VOLUME 11, ISSUE 24 | JULY 28, 2015

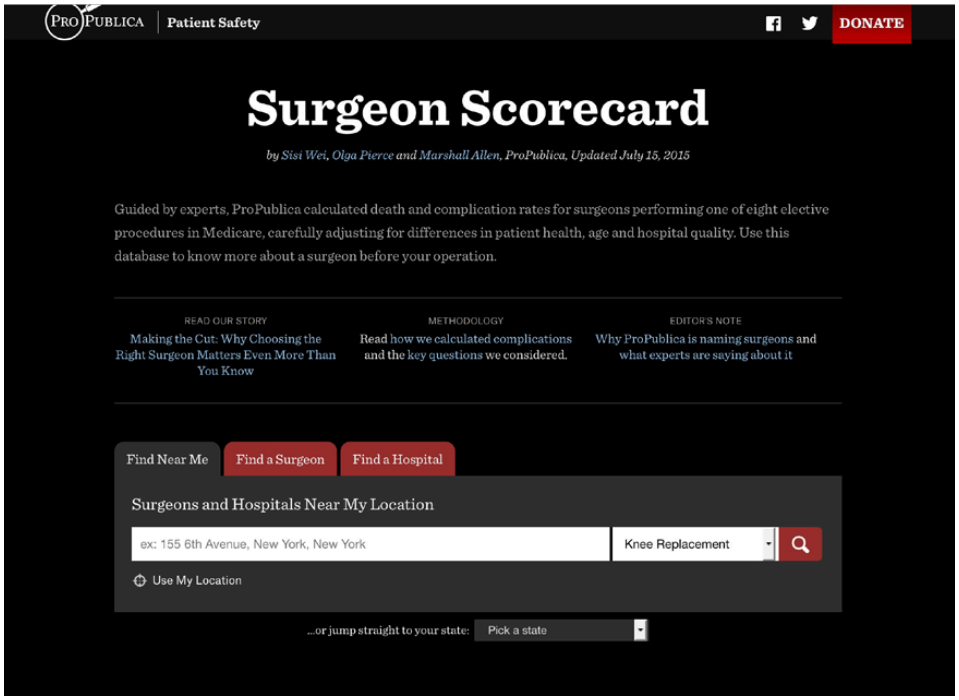
Orthopedics This Week

WEEK IN REVIEW

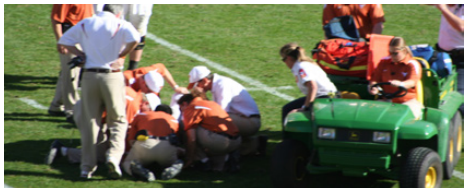
4 Hip Replacements: Safest Hospitals, Safest Doctors, Ranked >> All that new data from CMS about hospitals and surgeons is finding its way out. The most recent window into this data comes courtesy of *ProPublica*, an independent, non-profit public interest newsroom. It lists and ranks hospitals and surgeons according to complication rates. Here's what we found for hip replacement surgery, along with some caveats.

7 Tobacco Derived Human Collagen for Orthopedics >> Scientists are proving that tobacco, more than any other plant, is uniquely suited for manufacturing medicines, vaccines, antibodies and biologic materials. We always thought that tobacco was a drug delivery vehicle. But nothing like this.

11 Medicare Drops Bundle Bomb >> After years of warning that bundled payments were coming, CMS proposed a mandatory bundled payment program for 750 hospitals performing hip and knee replacements. This is what Pay-for-Performance looks like. What does it mean for providers and device makers? We found out.



15 Three Sports Med News Items: NEW Guidelines for Spine-Injured Athletes // New Study Data on Athlete Surgery Risk // New Study re: BMD Gender Differences for Adolescent Runners >> Do YOU know what to do with an athlete (in full gear) if a spine injury is suspected? Updated guidelines are here. Two New Studies of Note: New research indicates that athletes who undergo surgery before college more likely to have future surgeries. And female and male runners have different risk factors for low BMD.



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: It's another rout in China. Shanghai composite is off 8.5% and it is increasingly clear that Chinese government attempts to prop up the equity markets are failing. Adding fuel to the sell-off is news that private manufacturing in China declined in July to a 15-month low. Layer on the continuing European/Greece drama and the signals are pointing to an OUS economic slowdown. And higher dollar.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	22.78%	4.39%	Nice 2nd quarter. Better than forecasted earnings and sales AND raised guidance for the rest of the year. Still #1 on the Power Rankings.
2	3	Integra LifeSciences	13.74	4.62	When Integra reports its mid-year results later this week, most analysts expect to see double-digit earnings growth on low single-digit sales growth.
3	4	Smith & Nephew	20.19	0.66	Over last 3 months SNN got $99 million payment from Arthrex, bought Zimmer's Uni knee business and added to its Syncera logistics business.
4	2	ConMed	10.41	(1.10)	Clearly more work to do at CNMD. Analysts expected 43 cents per share, company reported 36 cents. Sales fell year over year too.
5	6	Medtronic	27.92	0.98	MDT making a big push into transforaminal lumbar interbody space with Voyager. Offers a 3D-navigated surgical experience.
6	7	Johnson & Johnson	28.44	(0.18)	Jim Cramer is arguing that JNJ should break up into 3 new companies. The value creation would be "enormous." The logic is hard to argue with.
7	9	Globus Medical	30.87	5.21	What is so interesting about GMED's valuation is the very high PSR but very low PE. Extreme profitability causes that.
8	5	Zimmer Biomet	30.35	(6.04)	The next 4-6 quarters will likely all be about integration. Sales and earnings will be more difficult to forecast than usual.
9	8	RTI Biologics	7.50	(3.24)	Holders are getting a little nervous ahead of this Thursday's earnings release. Again, managementt has beat for 4 quarters in a row.
10	10	Exactech	10.44	(7.81)	EXAC is the 3rd least expensive equity in ortho. P/E is low. PSR is low. PEG is low. But earnings change expectations are also low—which is why the stock is cheap.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.90	$145	13.33%
2	MicroPort Scientific	853	$12.34	$1,340	10.67%
3	Globus Medical	GMED	$26.87	$2,550	5.21%
4	Integra LifeSciences	IART	$65.11	$2,144	4.62%
5	LDR Holding Corp.	LDRH	$45.01	$1,196	4.60%
6	Stryker	SYK	$100.97	$38,208	4.39%
7	Medtronic	MDT	$76.01	$107,492	0.98%
8	NuVasive	NUVA	$49.51	$2,394	0.81%
9	Smith & Nephew	SNN	$35.06	$15,680	0.66%
10	Johnson & Johnson	JNJ	$99.15	$274,947	-0.18%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	$0.34	$6	-41.33%
2	MiMedx Group	MDXG	$0.42	$595	-18.99%
3	Exactech	EXAC	$19.59	$274	-7.81%
4	Tornier N.V.	TRNX	$24.65	$1,208	-7.02%
5	Wright Medical	WMGI	$25.55	$1,313	-6.44%
6	Zimmer Biomet	ZBH	$106.66	$21,681	-6.04%
7	CryoLife	CRY	$10.80	$306	-5.18%
8	K2M Group Holdings	KTWO	$23.00	$928	-4.49%
9	RTI Biologics Inc	RTIX	$6.58	$377	-3.24%
10	Bacterin Intl Holdings	BONE	$3.20	$23	-2.22%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$99.15	$274,947	16.85
2	Exactech	EXAC	$19.59	$274	16.89
3	Zimmer Biomet	ZBH	$106.66	$21,681	18.34
4	Globus Medical	GMED	$26.87	$2,550	19.88
5	Stryker	SYK	$100.97	$38,208	22.43

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MicroPort Scientific	853	$12.34	$1,340	123.40
2	NuVasive	NUVA	$49.51	$2,394	102.12
3	CryoLife	CRY	$10.80	$306	57.49
4	RTI Biologics Inc	RTIX	$6.58	$377	43.07
5	ConMed	CNMD	$57.70	$1,592	32.75

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$26.87	$2,550	1.63
2	Zimmer Biomet	ZBH	$106.66	$21,681	1.83
3	Exactech	EXAC	$19.59	$274	1.90
4	CryoLife	CRY	$10.80	$306	1.92
5	ConMed	CNMD	$57.70	$1,592	2.30

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MicroPort Scientific	853	$12.34	$1,340	8.23
2	NuVasive	NUVA	$49.51	$2,394	6.68
3	Johnson & Johnson	JNJ	$99.15	$274,947	3.49
4	Medtronic	MDT	$76.01	$107,492	3.45
5	Smith & Nephew	SNN	$35.06	$15,680	2.87

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$3.20	$23	0.63
2	Alphatec Holdings	ATEC	$1.36	$136	0.66
3	Exactech	EXAC	$19.59	$274	1.11
4	RTI Biologics Inc	RTIX	$6.58	$377	1.40
5	Orthofix	OFIX	$33.28	$625	1.59

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.90	$145	17.32
2	LDR Holding Corp.	LDRH	$45.01	$1,196	8.01
3	Medtronic	MDT	$76.01	$107,492	5.31
4	Globus Medical	GMED	$26.87	$2,550	5.19
5	K2M Group Holdings	KTWO	$23.00	$928	4.76

