VOLUME 6, ISSUE 7 | MARCH 2, 2010

# Orthopedics This Week

## week in review

**05 Large Joints: Revenues on the Upswing** ♦ The large joint reconstruction industry ended 2009 on a high note with a year-over-year revenue growth of 9.2% in the fourth quarter. After four previous quarters of low or declining growth, the large joints reconstruction market is back on the upswing.

**09 Medical Marijuana in Orthopedics** ♦ Fourteen states. Nearly 300,000 registered patients. Medical marijuana is firmly on the scene. Patients are self medicating for back pain and as an antispasmodic and muscle relaxant. What do we really know and how should physicians deal with medical marijuana patients?

**13 Haiti: Are We Learning Anything?** ♦ Dr. Christopher Born went to Haiti on a government mission (protected by the 82nd Airborne). Dr. David Helfet organized his own team. Their vastly different experiences illuminate the need to streamline and organize disaster preparedness.

## the picture of success

**25 Dr. Mininder Kocher** ♦ Dr. Mininder Kocher, Associate Professor of Orthopedic Surgery at Harvard Medical School, is a pediatric sports medicine specialist with credentials in both disciplines. And his knowledge of epidemiology means that he performs top notch studies.

## breaking news

**17 Distal Radius Fractures:** New Guidelines

Compression Socks for **DVT**

**Augment:** Final PMA Module Submitted

**Alphatec Scient'x** Merger Nearing Completion

**IOF:** Record Number of Abstracts Group Therapy for Arthritis Fears?

New **Stem Cell** CLI Data

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- Associated diagnoses
- State reimbursement data
- Comorbidities

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

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

| Extremity Market Reports | Code |
|---|---|
| Ankle Fusion | 81.11 |
| Triple Arthrodesis | 81.12 |
| Subtalar Fusion | 81.13 |
| Total Shoulder Replacement | 81.80 |
| Partial Shoulder Replacement | 81.81 |
| Rotator Cuff Repair | 81.63 |
| Total Ankle Replacement | 81.56 |
| Open Reduction of Fracture Radius & Ulna w/ Internal Fixation | 79.32 |
| Open Reduction of Fracture Humerus w/ Internal Fixation | 79.31 |
| Open Reduction of Fracture Tarsals & Metatarsals w/ Fixation | 79.37 |

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Orthopedics This Week

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# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**This Week:** The big news this past week was NuVasive's trifecta—largest sales increase of any major spinal implant company, largest single-day increase of any orthopedic stock this year and, finally, unequivocal support from two the major private insurers. A bit rich for Power Rankings but top quality is always expensive.

| Rank | Last Week | Company | TTM Op Margin | 30-Day Price Change | Comment |
|---|---|---|---|---|---|
| 1 | 4 | Orthofix | 11.00% | 14.09% | Five consecutive quarters of rising cash flows and yet OFIX is trading at only 1x PSR. The pattern of upside surprises is getting routine. |
| 2 | 3 | Smith & Nephew | 19.17 | 1.18 | SNN wins suit against Arthrex for patent infringement—4th lowest future P/E. |
| 3 | 5 | Medtronic | 31.37 | (0.82) | Spine disappointed, for sure, but at 13x trailing earnings, the bad news is baked in. |
| 4 | 10 | Exactech | 12.61 | 16.88 | Two Gainesville companies led all ortho stocks in price appreciation last month. Only EXAC has the fundamentals to be on Power Rankings. |
| 5 | 1 | Johnson & Johnson | 27.1 | 1.11 | Attractive new opportunities pushed JNJ down to #5. JNJ is still the dividend yield play—for widows, orphans and nervous investors. |
| 6 | 6 | Integra LifeSciences | 15.37 | (1.36) | Classic. There's always money to be made when earnings grow faster than sales, which Stu is doing right now at IART. |
| 7 | 2 | Symmetry | 11.48 | (6.52) | Terrible report for 4Q and 2009. Only reason SMA is still on Power Rankings is because they are so darn cheap. |
| 8 | 7 | Stryker | 24.71 | (2.68) | Not particularly cheap, given its new lower earnings growth rate, but if sales can grow at double-digit rates this year then… |
| 9 | 8 | Zimmer | 27.71 | (5.49) | Consensus of analysts is that ZMH can grow sales around 6% annually—which is lower than SYK, SNN and Synthes. |
| 10 | 9 | CONMED | 7.74 | 0.23 | Decent 4Q report and analysts are forecasting some pretty nice numbers for 1Q. The market isn't showing confidence, however. |

Orthopedics This Week

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# Robin Young's Orthopedic Universe

## Top Performers Last 30 Days

| | Company | Symbol | Price | Mkt Cap | 30-Day Chg |
|---|---|---|---|---|---|
| 1 | NuVasive | NUVA | $40.00 | $1,530 | 33.3% |
| 2 | Capstone Therapeutics | CAPS | $1.04 | $42 | 23.8% |
| 3 | RTI Biologics Inc | RTIX | $3.75 | $205 | 18.3% |
| 4 | Exactech | EXAC | $19.39 | $249 | 16.9% |
| 5 | Orthofix | OFIX | $34.09 | $584 | 14.1% |
| 6 | CryoLife | CRY | $7.05 | $201 | 13.5% |
| 7 | Osteotech | OSTE | $3.89 | $70 | 13.4% |
| 8 | Alphatec Holdings | ATEC | $5.13 | $270 | 11.5% |
| 9 | Orthovita | VITA | $3.84 | $294 | 8.8% |
| 10 | Mako Surgical | MAKO | $13.21 | $439 | 5.6% |

