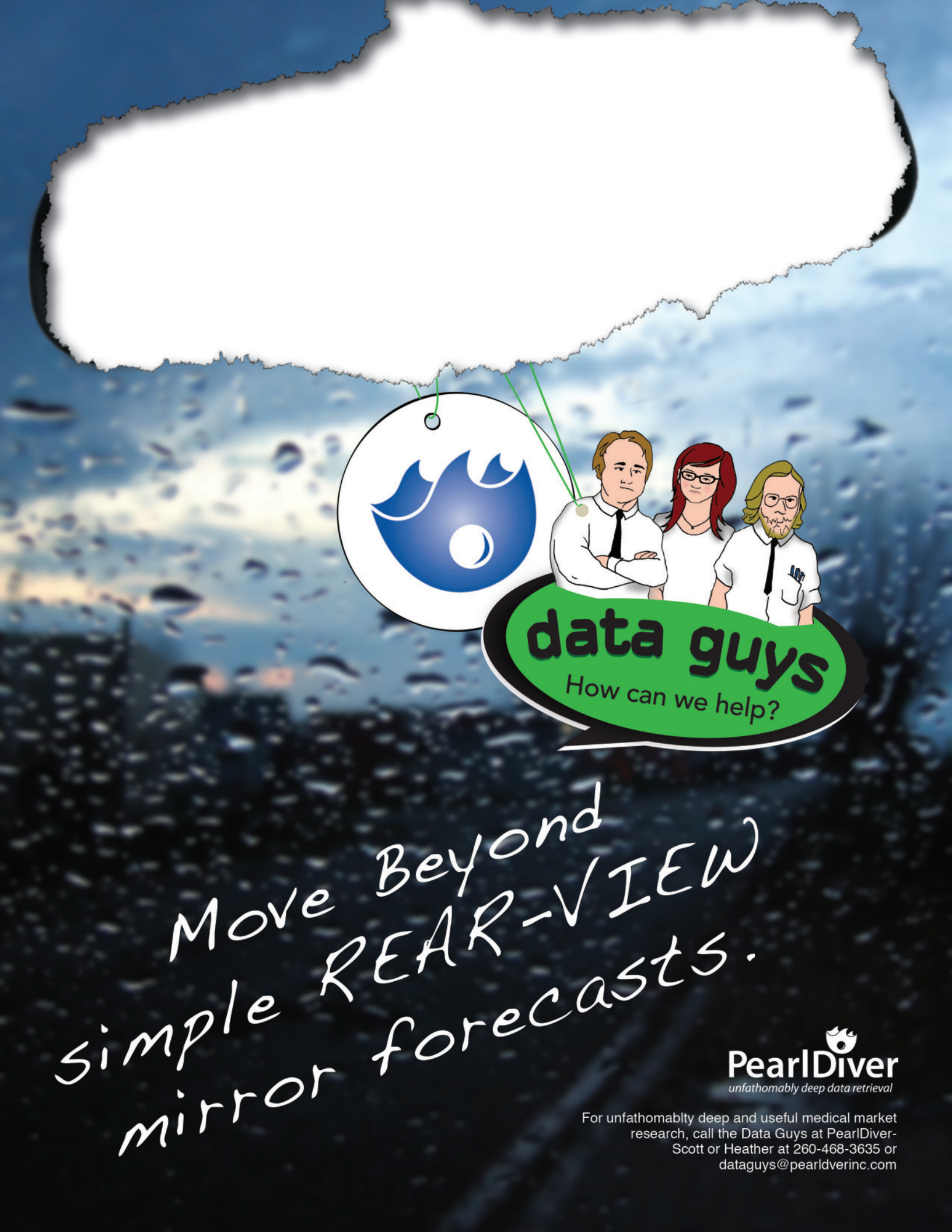
way I found that I preferred to be able to communicate with human patients, and I began to consider a career in medicine. I ended up being the first student from my school to be accepted to Yale University."

When asked about his most career-altering experience, Dr. Miclau states, "Hands down, my most professionally influential experience was the research that I did with the AO Research Institute in Switzerland. It was not the most important work I have ever done in terms of the impact on the field, but it stimulated my interest in orthopedic trauma and academic medicine. I was especially captivated by fracture healing, and found it fascinating that bone was capable of regenerating with tissue that was indistinguishable from its pre-injured state…this is what led me to study the cellular and molecular mechanisms behind musculoskeletal injury and repair."

After a trauma fellowship at Baylor, Dr. Miclau was recruited to UCSF. "My primary goal was to develop a research program at SFGH; four years into the process, I received a K08 career development award from the NIH [National Institutes of Health], which was the first one of its kind to be granted to an orthopedic surgeon in ten years. In order to be successful in this grant, I had to work within a highly supportive environment. The take home lesson—for me as well as the younger surgeons I advise—is that one should seek the best possible situation to achieve one's goals. It hasn't always been easy, however… the second year into the grant the orthopedic division at SFGH collapsed, and I had to juggle departmental rebuilding and patient care, with my NIH-mandated research commitment…and I was working well over 100 hours a week."

When asked about an unpopular topic—failure—Dr. Miclau is straightforward. "It's going to happen. The most valuable thing that I have learned from failure is to persist, be patient, and realize that just because you haven't yet achieved your goal doesn't mean that you can't try a different approach to the problem. The OTI is a good example of having to try something different when the first approach did not work. From something as simple as, 'No, you can't paint the door that color or put that sign there' to rolling up my sleeves with my last remaining partner, Dr. Rick Coughlin, to figure out ways to bring in revenue in a highly resource poor environment. These experiences, coupled with the challenges of my youth, have most definitely taught me the value of persistence and creativity." ◆

*In Part II, learn about Dr. Miclau's efforts to expand research capabilities for surgeons in Latin America, his research, and future plans for the ORS.*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