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

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Orthopedics This Week

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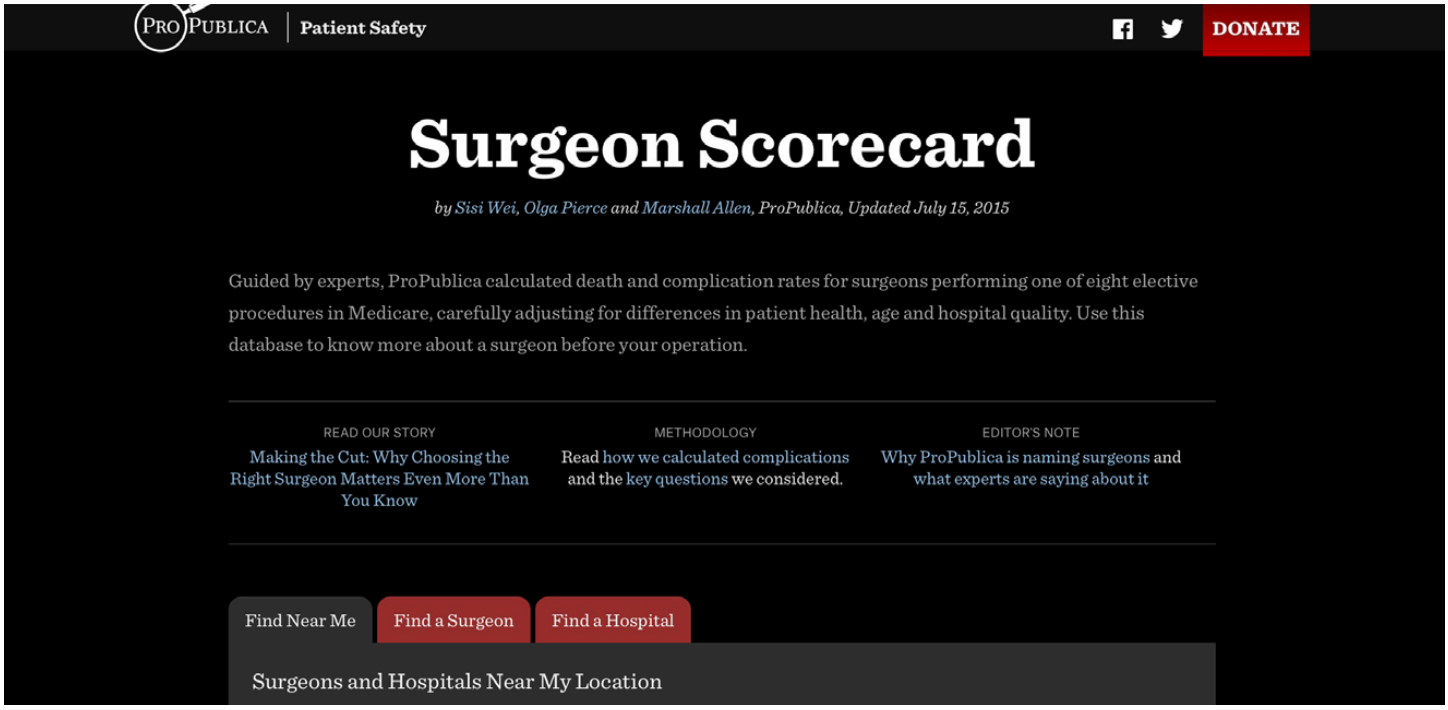
Hip Replacements: Safest Hospitals, Safest Doctors, Ranked

BY ROBIN YOUNG



Surgeon Scorecard and MRI of Lumbar spine / Source: ProPublica.org, Wikimedia Commons and Nevit

ProPublica, an independent, nonprofit newsroom that produces investigative journalism in the public interest, created a searchable web app which allows anyone to search the Medicare database for specific hospitals or doctors and then to see their complication rates per CMS (Centers for Medicare and Medicaid Services).

Additionally, the app ranks both the hospitals and physicians against their peers.

This data is okay, not great. There are many confounding reasons for any particular complication rate. There are patient specific issues. This data does not account for co-morbidities like obesity, diabetes, prior surgeries, heart disease and other diagnosis which are associated in the literature with higher rates of complications. Some physicians will not perform revision surgeries, so their complication rates will be lower.

This data should be treated as more interesting and entertaining than useful for actually selecting a care provider.

We know from our sister company PearlDiver Technologies, Inc. that the data coming from CMS has a lot of noise in it.

Here is how *ProPublica* described their methodology:

> *Our analysis is based on billing data hospitals submitted to Medicare from 2009-2013. We analyzed 2.3 million procedures: hip and knee replacements, three types of spinal fusion, gallbladder removals, prostate removals and prostate resections. ProPublica's analysis accounted for factors such as patients' health and age. We focused only on elective cases because they typically involve healthier patients with the best odds of a smooth recovery.*
>
> Sources: Centers for Medicare and Medicaid Services; ProPublica Analysis
> Authors and researchers: Marshall Allen, Olga Pierce, Mike Tigas, Al Shaw, Lena Groeger, Annie Waldman, Ryann Grochowski Jones, Jonathan Stray, Cecilia Reyes, Tobin Asher, Mariana Barbosa.
>
> If you spot an error, please let us know at scorecard@propublica.org.

The *ProPublica* researchers found that the overall complication rates in the United States are low, ranging from 2% to 4%, depending on the type of surgery.

Furthermore, *ProPublica* found 756 surgeons in the data who each performed at least 50 operations and who did not record a single complication in the five years covered by the analysis. Another 1,423 surgeons had only one.

If there is an obvious conclusion from this data, it is that U.S. surgeons are excellent and have very low complication rates.

So, for the ten largest metropolitan areas in the United States; here are the best of the best. We listed the five hospitals (as measured by the *ProPublica* data) in each metropolitan area and one surgeon at each hospital with the lowest complication rates.

(See tables below and on page 6.)

Metro Area	Hospitals With the Lowest Complication Rates and the Physician Associated With Each Hospital With the Lowest Complication Rate
10 San Jose, California	1. Washington Hospital, Fremont (John Dearborn) 2. O'Connor Hospital, San Jose (Jeffrey Anderson) 3. Stanford Hospital, Stanford (William Maloney) 4. Dominican Hospital, Santa Cruz (James Spiegel*) 5. Sutter Maternity & Surgery Center of Santa Cruz (Howard Schwartz)
9 Dallas, Texas	1. Texas Health Presbyterian, Dallas (Michael Champine) 2. Baylor University Medical Center, Dallas (Richard Shubert*) 3. North Central Surgical Center, Dallas (Paul Peters) 4. Texas Health Presbyterian, Plano (John Barrington) 5. Baylor Medical Center Uptown, Dallas (Charles Rutherford)
8 San Diego, California	1. University of California San Diego Medical Center, San Diego (Scott Ball) 2. Scripps Memorial Hospital, Encinitas (James Helgager) 3. Grossmont Hospital, La Mesa (Peter Hanson) 4. Scripps Green Hospital, La Jolla (Steven Copp) 5. Sharp Memorial Hospital, San Diego (Mark Mcbride)

Metro Area	Hospitals With the Lowest Complication Rates and the Physician Associated With Each Hospital With the Lowest Complication Rate
7 San Antonio, Texas	1. Christus Santa Rosa Hospital, San Antonio (David Templin*) 2. South Texas Spine and Surgical Hospital, San Antonio (Adam Harris) 3. Methodist Hospital, San Antonio (Richard Steffen*) 4. Methodist Stone Oak Hospital, San Antonio (Bryan Kaiser) 5. Baptist Medical Center, San Antonio (David Fox*)
6 Phoenix, Arizona	1. Scottsdale Healthcare – Thompson Peak Hospital, Scottsdale (Theodore Firestone) 2. Scottsdale Healthcare – Shea Medical Center, Scottsdale (Brian Miller*) 3. St. Lukes Medical Center, Phoenix (James Chow) 4. Banner Boswell Medical Center, Sun City (James Kort*) 5. Arrowhead Hospital, Glendale (Joseph Janzer)
5 Philadelphia, Pennsylvania	1. Crozier Chester Medical Center, Upland (Stuart Gordon) 2. Cooper University Hospital, Camden (Dino Nicol Dejusus*) 3. Kennedy University Hospital – Stratford Div, Stratford (Alvin Ong) 4. Riddle Memorial Hospital, Media (Peter Sharkey*) 5. Main Line Hospital Bryn Mawr Campus, Bryn Mawr (Joseph Vernance)
4 Houston, Texas	1. Methodist Hospital, Houston (Leland Winston) 2. Texas Orthopedic Hospital, Houston (Gregory Stocks) 3. Memorial Hermann Hospital (Kelly Blevins) 4. Christus St. John Hospital, Nassau Bay (Michael Monmouth) 5. Houston Physician's Hospital, Webster (Terry Siller)

**Occasionally, the same physician is listed at different hospitals but with the same CMS data. When that occurs, we selected the physician with the next lowest complication rate and designated this person with an asterisk.*

Metro Area	Hospitals With the Lowest Complication Rates and the Physician Associated With Each Hospital With the Lowest Complication Rate
3 Chicago, Illinois	1. Evanston Hospital, Evanston (James Kudrna) 2. Community Hospital, Munster (Gregory Mccomis) 3. Franciscan St. Margaret Health – Hammond, Hammond (Upendra Patel*) 4. Elmhurst Memorial Hospital, Elmhurst (Lawrence Lieber) 5. Advocate Good Samaritan Hospital, Downers Grove (Kevin Walsh*)
2 Los Angeles, California	1. Saint John's Health Center, Santa Monica (Andrew Yun) 2. Good Samaritan Hospital, Los Angeles (William Long) 3. Santa Monica – UCLA Medical Ctr & Orthopaedic Hospital, Santa Monica (Brad Penenberg) 4. Cedars Sinai Medical Center, Los Angeles (Jason Snibbe*) 5. Huntington Memorial Hospital, Pasadena (Paul Gilbert)
1 New York City, New York	1. Riverview Medical Center, Red Bank (Anthony Costa) 2. Hospital for Special Surgery, New York (Chitranjan Ranawat) 3. NYU Hospitals Center, New York (Roy Davidovitch) 4. Beth Israel Medical Center, New York (David Drucker) 5. Staten Island University Hospital, Staten Island (John Reilly*)

**Occasionally, the same physician is listed at different hospitals but with the same CMS data. When that occurs, we selected the physician with the next lowest complication rate and designated this person with an asterisk.*

Coming in future articles are the rankings for knee replacements, lumbar spine fusion posterior approach, lumbar spine fusion anterior approach and cervical spine fusion.

The ProPublica app may be accessed at the following website: https://projects.propublica.org/surgeons/ ◆

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Tobacco Derived Human Collagen for Orthopedics

BY ROBIN YOUNG

Human cadaver or bovine derived collagens are routine additions to many orthopedic procedures. But that could change.

A July 12 announcement from Israeli company CollPlant Ltd. signals that tobacco derived human type 1 collagen is moving into orthopedics. CollPlant received CE Mark for its Verginix WD tobacco plant derived human collagen in 2012. And then earlier this year, the company announced the interim results from two human clinical studies of its tobacco derived collagen.

Could FDA approval and U.S. commercialization be on the near horizon?