## Worst Performers Last 30 Days

| | Company | Symbol | Price | Mkt Cap | 30-Day Chg |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $4.72 | $116 | -14.4% |
| 2 | Kensey Nash | KNSY | $22.07 | $241 | -12.9% |
| 3 | Synthes | SYST.VX | $118.16 | 14,023 | -12.2% |
| 4 | Wright Medical | WMGI | $16.85 | $631 | -6.7% |
| 5 | Symmetry Medical | SMA | $8.60 | $308 | -6.5% |
| 6 | Zimmer Holdings | ZMH | $57.33 | $12,040 | -5.5% |
| 7 | Stryker | SYK | $53.10 | $21,120 | -2.7% |
| 8 | Integra LifeSciences | IART | $39.80 | $1,130 | -1.4% |
| 9 | Medtronic | MDT | $43.40 | $47,940 | -0.8% |
| *10* | *Average* | | | *$11,431* | *-0.4%* |

## Lowest Price / Earnings Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | P/E |
|---|---|---|---|---|---|
| 1 | Kensey Nash | KNSY | $22.07 | $241 | 12.52 |
| 2 | Medtronic | MDT | $43.40 | $47,940 | 13.39 |
| 3 | Symmetry Medical | SMA | $8.60 | $308 | 13.45 |
| 4 | Johnson & Johnson | JNJ | $63.00 | $173,820 | 13.61 |
| *5* | *Average* | | | *$11,431* | *14.03* |

## Highest Price / Earnings Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | P/E |
|---|---|---|---|---|---|
| 1 | Smith & Nephew | SNN | $51.47 | $9,120 | 78.54 |
| 2 | RTI Biologics Inc | RTIX | $3.75 | $205 | 42.44 |
| 3 | NuVasive | NUVA | $40.00 | $1,530 | 38.45 |
| 4 | ArthroCare | ARTC | $26.57 | $712 | 23.38 |
| 5 | CONMED | CNMD | $21.88 | $637 | 22.00 |

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

| | Company | Symbol | Price | Mkt Cap | PEG |
|---|---|---|---|---|---|
| 1 | Alphatec Holdings | ATEC | $5.13 | $270 | 0.70 |
| 2 | CryoLife | CRY | $7.05 | $201 | 0.77 |
| 3 | Medtronic | MDT | $43.40 | $47,940 | 1.27 |
| 4 | Exactech | EXAC | $19.39 | $249 | 1.28 |
| 5 | Smith & Nephew | SNN | $51.47 | $9,120 | 1.30 |

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

| | Company | Symbol | Price | Mkt Cap | PEG |
|---|---|---|---|---|---|
| 1 | CONMED | CNMD | $21.88 | $637 | 8.97 |
| 2 | Johnson & Johnson | JNJ | $63.00 | 173,820 | 1.84 |
| *3* | *Average* | | | *$11,431* | *1.67* |
| 4 | Wright Medical | WMGI | $16.85 | $631 | 1.47 |
| 5 | Zimmer Holdings | ZMH | $57.33 | $12,040 | 1.46 |

## Lowest Price to Sales Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | PSR |
|---|---|---|---|---|---|
| 1 | Osteotech | OSTE | $3.89 | $70 | 0.72 |
| 2 | Symmetry Medical | SMA | $8.60 | $308 | 0.79 |
| 3 | CONMED | CNMD | $21.88 | $637 | 0.92 |
| 4 | Orthofix | OFIX | $34.09 | $584 | 1.07 |
| 5 | RTI Biologics Inc | RTIX | $3.75 | $205 | 1.18 |

## Highest Price to Sales Ratio (TTM)

| | Company | Symbol | Price | Mkt Cap | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $4.72 | $116 | 162.33 |
| 2 | Mako Surgical | MAKO | $13.21 | $439 | 16.71 |
| 3 | Synthes | SYST.VX | $118.16 | $14,023 | 4.13 |
| 4 | NuVasive | NUVA | $40.00 | $1,530 | 3.36 |
| 5 | Orthovita | VITA | $3.84 | $294 | 3.27 |

Orthopedics This Week

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# Large Joints: Revenues on the Upswing