Human Collagen From Tobacco

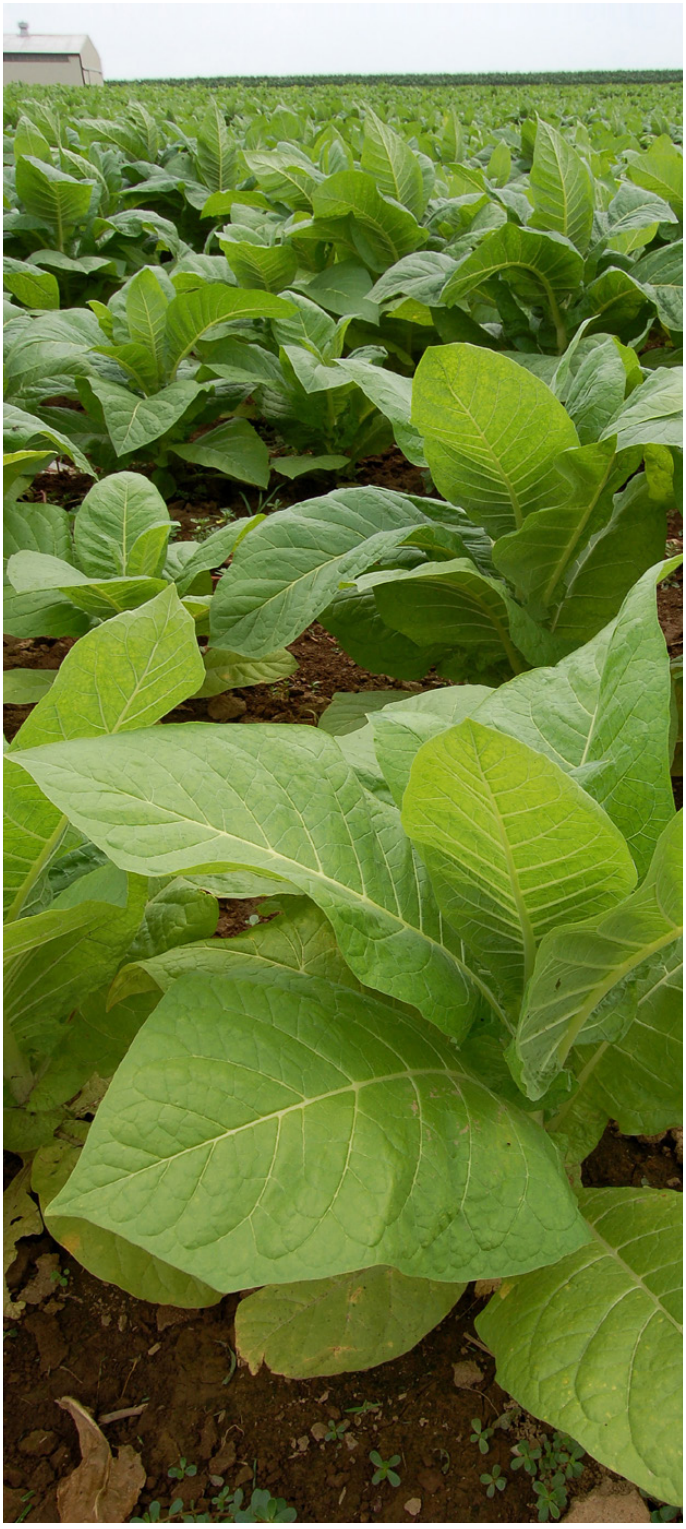
Tobacco is complex and, it turns out, is one of the most exciting new innovations in medicine—successfully tackling the Ebola virus, wound care and surgical orthopedics.

When the Ebola outbreak was at its worst, it was a tobacco derived product that turned out to be the best hope for those desperate patients. As long time *CBS* reporter Bob Simon described in his final story for *60 Minutes* on February 15, 2015, a tobacco grown drug, ZMapp, had successfully treated Ebola patients. In his dramatic story, Simon interviewed the U.S. doctor who'd contracted the Ebola virus while treating patients in Africa and was then airlifted back to the U.S. and treated with ZMapp. When he arrived in the U.S. he was fighting for his life. Injections of ZMapp, he said, cured him.

ZMapp is produced in Owensboro, Kentucky, by Kentucky Bioprocessing, LLC (which was recently purchased by cigarette giant Reynolds American Inc.) in a tobacco plant greenhouse. The tobacco plants have an ability to produce antibodies to the Ebola virus. Which is amazing. Kentucky Bioprocessing extracts the Ebola antibodies from the plants and produces dosages of ZMapp.

Before ZMapp, however, it was an Israeli professor, Oded Shoseyov, from Hebrew University, who first coaxed transgenic tobacco to express all five essential genes necessary to produce the first medical product from tobacco. For his discoveries, Professor Shoseyov received the Kaye Innovation Award from the Hebrew University Board of Governors.

CollPlant then developed the mass production techniques which allow for the production of large quantities of medical grade, human col-



Wikimedia Commons and Derek Ramsey

lagen. Yissum, the technology transfer company of Hebrew University, is one of the shareholders of CollPlant, an Israeli public company traded under the symbol "TASE."

Why Collagen?

Collagen is a primary building block for the human body and has long been a vital protein in the medical field. Essential for tissue repair, physicians routinely use collagen products in a wide range of bone void fill or soft tissue augmentation procedures as well as treating chronic wounds, burns, or for aesthetic indications. Virtually all medical grade collagen, in whatever form, is presently derived from cadaveric or bovine or porcine sources.

The Tobacco Derived Collagen Difference

Enter tobacco derived human type 1 collagen.

CollPlant derives pure recombinant type 1 human collagen, which starts in tobacco leaves, and purifies the collagen in an extremely complex process to a level suitable for medical implantation.

Among the advantages of CollPlant's approach are:

1. No immunogenic response — Turns out that human collagen produced from genetically modified tobacco does not trigger an immunogenic response.
2. Bioactive — Tobacco extracted recombinant human collagen type I forms thermally stable helical structures and fibrillates. It's bioactivity—as confirmed with its human clinical trials—resembles native human collagen.
3. Very homogenous — Being plant derived, its molecular structure is more "pure" than either cadaveric or xenografic collagen. One theoretical advantage is a shorter patient recovery time.
4. No disease or pathogen transmission.
5. Grows fast — It takes tobacco just eight weeks to grow to harvestable size. Lower prices, higher volumes—in theory.

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Vergenix® WD

The first commercial medical product derived from tobacco derived human collagen is Vergenix WD. It is a collagen-based bandage for treating chronic wounds (diabetic ulcers, venous ulcers, bedsores, poor healing trauma wounds or burns). It was awarded CE Mark for commercialization in Europe and approved by several other countries in 2012.

In the pipeline are products to treat tendonitis, bone voids, spinal fusions and trauma indications.

Clinical Outcomes – So Far

On March 18, 2015 CollPlant announced that 11 out of 20 patients participating in a chronic wound care study had completed their enrollment. Interim results, said the company, showed that 10 patients reported 80%-100% wound closure within four weeks of starting treatment. The study is being conducted in three leading HMO clinics in Israel.

In January 12, 2015 CollPlant announced that it had begun human clinical trials for a tendon repair form of its tobacco derived collagen called, Vergenix STR. The product is intended to be used for patients with tendonitis, specifically "tennis elbow." The protocol calls for mixing Vergenix with a concentration of platelet-rich-plasma, derived from the patient's blood, and injecting it one-time at the point of tendon injury.

When the tendonitis study was announced, the company said that it would begin commercializing Vergenix in Europe this year.

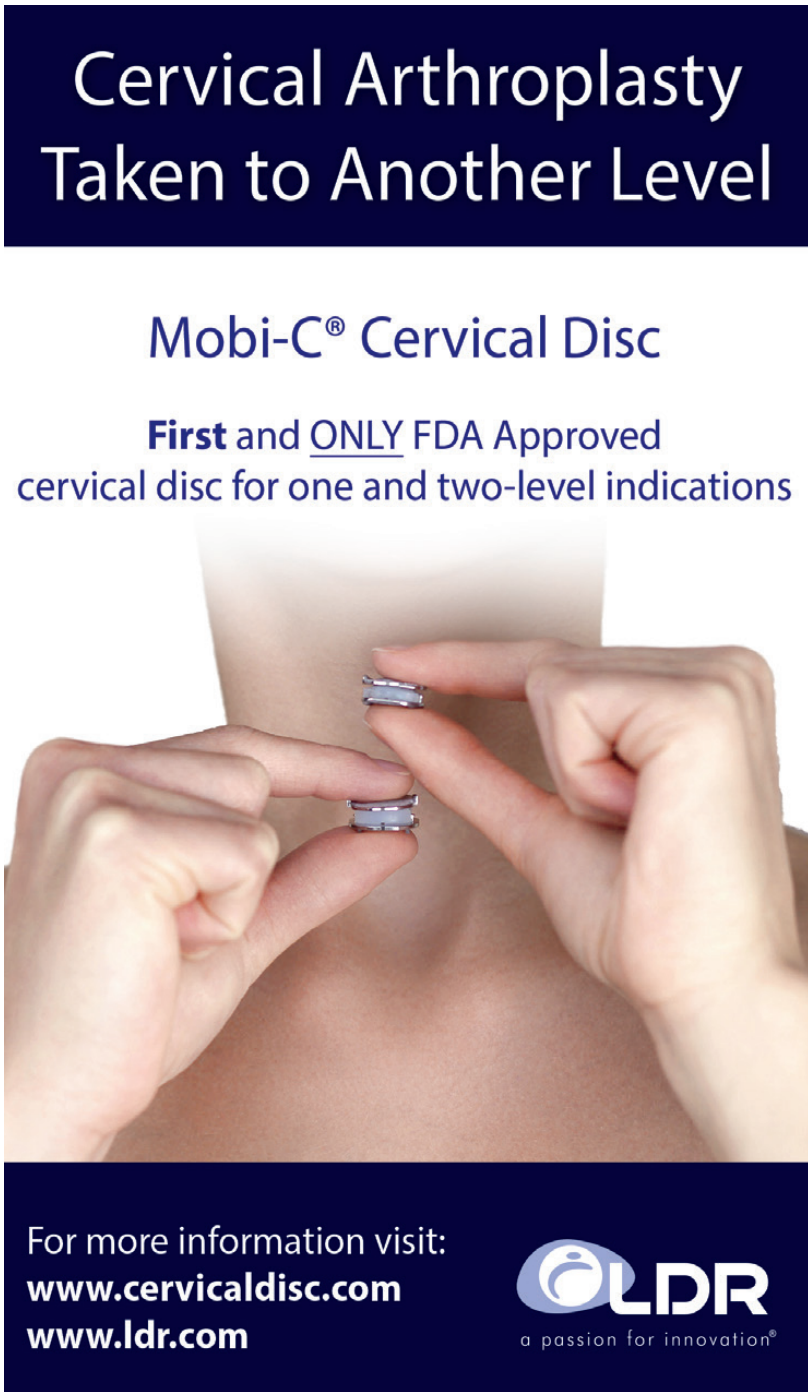
Then came last week's announcement.

Entering the U.S. Market

On July 12, CollPlant announced that it had signed a term sheet to develop and commercialize a new collagen (tobacco derived, of course) product for spine fusion and trauma indications with an un-named U.S. based partner (can't be Medtronic—they're Irish now).

Since the newly signed term sheet is non-binding, both parties to the agreement have decided to keep the identity of the U.S. company confidential pending negotiation of a final agreement.

But the company, which CollPlant characterized as, "a leading U.S company in the field of orthobiologics," would partner with CollPlant to develop and commercialize a new absorbable bio-active surgical matrix



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intended for use in spinal fusion and trauma applications.

The new matrix would be composed of CollPlant's type 1 recombinant human collagen and synthetic minerals that mimic bone structure. Interestingly, the term sheet would allow for adding in so-called "bio-functional molecules." Stem cells?

According to the press announcement accompanying the term sheet signing, "CollPlant's rhCollagen is identical to the type I collagen produced by the human body, and has significant advantages compared to currently marketed tissue derived collagen, including improved biofunctionality, superior homogeneity, and reduced risk of immune response and transmission of diseases."