**By Scott Ellison, PearlDiver Large Joint Reconstruction Senior Analyst**

*Wikimedia Commons*



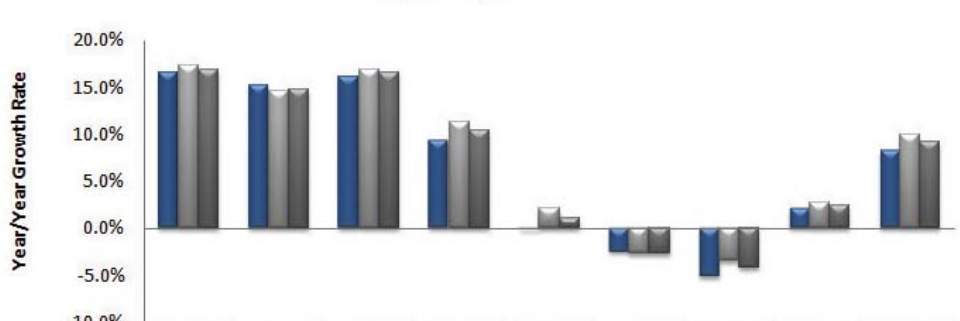
Large joint reconstruction industry suppliers sold $3.03 billion of products in the fourth quarter of 2009 (4Q09), exceeding our forecast by $156.9 million, or 5.5%. We have, therefore, increased our revenue forecast for the large joint reconstruction industry by 1.3% to $2.87 billion for 1Q10. We have also increased our full-year forecast for 2010 from $11.5 billion to $11.95 billion.

Prior quarters of 2009 could be described as rocky at best with a 1Q09 revenue decline of 2.6% year-over-year (YOY) and a 2Q09 revenue decline of 4.2%. Finally in the third quarter, the large joint reconstruction industry showed a stronger pulse with a revenue growth of 2.4%. Now the fourth quarter has brought 2009 to a close with a solid upward swing in revenue.

Three reasons, we believe, gave the industry its biggest revenue increase of the year:

- Procedure volumes continue to return in higher numbers
- Sales outside of the U.S. (OUS) improved dramatically
- Large companies with the most market share finally turned the corner from revenue declines

**Chart 1: Large Joint Reconstruction Market Revenue Growth (YOY)**




| | 4Q07 A | 1Q08 A | 2Q08A | 3Q08A | 4Q08A | 1Q09 A | 2Q09 A | 3Q09 A | 4Q09 E |
|---|---|---|---|---|---|---|---|---|---|
| Hips | 16.5% | 15.2% | 16.1% | 9.3% | -0.2% | -2.5% | -5.2% | 2.1% | 8.2% |
| Knees | 17.3% | 14.5% | 16.8% | 11.3% | 2.1% | -2.7% | -3.5% | 2.7% | 9.9% |
| Large Joint Market | 16.9% | 14.8% | 16.5% | 10.4% | 1.1% | -2.6% | -4.2% | 2.4% | 9.2% |

*Source: Company reports*

- Fourth quarter results showed a YOY revenue increase of 9.2% for the overall large joint reconstruction industry as shown in Chart 1. While hip product revenues showed substantial growth in comparison to the previous three quarters, the greatest revenue growth came from the knee implant sector which increased 9.9%. Hip product revenue growth remained close behind, increasing 8.2% YOY.

## The Upward Swing

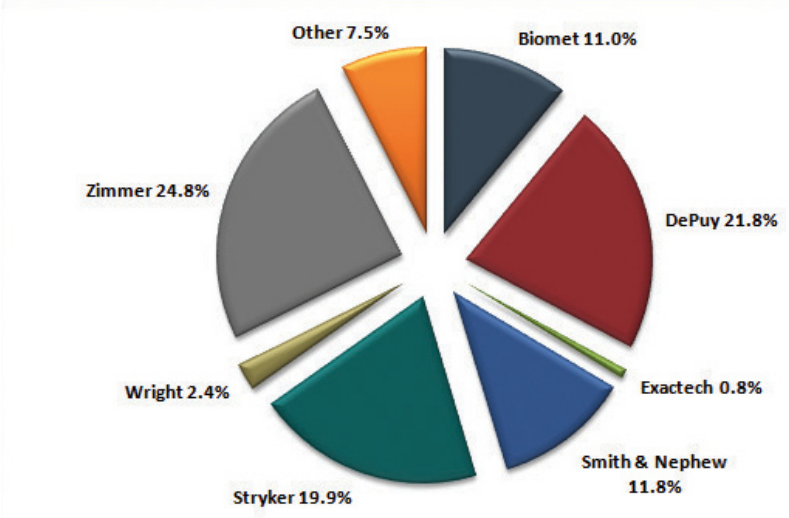
After four quarters of relatively low or declining revenue growth, the last quarter of 2009 has sent the industry on an upswing. There is clear indication that procedure volumes are returning to higher levels. According to Jim Crines, Executive Vice President of Finance and Chief Financial Officer of Zimmer, Inc., "In the second half of 2009, we saw encouraging signs that orthopedic procedure volumes in certain markets were recovering."

While Zimmer was helped by an increase in procedure volume and mix, pricing continued on a downward trend. According to Zimmer President and Chief Executive Officer David Dvorak, "Pricing on knee products on a consolidated basis in 4Q09 was down 0.7 % and on hip products, down 0.8%"

This sentiment was the common theme throughout each of the major large joint reconstruction manufacturers. Biomet, Inc. reported that average selling prices were down in both U.S. and OUS sales for both hip and knee products, as did Stryker, Inc. and DePuy, Inc. (a Johnson & Johnson company). But even with pricing decreases, the positive procedure volumes and mix have helped lead the sector toward much needed growth.

In addition, low OUS sales, which had been weighing heavily on quarterly growth, made positive increases as well. In 2Q09, both Stryker and Zimmer saw YOY declines of 13.5% and 13.1%, respectively, in OUS sales. This leveled out in the third quarter, with declines of only 1% and 0.3%. As of the end of 4Q09, Stryker bounced back with reported YOY gains of 12.7% in OUS sales, and Zimmer reported a YOY increase of 13.3%. Because of these positive gains, the major companies in the large joint reconstruction industry were able to hang on to their substantial shares of the total market, as shown in Chart 2. Zimmer, DePuy, and Stryker, the three largest manufacturers in this industry by market share, together account for 66.5% of the total large joint reconstruction market. With these three companies representing such a significant portion of the market, a successful quarter for each company has been a major boost for the entire sector.

**Chart 2: Large Joint Reconstruction Market Share as of 4Q09**




*Source: Company reports*

## Individual Company Commentary

***Biomet, Inc.***

Biomet, Inc. reported large joint reconstruction product sales of $357.8 million in its second quarter of 2010 (which ends November 30, 2009), an overall YOY increase of 12.0%. Hip repair product sales increased 8.0% YOY on strong U.S. sales of acetabular cups such as Ringloc and M2a-Magnum along with strong European sales of the Exceed ABT Advance Bearing Technologies System. Knee repair product sales increased 15.0% on the continued success of the Vanguard Complete Knee System.

***DePuy, Inc.***
***(a Johnson & Johnson company)***

DePuy, Inc. reported large joint reconstruction sales of $732.8 million, a 10.4% increase from 4Q08. Hip repair product sales increased YOY by 12.0% to $338.2 million. We attribute the success to product mix and innovation, with new products as the aSphere M-Spec Femoral Head. DePuy reported knee repair product sales at $394.6 million, an increase of 9% YOY. We also attribute this success to the strength of the underlying business and new product launches, including the Sigma Knee Portfolio additions earlier in the year.

***Stryker, Inc.***

Stryker, Inc. reported YOY revenue growth in both the hip and knee reconstruction markets. Overall, company officials reported large joint repair product sales to be $652.8 million, an increase of 10.5% over the previous year. Stryker hip repair product sales increased 10.0% YOY to $305.0 million on strong sales of Accolade, X3, and Trident product lines. Revenues for hip repair products exceeded Wall Street expectations of $302.1 million and PearlDiver expectations $282.8 million.

Knee repair product revenues increase 11.0% to $347.8 million, beating Wall Street expectations of $340.7 million and PearlDiver expectations of $335.1 million on the continued strength of the Triathalon product line.

***Zimmer, Inc.***

Zimmer, Inc. reported sales well above expectations in both hip and knee reconstruction markets with revenues of $333 million and $476 million, respectively. In total, large joint reconstruction product sales increased 8.6% from 4Q08 to $809 million in 4Q09 ahead of both Wall Street expectations of $789.9 million and PearlDiver expectations of $760 million.

New products such as the M/L Taper Hip Prosthesis and the Fitmore Hip Stem lifted revenues for hip repair products, and growth in knee repair product revenues increased with strong Flex Knee sales.

## Looking Forward

The fourth quarter demonstrated evidence that procedure volumes are increasing at a greater-than-expected pace within the large joint

reconstruction market. Taking this into account, we have increased our forecasts for the beginning of 2010 with a 6.4% YOY increase in hip product revenues across the sector, and an 8.4% increase in knee product revenues. In total, our forecast for the first quarter of 2010 reflects a 7.2% YOY increase across the large joint reconstruction market with gains on a per company basis shown in Table 1.

As we have seen during the fourth quarter, OUS sales are finally showing growth after several painful quarters. These previously low sales have been a key piece to slumping revenues over the past year and the present strength of OUS sales will remain vital as revenues stabilize and return to long-term growth. In addition to OUS improvement, increasing procedure volumes have helped to end the year on an upswing, leaving the large joints reconstruction market poised for a positive start in 2010.