Said CollPlant CEO Yehiel Tal: "This agreement represents recognition of the value of our proprietary rhCollagen technology and biomaterials knowhow, and, over time, should help to catapult CollPlant to the forefront of the orthopedic market."

Under the terms of the agreement, if consummated, CollPlant would receive payments for the license to use its technology, milestones for achieving certain clinical and regulatory events and single-digit royalty payments for future global sales, as well as participation in costs associated with the building of a CollPlant-run manufacturing facility for the production of rhCollagen and the product in the U.S.

The agreement is non-binding and may not ultimately result in a definitive agreement.

Tobacco

Tobacco, a uniquely American plant, was used by generations of Native Americans as offerings to the spirits, for planting, for healings and for ceremonies. Among the many Native American tribes, tobacco was a sacred plant. It represented prayer, protection, respect and healing.

Before it was a recreational drug, tobacco was medicine.

After Europeans migrated to the Americas tobacco became "gold power" and funded the colonies, the clergy and the militia. In 1723 Maryland and Virginia exported thirty thousand kegs per year requiring 200 ships to transport it. It was no accident that tobacco leaves were sculpted into the columns of the capital building in Washington, .DC.

A century later tobacco became synonymous with the destruction of public health.

But, as scientists are now demonstrating, tobacco, perhaps more than any other plant known to science, is well suited for rapid development of a wide variety of valuable medicines and biologics.

Besides CollPlant several companies are developing advanced medicines or biologics by exposing tobacco plants to genetic materials and then extracting vaccines, antibodies or biologic materials.

What is so amazing is tobacco's capability to generate all of these valuable medicines and human biologics in their leaves.

We always thought that tobacco was a drug delivery vehicle. But nothing like this.

Remarkable. ♦

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Medicare Drops Bundle Bomb

BY WALTER EISNER

On July 9, 2015, CMS (Centers for Medicare and Medicaid Services) proposed a new reimbursement model that will hold hospitals financially accountable for the outcomes of inpatient hip and knee replacements—from surgery through recovery.

The five-year bundled payment model, called the "Comprehensive Care for Joint Replacement (CCJR) Program" will pay 750 hospitals in 75 geographic areas a lump sum for each hip and knee replacement episode starting from hospital admission to 90 days after discharge. At the end of a year, those hospitals will have a chance to earn more money or have some of their payments clawed back by Medicare, depending on patient outcomes.

More on the specific details below.

Value-Based Payments

Medicare is clearly moving full speed ahead with their plan to dump the fee-for-service model in favor of the pay-for-performance payment model. Alan Sager, Ph.D., professor of health policy and management at Boston University, said that "CMS continues to plan for the next decade's demon: Medicare's greater reliance on value-based payments resting on PQRS data."

While some industry analysts and leaders noted what a "bombshell" the shifting of risk is for providers and device makers, no one should be surprised. CMS has telegraphed this move as plainly as the Brits warned the Argentines the navy was slowly sailing across the Atlantic to reclaim the Falkland Islands.

Image creation by RRY Publications, LLC

This proposal builds on CMS' original announcement that by 2020, 100% of all Medicare reimbursements will be based upon value-based care, which basically means thru ACOs (accountable care organizations) and bundled payments for specific episodes of care.

The Bundle Is Here

Richard Rothman, M.D., founder of the Rothman Institute of Philadelphia, urged his provider colleagues to "Capture the Bundle" at the 2014 Annual Meeting of the American Academy of Orthopaedic Surgeons.

CMS is now going to allow the bundle to capture providers starting in January 2016.

Opportunity for Control

Rothman and other surgeon leaders of physician-owned hospitals, like David Jacofsky, M.D., had just formed the National Orthopaedic and Spine Alliance (NOSA), made up of the CORE Institute, the Cleveland Clinic, the Rothman Institute and OrthoCarolina.

NOSA collected episode of care data for 27 procedures and then showed payers the all-in cost of treating their employees and **not** charge a deductible, **not** charge co-pay, fly the patient and their family to one of the NOSA sites, put them up in a hotel and fly them back. NOSA showed payers that the total cost of care—whether for the 90 days of treatment or over the following 12 months plus work-time missed—was less expensive than paying for that employee's health insurance with the average local provider.

The proposed Medicare payment model is also consistent with the private sector, where major employers and leading providers and care systems are moving

towards bundled payments for orthopedic services. Large employers like Boeing and Wal-Mart have entered into highly publicized bundle agreements with ACOs to provide hip and knee replacement services for their employees.

Orthopedic Bundles Payments for Dummies

Hoag Orthopedic Institute, Gabrielle White, RN, CASC, told *OTW* in a May 2014 story titled: "A Survivor's Guide To Bundling" (http://ryortho.com/2014/05/a-survivors-guide-to-bundling/) that when a clinic or physician enters into a bundled payment program with a payer, they are playing the game with the masters of risk management. Providers can't win in this game unless they know how to manage and reduce their risks.

If you are a provider, to reduce your risk, White says you have to pick high volume and predictable procedures. Like hip and knee replacements, for example. You must also pick the right patients and the right surgeon. The patients need to meet predetermined criteria. The surgeons need to stay within the metrics of a standardized delivery program.

Then, you have to have great data to know what things cost. Only then are you ready to start.

The Pittsburgh Example

Pittsburgh-based UPMC (University of Pittsburgh Medical Center) is ready.

Bundled payments for orthopedic procedures are well under way at the $10 billion integrated health system with 21 hospitals and more than 5,100 licensed beds. UPMC's program launched in 2013 with hip and knee surgeries, and was extended to spine surgeries at the beginning of this year.

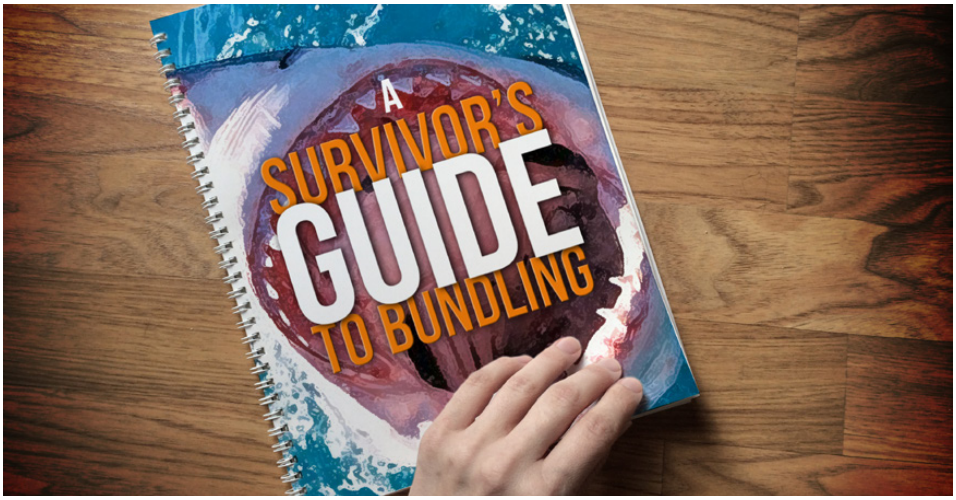


Photo creation by RRY Publicaitons, LLC.

UPMC is unique because the provider is also the insurer. Through its insurance entity, UPMC Health Plan, UPMC has determined the average cost per procedure and created bundled payments to push physicians to reduce costs.

"We are really trying to change our payment models as much as we can from volume to value and are really trying to transform our network to something that isn't based on fee-for-service or RVUs (Relative Value Units) anymore," Tom Aubel, director of medical payment strategy and policy at UPMC Health Plan, said in a recently published interview.

"If [physicians] come in under the average cost, they can reap that benefit financially. As they are spending less, they are making more. It's a pretty basic design."

Winners and Losers

Certainly there will be winners and losers under the bundle.

Since CMS determined through a demonstration project that half of the cost of providing care for joint replacements occurred post-surgery and the bulk of that cost occurring in either acute inpatient rehabilitation units or sub-acute rehab units in skilled nursing facilities (SNFs), such facilities will be pressured as providers search for lower cost alternatives such as home health services.

Vanishing SNFs and "Demand Destruction"

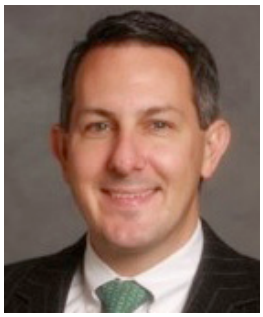
One health care finance expert, David Friend, M.D., MBA predicts that one in four skilled nursing facilities will be shuttered, while medically advanced SNFs will flourish.

Another expert, Deirdre Baggot, Ph.D., reportedly said mandatory bundling will likely trigger "demand destruction in areas such as diagnostic testing, hospital stays, and avoidable readmissions."

Implant Pricing Pressure and the MAKO Effect

Needham & Company analyst Mike Matson thinks that since CCJR would allow gainsharing, the proposal would increase implant pricing pressure.

"As with prior bundled payment programs, CCJR allows hospitals to estab-



Mike Matson

lish gainsharing, which allows the hospitals to share either internal cost savings and/or the CCJR reconciliation payments with surgeons for up to 50% above their Physician Fee Schedule payments. With gainsharing, we think hospitals would be able to reduce implant costs by consolidating vendors, since they would now have the ability to incentivize surgeons to switch implant brands," said Matson.

However, Matson says he also believes that CCJR quality incentives could drive more hospitals to adopt Stryker Corporation's MAKO robotics system.

Pushback and Delay?

He predicts that with less than six months for hospitals to prepare for CCJR, the hospital industry will put up a fight that could potential cause the CCJR program to be delayed.

Blair Childs, senior vice president of public affairs of Premier Inc., a group-purchasing organization for hospitals, reportedly said the proposed rule, "is too much, too fast." He says a voluntary, national program would ensure that only providers who are ready to take on this challenge enter the program and avoid unintended consequences.

Inside the CCJR Program

By 2016, CMS expects to pay for about 25% of all hip and knee replacement surgeries in the U.S.

Medicare currently spends about $7 billion for those surgeries, with expenditure variations from $16,500 to $33,000 depending on geographic locations. While some of the variance in costs is due to geographic differences in price, other variance is due to what providers charge.

In addition, the rate of complications like infections or implant failures after surgery can be more than three times higher at some facilities than others, increasing the chances that the patient may be readmitted to the hospital.

By setting a fixed rate, CMS expects to save $150 million over the five-year life of the initiative.

Carrots and Sticks

Here's how the program will work and how the money will flow.

Through the proposed model, providers would continue to be paid under existing Medicare payment systems.

Advertisement

However, the hospital where the hip or knee replacement takes place would be held accountable for the cost of care from the time of the surgery through 90 days after discharge.

Depending on the hospital's quality and cost performance during the episode, the hospital may receive an additional payment or be required to repay Medicare for a portion of costs.

The "True-Up:" Moment

Under the model, CMS will provide target prices for the entire 90-day care episode prior to the start of each year which would generally include a 2% discount over expected spending. During the year, all providers are paid under the existing Medicare payment system. There is then a "true-up" at year-end where hospitals with spending below the target price receive the difference from CMS and hospitals with spending above the target price return the difference to CMS.

Sylvia Burwell/Department of Health and Human Services

"By focusing on episodes of care, rather than a piecemeal system, hospitals and physicians have an incentive to work together to deliver more effective and efficient care. This model will incentivize providing patients with the right care the first time and finding better ways to help them recover successfully. It will reward providers and doctors for helping patients get and stay healthy," said Health and Human Services Secretary Sylvia M. Burwell in the July 9 announcement.

Review Proposal Here

The proposal is available at https://www.federalregister.gov/public-inspection and can be viewed at https://www.federalregister.gov starting July 14, 2015. The deadline to submit comments is September 8, 2015.

Additional information can be found at: http://innovation.cms.gov/initiatives/ccjr/. ♦

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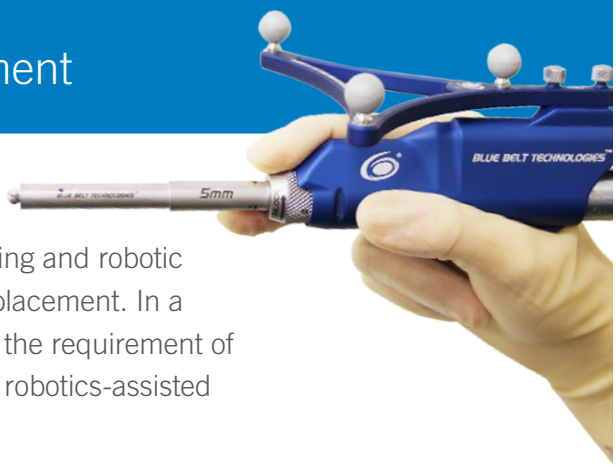

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Three Sports Med News Items: New Study Data on Athlete Surgery Risk // NEW Guidelines for Spine-Injured Athletes // New Study re: BMD Gender Differences for Adolescent Runners

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Guidelines for the Sidelines: Updates on Treating Spine Injured Athletes If a 15 year old football player with a spine injury is lying on the field, does anyone present know what to do and how to safely remove the athletic equipment? Does anyone know what kind of cervical collar to put on the athlete…or when? To clarify these and other issues, the National Athletic Trainers' Association (NATA) has released an executive summary of a new inter-association consensus statement: "Appropriate Care of the Spine Injured Athlete."

Wikimedia Commons and Johntex

MaryBeth Horodyski, Ed.D., ATC, FNATA, is vice president of NATA, and chaired the task force that developed the document. She told *OTW*, "We have updated the 2001 guidelines due to advances in the literature regarding prehospital treatment protocols, as well as improvements in technology. If a physician or an athletic trainer suspects that a player has a spinal cord injury then the equipment he or she is wearing may actually be an obstruction to prompt, safe medical treatment (life support needing access to the chest and airway). Often, doctors on the field or in the emergency department are not going to know how to remove protective equipment."

"Let me add that these are only guidelines. We know that there are going to be situations where removing the equipment is not the best course of action (such as when you do not have enough trained people present or there are extenuating medical circumstances). However, there are several studies showing that doing CPR while a player is still wearing shoulder pads is not as efficient as if the pads were removed. Additionally, if you put the athlete in the back of an ambulance with their equipment on and they deteriorate then the paramedics have to figure out what to do with the equipment. This is why we now recommend that protective athletic equipment be removed prior to transport to an emergency facility when a cervical spine instability is suspected."

"Another updated recommendation was that equipment removal should be performed by at least three rescuers trained and experienced with equipment removal—and that it should be done at the earliest possible time. If you don't have at least three people, then the equipment should be removed at the earliest possible time after enough trained individuals arrive on the scene or transport to the emergency department with equipment on if not able to remove in the field."

"We continue recommend that spine injured athletes be transported using a rigid immobilization device, to ensure that moving a patient from the field to the ambulance minimizes spinal motion."

"One of the most important updated recommendations is the 'Time Out.' Done before the athletic event—just like surgeons do preoperatively—it is a chance to get the sports medicine team together and review the emergency action plan for that particular event."

"These new guidelines will also help us work with Emergency Medical Services (EMS) so as to allow for safe equipment removal. Training sessions with team physicians, athletic trainers and

EMS staff are beginning to take place across the country. We have had more than one Emergency Department (ED) doctor say that when an athlete arrives fully geared that they are not sure how get the equipment off. If the situation is such that the athletic trainer [AT] travels with the athlete to the hospital then he or she may be able to assist the treating physician. There are, however, questions remaining as to whether or not it is legal for the AT to assist with equipment removal once the athlete arrives in the emergency department."

Mark Prasarn, M.D. is an orthopedic surgeon at the University of Houston. Dr. Prasarn was a member of the task force group that developed the consensus statement. He told *OTW*, "It is important for colleagues to know just how valuable athletic trainers are to taking care of the injured athlete. Often times they are more educated on the appropriate management than even physicians, especially when dealing with the equipped athlete."

Asked which recommendations might prove to be the most challenging, Dr. Prasarn noted, "For sure the removal of equipment on the field will prove to be the most challenging. I think it's important for all to be aware these are recommendations and not hard and fast rules. In addition, every patient and clinical situation is different and the physicians, athletic trainers, and EMS at the scene should also have some autonomy and make decisions based on their best judgment."

"In most situations equipment removal should be done given that there is a trained athletic trainer at the scene to help out; there will probably not be one at the emergency department or in the ambulance/helicopter. Athletic trainers are critical in this situation and can be integral to the appropriate management of the injured athlete. In some situations where there are trained staff (including physicians) who will accompany the injured athlete this can be done at the hospital if deemed appropriate."

Adolescent Runners: Females, Males Differ in Low BMD Risk, Risk Factors

Are adolescent runners at risk for low bone mineral density (BMD)? And what are the differences between male and female runners regarding this risk? Adam Tenforde, M.D. is an avid runner who is completing a sports medicine fellowship at Stanford University. He recently published a study entitled, "Identifying Sex-Specific Risk Factors for Low Bone Mineral Density in Adolescent Runners." Dr. Tenforde told *OTW*, "The incidence rate of bone stress injuries in collegiate runners is up to 20% annually. For this study, we focused on high school runners because they have not yet reached peak bone mass and are at risk for low bone mass and bone stress injuries. Focusing on the younger population may help with prevention strategies and improve lifelong skeletal health. We obtained questionnaires and bone densitometry values in order to better understand which risk factors are most strongly associated with impaired bone health."

"A total of 94 females and 42 males completed an online survey where they were asked about training characteristics, fracture history, eating behaviors and attitudes, and menstrual history; we used a food frequency questionnaire to identify dietary patterns and measure calcium intake. Our goal was to identify the strongest variables that would predict impaired bone mass. To that end we collected bone density values (BMD) using dual energy x-ray absorptiometry (DXA), and evaluated z-scores on a continuum. We also evaluated risk factors that were most strongly associated with BMD Z-score values of -1 or less, a threshold we defined as low bone mass."

"In female runners, we found that risk factors for lower lumbar spine (LS) BMD included a lower android/gynoid fat mass ratio, lower fat mass, and combination of current menstrual irregularities and history of fracture. For total body less head (TBLH), later age of menarche, fewer cups of milk per day, and lower android/gynoid fat mass ratio were associated with lower BMD. The android/gynoid fat mass ratio has not been reported on in the running population prior to our report. This ratio may represent a marker for low energy availability or impaired nutrition. Additionally, it is unclear whether there is something inherent to the relative types of fat tissues that affects the overall endocrine system that in turn influences bone health."

"In male runners, lower body mass index (BMI) was associated with lower LS and TBLH BMD. Similar to female runners, lower android to gynoid fat mass was also associated with lower TBLH BMD. Additionally, athletes who answered yes to the questions 'Do you believe being thinner helps you run faster?' were more likely to have lower BMD. So perhaps this question is a marker for behaviors associated with impaired nutrition."

"Finally, we found risk factors for low BMD, defined as BMD Z-scores of -1 or less. In females, those with BMI at or below the threshold of 17.5 kg/m2 or runners with the combination of current menstrual irregularities and history of fracture were more likely to have low bone mass. In males, BMI of 17.5 kg/m2 or below and belief that being thinner leads to faster running performances were associated with low BMD. It is easy for orthopedic surgeons to screen for these risk factors to help evaluate runners who may have lower BMD. Like many things, it is a matter of awareness." ♦

COMPANY

Hospital for Special Surgery Maintains Grip on No. 1

For the sixth consecutive year, Hospital for Special Surgery (HSS), located in New York City, has been ranked the top hospital in the country for orthopedics. The ranking was by *U.S. News & World Report* in its 2015, "Best Hospital Survey."

In 2014 HSS cared for more than 120,000 patients with surgical and nonsurgical services in joint replacement, spine surgery, sports medicine, orthopedic trauma, hand surgery, foot and ankle surgery, pediatric orthopedics, limb lengthening, rheumatology, pain management, and osteoporosis.

In 2015 HSS expanded patient access to care through new Outpatient Centers in Stamford, Connecticut, and Paramus, New Jersey, and through an online second opinion service called HSS Consults.

HSS also provides care to professional and collegiate sports organizations both locally and around the world, HSS is the first designated National Medical Center of the United States Olympic Committee's National Medical Network.

"We are honored to receive the top national recognition in orthopedics with unprecedented consistency, which is an indication of our commitment to delivering value to all patients," said HSS President and CEO Louis A. Shapiro. "And, we are proud that HSS is the choice among patients who want to live life to the fullest. Our patients travel for our care from all 50 U.S. states and from more than 100 countries worldwide."

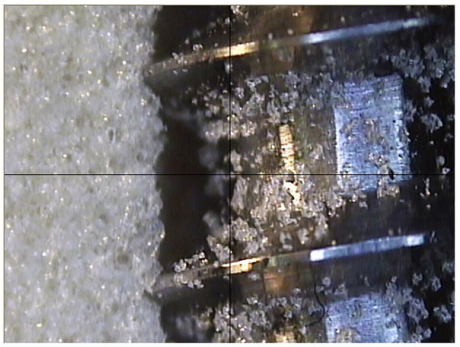
"This accolade is a testament to the work of all HSS staff who help patients get back to their own game of life every day," added Surgeon-in-Chief and Medical Director Todd J. Albert, M.D. "The entire clinical process at HSS—and all services we provide for patients—is developed to advance care, research, and education in our specialty field of musculoskeletal medicine."