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

**Table 1: Forecasted Hip and Knee Repair Revenues**

| | 4Q09E | 2009E | 4Q10E | 2010E | 2011E | 2012E |
|---|---|---|---|---|---|---|
| ***Zimmer*** | $809.0 | $2,989.0 | $767.2 | $3,162.7 | $3,281.4 | $3,442.1 |
| Hips | $333.0 | $1,229.0 | $306.0 | $1,275.1 | $1,318.3 | $1,371.0 |
| Knees | $476.0 | $1,760.0 | $461.2 | $1,887.6 | $1,963.1 | $2,071.1 |
| ***DePuy*** | $732.8 | $2,624.8 | $684.7 | $2,843.0 | $2,900.6 | $3,132.7 |
| Hips | $338.2 | $1,189.2 | $317.5 | $1,314.1 | $1,302.8 | $1,407.0 |
| Knees | $394.6 | $1,435.6 | $367.2 | $1,528.9 | $1,597.8 | $1,725.7 |
| ***Stryker*** | $652.8 | $2,391.6 | $600.6 | $2,537.1 | $2,455.1 | $2,590.9 |
| Hips | $305.0 | $1,129.3 | $278.7 | $1,180.1 | $1,147.9 | $1,205.3 |
| Knees | $347.8 | $1,262.3 | $321.9 | $1,356.9 | $1,307.2 | $1,385.6 |
| ***Smith & Nephew*** | $377.7 | $1,416.7 | $367.4 | $1,504.2 | $1,734.4 | $1,891.6 |
| Hips | $178.2 | $668.2 | $170.6 | $703.3 | $811.0 | $875.9 |
| Knees | $199.5 | $748.5 | $196.9 | $800.9 | $923.4 | $1,015.7 |
| ***Biomet**** | $357.8 | $1,364.7 | $342.6 | $1,477.5 | $1,568.2 | $1,690.6 |
| Hips | $148.7 | $569.1 | $143.2 | $604.8 | $629.0 | $658.9 |
| Knees | $209.1 | $795.6 | $199.4 | $872.7 | $939.2 | $1,031.7 |
| ***Wright*** | $76.3 | $290.0 | $77.9 | $318.7 | $335.1 | $357.6 |
| Hips | $44.8 | $167.9 | $45.3 | $185.5 | $194.3 | $206.9 |
| Knees | $31.5 | $122.2 | $32.7 | $133.2 | $140.8 | $150.7 |
| ***Exactech*** | $24.1 | $98.9 | $26.7 | $106.5 | $111.7 | $115.3 |
| Hips | $ 6.3 | $26.4 | $7.3 | $28.8 | $29.6 | $27.7 |
| Knees | $17.8 | $72.5 | $19.3 | $77.8 | $82.0 | $87.6 |
| ***Total*** | $3,030.5 | $11,175.7 | $2,867.2 | $11,949.7 | $12,386.5 | $13,220.8 |
| Hips | $1,354.3 | $4,979.0 | $1,268.6 | $5,291.7 | $5,433.0 | $5,752.7 |
| Knees | $1,676.2 | $6,196.7 | $1,598.6 | $6,658.0 | $6,953.6 | $7,468.0 |

** adjusted to match fiscal year of Jan 1 to Dec 31*
*** estimated*
*Source: Company reports*

# Medical Marijuana in Orthopedics

**By Robin Young**


*Wikipedia Commons*

Today, 14 states have approved the use of marijuana as a medical treatment. According to 12 of the 14 states (New Jersey and Michigan's registration programs started in 2010 and 2009, respectively, and no data is available), 269,420 people have registered and been issued a medical marijuana identification card. In California, the number of registered medical marijuana patients as of January 14, 2009, was 202,416 or 5.6 patients per 1,000 state residents. Overall in the 12 states that have approved the use of medical marijuana and provided statistics, the penetration rate is 1.90 patients per 1,000 state residents.

The ten most common reasons patients apply for a medical marijuana card are:

1. To relieve the effects of glaucoma
2. To relieve such side effects of chemotherapy and AIDS treatment as vomiting and lack of appetite
3. To provide pain relief for
   a. Neurogenic pain including chronic back pain
   b. Arthritis
   c. Fibromyalgia
   d. Migraines
4. To relieve some of the symptoms of multiple sclerosis
5. To provide pain relief from spinal cord injuries
6. To reduce the effects of depression
7. To relieve the symptoms from premenstrual syndrome
8. To improve breathing in asthma patients
9. To relieve the effects of such inflammatory bowel diseases as Crohn's and ulcerative colitis
10. To act as an antispasmodic and/or muscle relaxant

There are several active compounds in marijuana. With approximately 67 peer-review studies published,

a number of important insights are emerging. In terms of pain relief, the research appears to be focused on one compound in particular, beta-Caryophyllene. This compound reduces tissue inflammation by acting as a selective activator of the CB2 receptor. Cannabis oil contains about 12% to 35% beta-Caryophyllene.

Interestingly enough, beta-Caryophyllene is also found in clove oil and the cooking spice, rosemary. It is also the chemical compound that contributes to the spiciness of pepper. One pepper in particular is well known in China as the "numbing pepper."

In a study conducted by Jürg Gertsch et al., from the Swiss Federal Institute of Technology, beta-Caryophyllene was shown to selectively bind to the cannabinoid receptor type-2 and exert significant anti-inflammatory effects in mice. Beta-Caryophyllene, incidentally, is an FDA approved food additive.