HSS was founded n 1863. It is a member of the New York-Presbyterian Healthcare System and an affiliate of Weill Cornell Medical College. All Hospital for Special Surgery medical staff are faculty of Weill Cornell. — *BY*

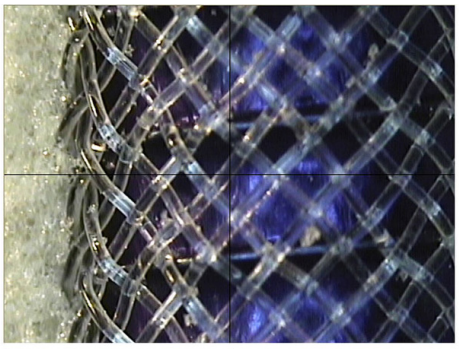
Courtesy of HSS

$6.6 Million for Woven Orthopedic Technologies

Those at Connecticut-based Woven Orthopedic Technologies, LLC are feeling pretty festive these days…they have hit the $6.6 million mark in equity financing since the company's inception in 2013. This is thanks to the recent sale of more than $4 million worth of capital.



SCREW ALONE



SCREW + WOVEN

Woven Orthopedic Technologies, LLC

Brandon Bendes, vice president of strategy & finance at Woven Technologies, told *OTW,* "After we raised our seed round in mid-2013, we started identifying the funds needed to help us optimize design, conduct preliminary tests, and roll-out the strategic business initiatives necessary to develop the business. As investment professionals who have built and exited companies in the past, we understood the essential components needed to raise capital from investors: (1) a superb idea that solves

an unmet need, (2) external validation from industry experts, and (3) a great leadership team with grit to execute the business plan."

"In regards to the idea, Viscogliosi Brothers, a VC [venture capital] firm that specializes in the neuro-musculoskeletal industry and is known for identifying and developing successful medical devices, co-founded the business. We also raised seed funds from some outside investors and were confident that the technology filled an unmet need."

"The next step was to obtain support in what we were doing from external industry experts. Our goal was to attract the people who knew the most about the clinical need. We approached surgeons who use the products, distributors who sell devices in our industry, and medical device executives who manage the large corporations that manufacture and supply products in our space. Through this process, we received investments from two of the top medical screw distributors in the world; a handful of world-renown surgeons in trauma, spine, and sports medicine; the former chairman and CEO of one of the world's largest medical device companies; and a former board member for the world's largest trauma business, among others. Given that we are creating a device to be used in conjunction with screws for orthopedic surgery, we were fortunate to have a very strong initial investor base to support the raise."

As for how the funds will be used, Bendes commented to *OTW*, "The funds are mainly being used for research and development. We are also dedicating funds for pre-clinical testing, quality systems, regulatory strategy and to expand our IP coverage to continue erecting barriers to entry for potential future competition. In addition, a small amount of funds are being utilized to build-out the systems necessary to reach the market (i.e., reimbursement, compliance, education) and we expect that this will increase as the business gets closer to commercialization."

"We are developing a technology intended to offer a bone-friendly solution that enhances fixation to prevent loss of screw engagement and the additional treatments that typically follow (including reoperations). AO [Foundation], the leading global organization in trauma research identified fracture fixation in osteoporotic bone as a focal area of interest so developing a solution to provide better, faster, and cheaper fixation in various fracture scenarios plays a pivotal role in our business strategy." — *EH*

LARGE JOINTS

Study: Telerehabilitation After TKR Equivalent to Traditional PT

A new study appearing in *The Journal of Bone & Joint Surgery* indicates that patients who received rehabilitation via video teleconference, or "telerehabilitation," following total knee replacement (TKR) had comparable outcomes to patients who received in-person physical therapy.

"This study is the first to provide strong evidence for use of telerehabilitation as an alternative to conventional face-to-face care following total knee replacement surgery," said Hélène Moffet, Ph.D., lead study author, physical therapist and professor at Université Laval in Quebec, in the July 15, 2015 news release.

A total of 205 patients scheduled for hospital discharge following TKR were divided into two groups: one that received home visits and one that received in-home telerehabilitation. "Both patient groups received the same instructions and number of interactions with a physical therapist over a two-month period. Patients were evaluated prior to TKR, immediately after the two-month rehabilitation program, and again at four months post-hospital discharge. Standard validated outcome measures were used to assess pain, stiffness, overall function, range of motion, strength, ability to participate in sports and daily activities, and overall life quality."

According to the news release, "Pain, function and stiffness scores were

Courtesy of Flickr and Intel Free Press

identical two months following hospital discharge in both the standard and telerehabilitation groups. At four months after discharge from the hospital, these outcomes remained comparable between the two groups. Range of motion, strength, activity and quality of life outcomes also were similar between the groups at two and four months after hospital discharge."

Asked for details on telerehab, Dr. Moffet told *OTW*, "The technology used to deliver telerehabilitation at home was a videoconferencing system (Tandberg 550 MXP). Communication between the two sites (home and rehabilitation centre) was ensured by a high speed internet connection. Telerehabilitation sessions were scheduled in advance by the physiotherapist. The physiotherapist initiated the session (from the rehabilitation centre) at the time scheduled with the patient, and the patient had only to push a button to accept the communication and start the session. Clinicians (physiotherapists) controlled cameras and audio signal intensity at both sites. The duration of the each session was about 45 to 50 minutes. During the session, the physical condition of the patient was briefly assessed to detect any complications, then exercises were performed and advice was given. The exercises prescribed were adapted to the specific condition and needs of each patient and were progressed during the two months-intervention."

As for what issues need to be resolved before this can be used in a more widespread manner, Dr. Moffet commented to *OTW*, "Different issues must be resolved to implement telerehabilitation in regular care. First, special program in telehealth/telerehabilitation must be put in place to support the health professionals with the technology and train them with this new mode of service delivery. Support should also be given to the patients (information, training, technical support with the technology and new communication modes, installation of at home equipment, etc.). Of course there are also some financial, ethical and regulatory considerations." — *EH*

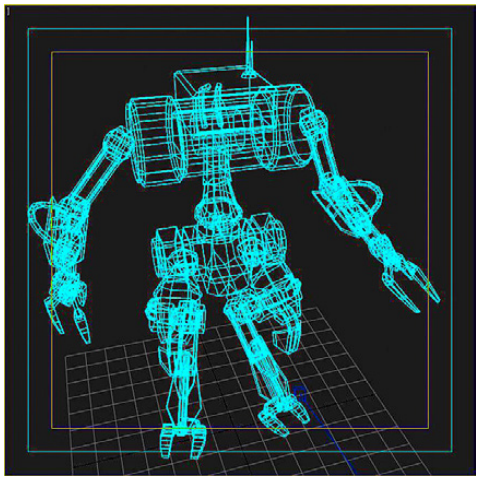
Robots Make Mistakes Too

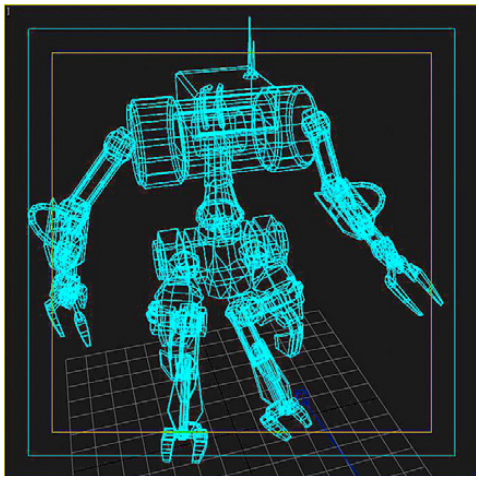
Fearful that robots may be taking over? Relax. It is not happening yet. A study by researchers from the University of Illinois at Urbana, the Massachusetts Institute of Technology and Rush University Medical Center found "a non-negligible number of technical difficulties and complications" during procedures performed by robots. The report is titled "Adverse Events in Robotic Surgery."

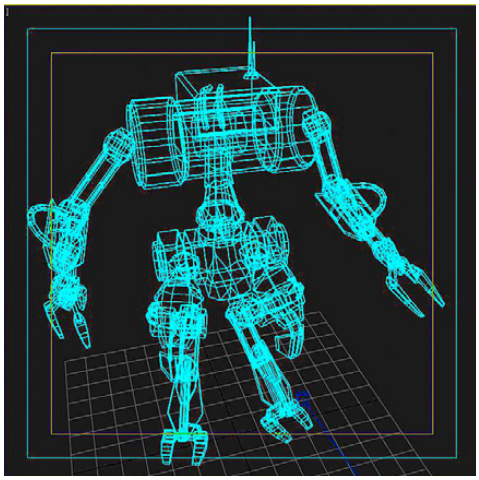
Researchers examined 10,624 events that were related to the use of robotic systems and instruments. Of these, they found that 1,535 had adverse results with negative impacts on patients. In 1,391 cases there were injuries to patients. In 144 cases deaths resulted. Malfunctions of the robot device accounted for 9,061 of the cases. Cardiothoracic and head and neck surgery had the highest rates of injury or death, according to the report.

Investigators attributed the problems to the complexity of the procedures, the infrequent use of robotic devices and less expertise in using robotic instruments. They wrote, "some of the reported events could be prevented by employing substantially improved safety practices and controls in the design and operation of surgical systems."

They noted that "As healthcare professionals increasingly use computer consoles and robotic tools in care, it is creating a need for a more tech-savvy workforce in the industry." — *BY*







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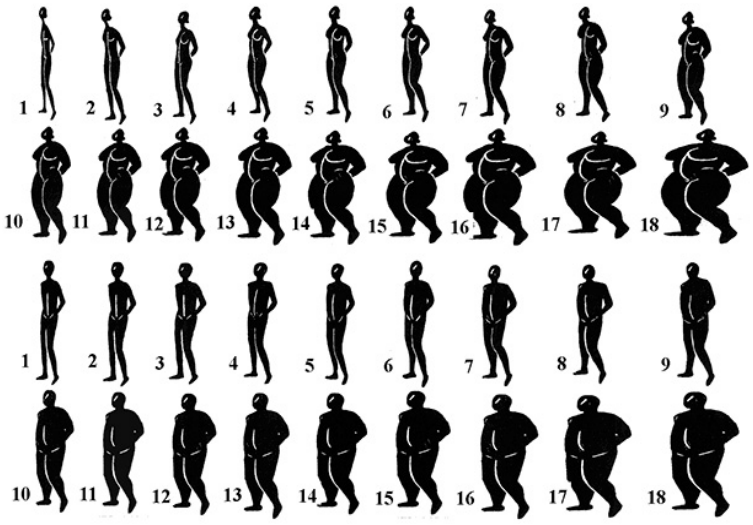
Tenacity of Obesity Revealed in Study



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Want to delay surgery until your patient loses weight? Think again.