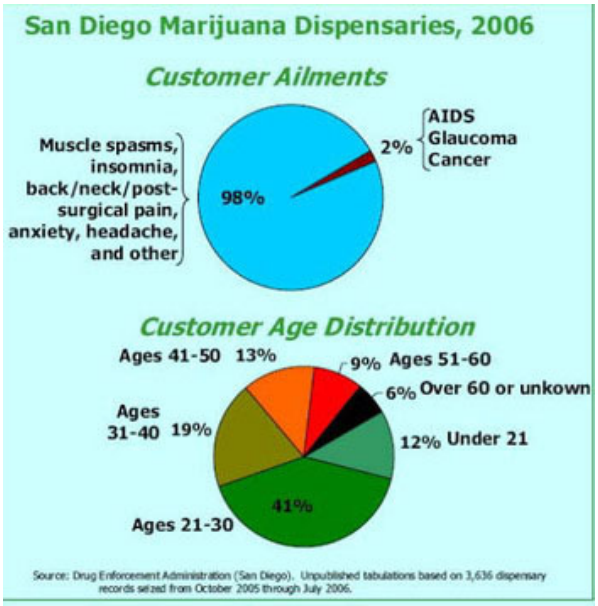
Another study we ran across looked specifically at the role of cannabis for spine pain relief when morphine fails. The study was conducted by Dr. Andrew Rice at the Imperial College of London and was published in the June issue of the journal *Molecular and Cellular Neuroscience:* Vol. 15, No.6, Jun 2000, pp. 510-521.

Dr. Rice's principal conclusion was: "We have achieved a really important step in terms of divorcing the psychoactive side effects of cannabis from their pain-relieving effects. In order to develop clinically useful drugs based on cannabis, it is important to show that the receptors for cannabinoids are found in the spinal cord, particularly the areas concerned with pain processing. And that's what we've done.

"The potential for cannabis in pain relief can now be developed in several ways: for instance we can either develop drugs based on cannabinoids acting on spinal receptors that don't have the psychoactive side effects or we can deliver the cannabinoids to the spinal cord site of pain relief without involving the brain."

Getting to the conclusion, however, was based on tackling one of the more difficult problems in treating chronic or severe back pain—namely the limited effectiveness of morphine and similar drugs that are currently the gold standard for serious pain relief.

Where morphine fails, marijuana may work.




*San Diego Drug Enforcement Administration*

Again, to quote Dr. Rice; "It's known that if you injure a nerve, the morphine receptors in the spinal cord disappear and that's probably why morphine isn't a very effective pain killer for such conditions as shingles, people who have had an amputation or perhaps if cancer has invaded the spinal cord."

"But what we've shown is that the cannabinoid receptors do not disappear when you injure a nerve. So this could offer a therapeutic advantage over morphine for treating such pain."

For physicians at the front lines of treating spinal injury or chronic pain patients, this is clearly interesting and potentially helpful information, but many hard questions remain. Specifically, clinicians still do not understand such elemental issues regarding medical marijuana as:

1. What's the right dose?
2. How does it interact with other medications?
3. And what physician in their right mind would prescribe smoking of anything?

In terms of the latter problem, several companies have developed a kind of vaporizer/inhaler that is similar to those used by asthma sufferers. These machines heat the cannabinoid oils in the marijuana leaves and convert them into an inhalable vapor. The marijuana leaves are not burned so no carbon or other "smoke" is released.

With nearly 300,000 patients self dosing regardless of other medications, clinicians are

increasingly asking the question about how they should deal with patients who are using medicinal marijuana and whether medicinal marijuana has a place in the drug armamentarium.

Dr. K. Allan Ward, a pain specialist at Great Falls, Montana Orthopedic Associates, is tackling these issues head on. "Most providers are very concerned and wonder what to do" with medical marijuana patients, Ward said. "In examining the medical literature, there are presently no definitive answers on the basic questions. There are currently, as far as I know, no published studies looking at legal marijuana use on a large scale."

Dr. Ward is hoping to put in place a survey to ask patients about their drug use and whether they have a history of alcohol or drug dependency, how they get their medical marijuana and how much they pay for it. Those answering the online survey can remain anonymous.

Dr. Ward said he hopes to use his findings to provide lawmakers and medical providers with more comprehensive information on the drug's usage in Montana. "I'm a pharmacologist and a technician," Ward said. "I'm being asked by other doctors for advice, and I don't have an answer at this time for all of the things that people are asking me." Dr. Ward is hoping that at least 1,000 of the state's 8,604 registered medical marijuana patients will participate in the online study.

The Canadian Medical Association published on their web site an August 7, 2001 article titled "A Primer For Patients' Use of Medicinal Marijuana," which addressed the issue of dosing:

*Dr. Mary Lynch, a pain researcher and head of the Canadian Consortium for the Investigation of Cannabinoids in Human Therapeutics, says there is very little research to guide practice so it's best to start with the lowest dose possible, particularly for the 'naïve' (first-time) user.*

*Using the protocols she and colleagues are developing for their research on the medicinal use of smoked marijuana, she recommends that naïve users begin with 1 puff (or toke), usually before bed, to help with symptoms such as pain or spasticity and improve sleep quality.*

*To get the most out of a dose while limiting the amount of smoke exposure, she tells patients to inhale on the pipe or joint and hold it in their lungs as long as possible.*

*Experienced users often know what dose is most effective, though Lynch recommends that a dose of 2 to 4 puffs per dose, 3 times per day is reasonable and, depending on response, the dose can be titrated accordingly. (Health Canada has suggested a daily maximum dose of 5 grams.)"*

In a roundabout way, the U.S. government has established dosing guidelines. For approximately three decades, federally grown (in Mississippi) medical marijuana has been available to a small number of patients under a Compassionate Use Investigational New Drug program. These patients are prescribed 300 pre-rolled marijuana cigarettes per month. Patients with chronic pain conditions receive 50% more than others or 450 per month. Each cigarette is approximately 0.9 grams, not including the paper. In effect, each patient is receiving a little more than one half-pound (8 ounces) per month.