A study of 75,000 obese men and 100,000 obese women in the United Kingdom is discouraging. Researchers found that less than 1% of obese individuals will, in their lifetimes, attain normal weight.

Parker Brown, wrote for *MedPage Today* that the study found that the chance of attaining normal weight is about 1 in 210 for the men and 1 in 124 for women. For those who are extremely overweight the chances of pulling their BMI (body mass index) down to a more normal range was an astonishingly small 1 in 1,290 for men and 1 in 677 for women. The study, conducted by Alison Fildes, Ph.D., at King's College in London and she observed these patients for 9.9 years. None of the subjects had undergone bariatric surgery.

"Our findings indicate that current nonsurgical obesity treatment strategies are failing to achieve sustained weight loss for the majority of obese patients," wrote Fildes and her colleagues. "These findings raise questions concerning whether current obesity treatment frameworks, grounded in weight management programs accessed through primary care, may be expected to achieve clinically relevant and sustained reductions in BMI for the vast majority of obese patients and whether they could be expected to do so in the future."

Brown wrote that, "of those who did achieve 5% weight loss, 53% regained the weight within 2 years and 78% had regained it within 5 years. Probability of achieving the weight loss increased as BMI categories increased. For both men and women, 12% recorded only BMI increases."

"Fildes noted that, because of the high levels of comorbidity seen in obese people, it's possible that they consulted more often with a doctor—and had their BMI recorded more often—than did those in the normal weight group. If so, she wrote, it is possible that all of the patients in the study represent a biased, less healthy sample. — *BY*

Advertisement

OrthAlign Wins Frost & Sullivan Innovation Award

OrthAlign, Inc. and Frost & Sullivan

Kudos to OrthAlign, Inc. for its novel thinking…the company is announcing that its precision alignment technology was awarded the 2015 Frost & Sullivan Technology Innovation Award in Orthopedic Alignment.

"Building on a powerful and sensitive navigation platform, OrthAlign's products not only surpass conventional mechanical guides in performance, but also match the precision of CAS (Computer Assisted Surgery) devices, which are widely accepted as the industry standard," said Bhargav Rajan, senior research analyst at Frost & Sullivan, in the July 13, 2015 news release. "OrthAlign deserves credit for successfully offering a single-use, handheld device without any capital investment as an alternative to the million-dollar, space-consuming CAS device. Development of these products marks an important milestone in the design and advancement of surgical navigation devices."

As indicated by the company, "OrthAlign's alignment technology platform addresses both total knee (TKA) and total hip (THA) arthroplasty procedures in a simple, palm-sized, single-use device and is compatible with all implant systems. More than 30,000 arthroplasty cases have been successfully completed, worldwide, using OrthAlign technology."

"The THA application, branded as OrthAlign Plus and commercially available in the United States and Australia this summer, provides measurement accuracy of ±3°, with at least 95% confidence when measuring the angle of the shell impactor, relative to the frame of reference defined by the registered landmarks. The device has been tested and validated to achieve 1) acetabular shell navigation accuracy for both inclination and anteversion, 2) measurement accuracy for changes in the femoral position in the superior-inferior direction, and 3) measurement accuracy for changes in the femoral position in the medial-lateral direction."

"OrthAlign set out on a mission to develop an innovative technology that improves surgical accuracy and precision in a field where expensive, time-consuming, and intrusive technologies failed to make inroads and be relevant," said David Mayman, M.D., an associate attending orthopedic surgeon at Hospital for Special Surgery. "Frost & Sullivan's recognition of OrthAlign, combined with proven clinical studies, increasing surgeon adoption, and my very own experience, reaffirm my enthusiasm and continued use of this game-changing technology."

Denis Nam, M.D., an assistant professor of Orthopedic Surgery at Washington University in St. Louis, has conducted two TKA studies with the company's technology. He told *OTW*, "OrthAlign empowers surgeons to achieve precise and accurate component alignment and positioning, in an efficient handheld device. Prior iterations of computer-assisted navigation have not received widespread adoption as they have been cumbersome, have required additional steps both preoperatively and intraoperatively, and disrupt a surgeon's normal workflow. OrthAlign just makes sense."

OrthAlign CEO William E. Maya told *OTW*, "OrthAlign technology has proven itself in ten published clinical studies, equipping surgeons who place value on precision with a unique and valuable tool that provides real time data. It can potentially increase patient satisfaction through reduced complication rates and readmissions due to revision. Over the next year, the organization will focus on its launch of OrthAlign Plus, its rapidly growing international business, and further expand its IP-protected technology into other applications. Anterior hip is coming. Uni is coming. A gap balancing feature will be added. And we are in discussions to address the shoulder." — *EH*

Biodegradable Implant Metals – Next Big Thing?

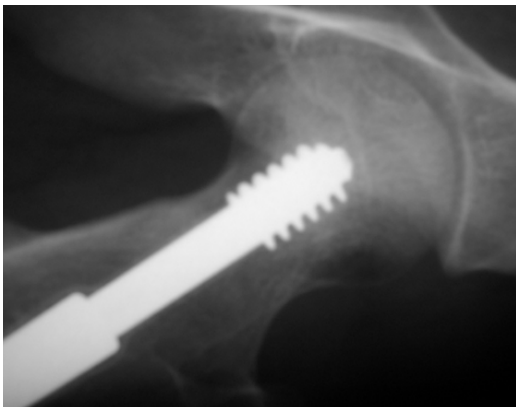
It is hazardous to try to predict the "next big thing" in medicine, but the National Science Foundation may be doing just that by investing $31 million in an attempt to discover metal surgical implants that will deteriorate in the body.

Getting some of those research funds is University of Pittsburgh engineering professor Prashant Kumta, Ph.D.

According to Stacy Lawrence, writing for *Fierce Medical Devices*, Kumta has developed biodegradable implants made of iron and magnesium that are built using a 3-D printer that mixes glue droplets with mineral powder. Kumta says that magnesium "has the mechanical characteristics that meet natural bone, both from the strength [and] the toughness as well as the density." He says that magnesium has the perfect density to match with natural bone. His hope is to do away with metal screws, rods, pins and plates in the body in favor of favor of implants of "biologically necessary minerals that would serve as the basis for healing and then safely biodegrade."

Lawrence quoted Kumta as saying, "You can actually create an architecture that mimics the original bone that the patient has lost. The fixation plate will provide the mechanical strength needed to carry the load, and the bone-wide filler would help provide the healing and the bone formation."

Kumta is also working on a novel calcium phosphate putty to be injected in the spaces around its 3-D printed biodegradable implants, as well as between fractured bones. — *BY*



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REIMBURSEMENT

AMA Objects to Proposed Anthem/Cigna Merger

The American Medical Association (AMA) is drawing a line in the sand. The proposed merger of Anthem and Cigna will "reduce competition and choice" said the AMA President Steven J. Stack, M.D. today in a widely distributed press release.

Dr. Stack went on to say: "The proposed Anthem-Cigna merger would be presumed to be anticompetitive in the commercial, combined (HMO+PPO+POS) markets in 9 of the 14 states (NH, ME, IN, CT, VA, CO, GA, NV, KY) in which Anthem is licensed to provide coverage. The lack of a competitive health insurance market allows the few remaining companies to exploit their market power, dictate premium increases and pursue corporate policies that are contrary to patient interests."

Urge to Merge Is Spreading

Anthem's July 23 announcement is the third major merger announcement among private health insurance providers in July alone.

On July 2, Centene announced a $6.3 billion bid to buy Health Net, Inc.

On July 3, Aetna announced a $35 billion bid to buy Humana.

The Anthem deal, if it passes FTC muster, will be the largest deal ***ever*** in the health insurance industry.

Most analysts agree the triggering event for this mega-merger was the Supreme Court's ruling in favor of continued subsidies for Obamacare. Subsidized health insurance for lower-income Americans essentially guarantees huge new markets for insurers.

AMA's Position

"The American Medical Association believes patients are better served in a health care system that promotes com-

AMA AMERICAN MEDICAL ASSOCIATION

Courtesy of American Medical Association

petition and choice. We have long cautioned about the negative consequences of large health insurers pursuing merger strategies to assume dominant positions in local markets. Recently proposed mergers threaten to increase health insurer concentration, reduce competition and decrease choice."

"The AMA's own study shows that there has been a serious decline in competition among health insurers with nearly 3 out of 4 metropolitan areas rated as 'highly concentrated' according to federal guidelines used to assess market competition. In fact, 41% of metropolitan areas had a single health insurer with a commercial market share of 50% or more."

Health insurers have been unable to demonstrate that mergers create efficiency and lower health insurance premiums. An AMA study of the 2008 merger involving UnitedHealth Group and Sierra Health Services found that premiums increased after the merger by almost 14% relative to a control group.

Bypassing the Insurers

One possible outcome of these mergers will be some dis-intermediation of the health care system.

A couple years ago Wal-Mart, in collaboration with Home Depot, put in place a program that offered a hip or knee replacement surgery, plus transportation for the employee and one other person to and from the hospital, plus hotel rooms and food at no charge if they used one of three designated hospitals for their surgery.

No Aetna, Anthem, Humana or United required.

Last year, Boeing and some of the hospitals in the Seattle/Puget Sound area teamed up to provide healthcare services—also without the benefit of an health insurer in the middle. The mechanism Boeing used to make this happen is the new system of accountable care organizations, or ACOs.

Under this new program, Boeing negotiated its own healthcare service contracts with ACOs in the Puget Sound-area. Their employees started using these providers in 2015. The three ACOS were set up by University of Washington Hospitals, Providence Health and Swedish Heath Services.

Are there more insurance company mergers on the horizon? Odds are, yes. Could we have a system with fewer private insurance companies servicing a shrinking number of privately insured patients? Yes, again. — *RRY*

SPORTS MEDICINE

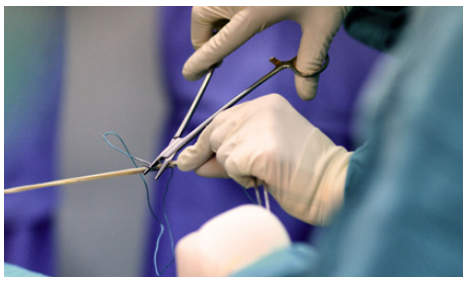
BTB Grafts: No Faster Healing Than Hamstring Grafts

Potentially practice changing information regarding anterior cruciate ligament (ACL) reconstruction is coming out of the University of Pittsburgh Medical Center (UPMC). Surgeons treating patients with ACL injuries can now consider both bone-tendon-bone (BTB) grafts and hamstring autografts on an equal footing in terms of healing.

"We compared the graft-tunnel motion of patients receiving either kind of graft, and noted both groups had similar graft motion at six weeks and one year from surgery, both ranged between 1-2 mm," commented Justin W. Arner, M.D., from the University of Pittsburgh Medical Center (UPMC), in the July 9, 2015 news release. "Often surgeons will recommend earlier return to play in patients receiving a BTB graft, but with these findings we cannot support the commonly perceived assumption of earlier healing with BTB."

In this pilot study, the researchers examined 12 patients with an average age of 24 undergoing anatomic single-bundle ACL reconstruction (with six receiving hamstring autograft and six receiving a BTB graft). All participants underwent a physical therapy (PT) program postoperatively.

Dr. Arner told *OTW,* "The assumption that patients with BTB grafts can return to sport more quickly is brought into question. In this study, BTB and hamstring grafts seemed to have similar incorporation into bone tunnels and showed 1-3 mm of motion at both 6 weeks and 1 year. These patients are doing well clinically and have returned to sport and regular activities."



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Asked for details about the possible ramifications on PT protocols and timing of return to sport, Dr. Arner commented to *OTW*, "Currently, it is believed BTB grafts heal more quickly than hamstring grafts, and therefore physical therapy is often initiated sooner and more aggressively. Further, surgeons historically have allowed patients with BTB grafts to return to sport sooner. With our results, we question if BTB grafts really do heal faster than hamstring and if those patients should return to sport sooner. Further studies must be conducted to investigate graft healing. We plan to use quantitative MRI to evaluate bone tunnel and mid substance healing." — *EH*

SPINE

FH Orthopedics: New European Distribution Agreements

France and Germany, get ready… FH Orthopedics, developer of the Elastic Spine Prosthesis (ESP), is on its way to a hospital near you. The company has recently signed two new agreements, one with France Rachis and the other with Via 4 Spine in Germany.

Eric Hermann, FH Orthopedics' Spine Business Unit Director, said in the July 21, 2015 news release, "These two agents have the best profiles to promote the ESP disc ranges as they both strongly believe in non-fusion solutions, they are already working with spine surgeons, the prostheses fit perfectly their current portfolio without any conflict with existing business, and they are active nationwide."

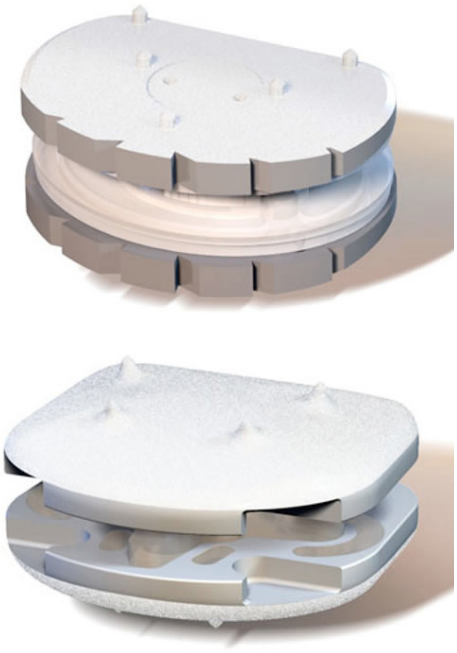
France Rachis (FR2D or French Spine Distribution & Development) has its own spine-focused sales force of five representatives who specialize in non-fusion solutions. Via 4 Spine, with a network of six sales representatives in Germany, will market FH Orthopedics' LP-ESP and CP-ESP.

According to the news release, "The LP-ESP is indicated for lumbar discopathy that is resistant to medical treatment, lumbar discopathy disease after treatment of a herniated disc, and radiculopathy by a recurrence of a disc hernia (except for excluded hernias). Patients implanted with the LP-ESP showed significant improvement in VAS and OSWESTRY scores of 75% and 74%, respectively."

"The LP-ESP has nine years of clinical experience; the CP-ESP for cervical applications is available in heights from 5mm to 7mm with three different footprints. Both devices provide up to six degrees of freedom: flexion, extension, right and left bending, axial rotation, and translation. In addition, they offer an adaptive center of rotation and improved stability. These latest generation intervertebral disc replacements offer greater shock absorption and automatic return versus traditional disc replacements using ball and socket technology. The ESP discs are also non-surface-bearing for increased life of the devices and have been tested up to 40 million cycles."

Hermann told *OTW,* "Both distributors were given the instruction to find, train and help start new surgeons to use the ESP disc prosthesis. They both got product trainings by our team and fortunately our mono bloc disc design meets great interest from surgeons and patients."

"For next year, we are looking to expand to UK and Spain and other countries outside of Europe." — *EH*



Top to bottom: LP-ESP and CP-ESP/Courtesy of FH Orthopedics

Centinel Spine Receives First Cervical Multilevel Clearance

The FDA has just granted Centinel Spine, Inc., the first cervical multilevel indication for a stand-alone interbody device.

STALIF C/Centinel Spine, Inc.

The company, the first to gain such clearance, announced in late June that its STALIF C and STALIF C-TITM now can be used on-label in multilevel, cervical spine fusion procedures. Company Chairman and CEO John Viscogliosi said the indication clearance from the FDA is valuable given the high incidence of multilevel degenerative disc disease in the cervical spine.

The STALIF C family of products was previously cleared by the FDA for use in conjunction with autograft or allogeneic bone graft at a single level in patients with degenerative disc disease of the cervical spine. The new clearance expands the on-label use to include the multilevel cervical spinal fusion procedures.

John Demakas, M.D. of the Rockwood Neuroscience Institute in Spokane, Washington, said as an integrated interbody, the dynamic capability of the STALIF C-Ti screws "allow the ver-

tebral bodies to settle on to the graft site. Combine this with compressive lag fixation and the osteoconductive advantage of the titanium coating, and STALIF C-Ti gives my patients the best opportunity for a solid fusion."

According to the company, the lag effect provides constant compressive forces against the implant which results "in a greater interface between the graft and the endplate to facilitate the fusion process." The company also says the STALIF C screws are angled and biomechanically designed to direct axial forces along the long axis of the screws to "significantly reduce bending moments and preventing de-rotation of the screw and/or screw back-out."

Centinel Spine is privately owned and began operations seven years ago. The company was created from a merger and acquisition of Raymedica LLC and Surgicraft LTD. The Viscogliosi's mission is to make the company the leading anterior column support spine franchise. — *WE*

Older Patients With Spinal Cord Injuries Less Likely to Receive Surgery

New research from St. Michael's Hospital in Toronto is indicating that older patients with traumatic spinal cord injuries are less likely to receive surgery compared with younger patients. And the bad news doesn't end there…these patients also experience a significant lag between injury and surgery.

Flickr and Fran Urbano

The research team utilized data from the Rick Hansen Spinal Cord Injury Registry, a database containing information on 1,440 individuals who had a traumatic spinal cord injury. Of the total, 167 (11.7%) were aged 70 years or older.

According to the July 6, 2015 news release, "These patients were more likely to have fallen compared with younger patients (83.1% vs. 37.4%) and to have a longer stay in an acute care hospital, according to the paper published today in the *Canadian Medical Association Journal*. Younger patients were more likely to have severe injuries resulting in paralysis below the trauma site whereas older patients had less severe injuries. The time between injury to arrival at an acute care center was about twice as long for older patients than younger patients. Once admitted, older patients also waited about twice as long for surgery as younger patients."

"These delays may be due to delays in recognizing the less severe injuries in seniors or they may reflect a potential age related therapeutic bias," said study author Dr. Henry Ahn.

The researchers also found that older patients were also significantly more likely to die from a traumatic spinal cord injury than younger people. "These significant differences in injury

Advertisement

demographics, timing of surgery and outcomes in older compared with younger patients necessitates rethinking the management of traumatic spinal cord injury in those in the oldest age group," Dr. Ahn said.

Dr. Ahn told *OTW*, "We were surprised with where the delays in treatment occurred. Elderly patients, on average, took twice as long to get transferred to a spinal center compared to a younger patient. These delays can hinder timely care for these patients, during which time patients are often immobilized, increasing their risks of adverse events such as blood clots and pneumonia related to being immobilized. The study did not assess exactly why these delays occurred. Recent studies have shown early surgery maybe better for neurologic recovery in patients with incomplete cervical spinal cord injuries."

As for how long it might take before this could be available for widespread use, Dr. Ahn commented to *OTW,* "Future studies are being set up to plot out factor affecting transfer times and timing for surgery in hospital. From this, specific interventions such as education and guideline changes can be implemented." — *EH*

PEOPLE

Allen F. Anderson, M.D. Installed at AOSSM President

He has plans—and long term plans—for the American Orthopaedic Society for Sports Medicine (AOSSM). Allen F. Anderson, M.D. of the Tennessee Orthopaedic Alliance was recently installed as the 44th president of this fine institution. Dr. Anderson, who is also a chairman of AOSSM's Research Scientific Advisory Committee, was awarded with the organization's O'Donoghue Sports Injury Research Award for Most Outstanding Clinical Research in Sports Medicine in 2014.

As indicated in the July 8, 2015 news release, Dr. Anderson graduated from the University of Tennessee, College of Medicine in 1976 and completed an orthopedic residency at Vanderbilt University. "Dr. Anderson has had more than 91 scientific articles published in sports medicine books and various sports medicine journals. He has also had 21 scientific exhibits at national and international orthopaedic meetings and made numerous national/international presentations and 53 instructional course lectures."

"Dr. Anderson was asked to be a visiting professor at the Universities of Vermont and Cincinnati. He was appointed Associate Editor of the *American Journal of Sports Medicine,* and *The Orthopaedic Journal of Sports Medicine*. He is a member of the AOSSM Medical Publishing Board of Trustees and Board of Directors and has previously served on the Board of Directors of the Canby Robinson Society at Vanderbilt University and the Board of Directors of the International Cartilage Repair Society. Dr. Anderson is chairman of the International Knee Documentation Committee, which sets standards for orthopaedic surgeons around the world to use to evaluate the results of treatment."

Allen Anderson, MD and Robert A Arciero, MD

Dr. Anderson told *OTW*, "One of the AOSSM's strengths is that the leadership has established a strategic plan for education, research, communication, publishing and fellowship. As president, one of my primary responsibilities is to ensure that AOSSM continues fulfilling those priorities. In publishing, we have launched a new journal—the *Orthopaedic Journal of Sports Medicine* (*OJSM*)—which as an open access journal provides a new publishing paradigm for the profession around the world. My priority is to ensure that *OJSM* provides a rigorous accessible scientific publication for researchers and readers worldwide while maintaining the same high standards as *AJSM* and *Sports Health*. In education, we will look to maintaining our stable of live courses and enduring education materials while expanding our involvement with skills education. And in research, AOSSM's priority is to facilitate not just the funding of research projects but the collaboration of the research community and funding sources, such as the NIH [National Institutes of Health], to maximize the impact of our research endeavors. Finally, as president, my priority will be to not only advance the established AOSSM priorities but to also look to the next steps so our organization and profession continues to thrive. We have both unique opportunities and challenges ahead, and my responsibility will be to work with the leadership so we can identify and capitalize on those factors." — *EH*

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