As to what you can say to your patients, it depends on a combination of state and federal law. The federal law is evolving and here is the latest iteration:

> The Ninth U.S. Circuit Court of Appeals has ruled that doctors may discuss medical marijuana with their patients and may issue written recommendations for its use as part of a comprehensive treatment plan—Conant v. Walters, 309 F.3d 629 (2002). That ruling was appealed to the U.S. Supreme Court which refused to hear the case, allowing the decision to stand. It is also the current policy of President Obama's administration not to prosecute

*Wikimedia Commons*

medical marijuana cases where no state laws are being violated.

So, under current federal law, physicians can:

- Discuss, fully and candidly, the risks and benefits of medical marijuana with patients
- Recommend (or approve, endorse, suggest, or advise, etc.), in accordance with their medical judgment, marijuana for patient use
- Record in their patients' charts discussions about and recommendations of medical marijuana. Sign a government form or otherwise inform state or local officials that they have recommended medical marijuana for particular patients
- Testify in court or through written declaration about recommending medical marijuana for a certain patient.

But, under current federal law, physicians cannot:

- Prescribe medical marijuana. This includes writing a recommendation on an Rx form
- Assist patients in obtaining marijuana
- Cultivate or possess marijuana for patient use
- Physically assist patients in using marijuana
- Recommend marijuana without a justifiable medical cause

There is little doubt that medical marijuana will continue to grow as a treatment modality for back pain, arthritis pain and other neurological and orthopedic indications. While there is much more to learn, it is probably time for physicians to educate themselves about these compounds and for researchers to start studying in a more systematic way the emerging and preferred use patterns for medical marijuana.

# Haiti: Are We Learning Anything?

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

*Grounds at Hôpital de la Communauté Haitienne/Hospital for Special Surgery*

Methodical versus agile… resources guaranteed versus resources hoped for… government versus private. Sound like a competition? It shouldn't be.

Dr. Christopher Born, Chief of Orthopedic Trauma at Brown University, went to Haiti on an official U.S. government mission that was self sufficient and protected by the Army's 82nd Airborne Division. Dr. David Helfet, Director of the Orthopaedic Trauma Service at both Hospital for Special Surgery (HSS) and New York-Presbyterian Hospital, moved by the disaster, organized his own team, secured whatever resources he could and struck out on his own mission. Their experiences, vastly different, shed light on the need to find a middle ground between the two extremes. Why? Because unlike many orthopedic situations, disasters such as the Haiti earthquake can mean swift death for those left untreated.

## Aid With Government Support

Dr. Born: "There are three International Medical Surgical Response Teams (IMSuRT), one in Seattle, one in Miami, and another in Boston—all of which are under the auspices of HHS/National Medical Disaster System. When the volunteer team is activated, each member becomes a federal employee. After that, things start clicking according to a well-established plan."

IMSuRT field hospital patients being loaded for medivac to USNS Comfort

So the question is, "How do you plan without plodding?" Dr. Born says, "The benefits of being part of the IMSuRT team were many—no transportation glitches, full complement of materials, etc. The downside was that, as a government entity, we were at the behest of the decision making chain operating above us. This meant that we could not leap into action upon our arrival in Haiti…in fact, it was three days before we could begin operating. This is obviously in great contrast to the nimbleness of non governmental organizations (NGOs) or private groups that can do whatever they deem necessary."

Dr. Born, Chair of the Mass Casualty Response Committee for the Orthopaedic Trauma Association (OTA), seeks common ground between the two approaches. "There should be a way for the government and non governmental entities to work together harmoniously. While the latter parties often managed to get themselves to Haiti quickly and were obviously well intentioned, they may have been naïve in their expectations. In fairness, however, I don't think anyone knew what they were getting into."

A glaring issue that could have been a distraction to the medical work at hand was security. "We were alerted early on that the security situation was questionable," says Dr. Born, "and in fact were unable to leave the U.S. Embassy compound until an advance team could identify a place to set up a hospital and establish provisions for security. They settled on the courtyard of Gheskio University, and we had the field hospital up in eight hours.

*IMSuRT field hospital patients being loaded for medivac to USNS Comfort*

By 9am there were several hundred people lined up for treatment, with an entire tent city just outside the university. We had set up gates in order to handle things in an orderly fashion…then the triage team just went down the line."

The enormity of the situation required extreme focus. There was no time or resources for A to Z care. Dr. Born: "There were numerous open fractures and crush wounds, most of which were several days old and festering. After amputations, debridements, splinting, casting, and external fixation, it is unfortunate, but there will be little follow up care for patients. The best we could do was to temporize, debride, and keep the wounds clean. Definitive surgery such as IM nails, plates, etc., would have to be done at larger centers when they are functioning. Several amputations were required secondary to the dirty open wounds and potential for sepsis. The complex injuries have little chance to undergo the reconstructive procedures required to treat them properly. Thus, we tried to deliver the 'minimal standard of care' under very austere circumstances."

Putting a fine point on it, Dr. Born states, "The medical legacy of this disaster is the musculoskeletal injury. There were so many amputations for injuries that under normal circumstances would have been treated differently. Thus, after the dust settles, there will be a cross generational component of the population who have lost limbs. This is a particular economic issue in Haiti because most people earn a living through manual labor."

## Preparing for Disaster

As Dr. Born made his way through the trauma of Haiti, one resounding message ran through his head… prepare. "Everything comes down to planning and organization. While you

cannot be ready for every eventuality, you are best off with some kind of preexisting plan for which you have drilled. And in any disaster you must have a chain of command with the appropriate person in charge. There should be clear delineations between who will be delivering the care, who will be handling logistics, etc. You don't want to send surgeons out foraging for water."

"The U.S. is in great need of a system that includes precredentialed individuals to respond quickly in disasters. But it is difficult to move through the government bureaucracy to develop a database of qualified people. Finding government entities and/or individuals to work with who will sidestep politics is a problem."

"Having experienced logistics people on board is invaluable," adds Dr. Born. "The people handling this for us were EMS personnel and firefighters, and they seemed to be able to troubleshoot anything. The generator went down, and they fixed it; we ran out of oxygen, and they figured out how to get it locally and brought it into our system."

Even someone experienced with disaster response can be jolted.

> *"I was unprepared for the depth and breadth of the devastation and sheer numbers of people. The death toll is likely around 200,000, with approximately 250,000 injuries. That level of destruction puts it at the top of all earthquakes in the last 70 to 80 years. Think about this…it was not just a small town that was destroyed…it was the capital. The devastation to the infrastructure is incalculable."*

"You block all of this out while you are working, though, and think about it later. When we arrived back in the U.S., we were debriefed by the U.S. Public Health Service. They were clear that help was available if we had any medical or psychological issues."

Lives will be saved, says Dr. Born, when all parties are willing to pull together. "We need to continue to develop an integrated disaster response system that includes the government, NGOs and private citizens who have valuable skills that can be rapidly mobilized in a coordinated fashion.

For disasters involving large numbers of musculoskeletal injuries, industry partners must also be involved. Finally, integrating all of this with the military for transportation, security and logistical support is imperative."

Dr. David Helfet, whose team was on the ground in Haiti within four days of the earthquake, couldn't agree more.

> *"While the U.S. has been remarkable in its response, the medical relief has been tremendously disorganized. If we have another devastating hurricane or earthquake, there is no organized mechanism to rely on. We have a very clear, tailored response to a nuclear issue…why not one for natural disasters or terrorism?"*

## Offering Aid With Private Funds

The earthquake struck Tuesday evening—by Wednesday morning Dr. Helfet had secured a commitment of staff and supplies from both HSS and New York Hospital. "I also contacted the Chair and CEO of Synthes, who said, 'We'll give you whatever you need.' They generously provided their company jet to get all 12 of us to Haiti. Despite contacting one of President Clinton's advisors about a landing slot, we had trouble. The Thursday slot was cancelled; we got one for Friday, but were denied access by Haitian air control…there was no one in charge."

Landing in the Dominican Republic Friday, Dr. Helfet and his team eventually flew into Port au Prince Saturday. "After circling the airport for three hours, we landed and were met

by Partners in Health, who brought us six SUVs and an armed guard. The first facility we went to was the main public hospital of Haiti (in Port au Prince). There were approximately 1,000 patients at the hospital, with about 1,000 bodies lying behind the hospital. Along with the evidence of decay and death, the hospital had no electricity or water, while the OR consisted of a plywood table in a storeroom. I quickly decided that this was not going to work."



"We located a community hospital with a similar amount of patients, which was in better shape—they had two ORs, electricity, and occasional water. (Saline was rationed—normally we would use nine 9 liters for lavage, but we cut that to one liter per patient)."

These doctors had to make quick, tough decisions. Dr. Helfet: "Working 20 hours a day for four days, we did over 100 cases. Along the way we were essentially playing God in deciding who received treatment when. The team agreed that children would be treated first. The following day, a plane came with more supplies, but somehow, between the airport and our hospital our supplies disappeared. There was no security, we began running out of supplies, and there were no Haitian police in sight. Patients were angry because we could not help them, and it was clear that the situation was deteriorating. The team left on a Canadian charter plane, depressed, and knowing that we had left the job unfinished."

In such a crisis, says Dr. Helfet, you need a General Patton. "I traveled to Istanbul in 1999 to help with the earthquake relief effort. Two days into that disaster they got over the 'government versus military' issue, declared a national disaster, and gave the military total control. We should take a lesson from that…any disaster plan should be under the control of the military with a top notch leader in charge."

Recalling the images from Haiti, Dr. Helfet notes, "No one had control of the streets, which of course is going to lead to supply issues. If the Haitian government had temporarily relinquished sovereignty in exchange for all the resources it was receiving, things could have gone much more smoothly."

Dr. Helfet, who has put his mission on hold until the team can be part of an umbrella organization, states,

> *"You just can't go in alone. It's inefficient, distracts from the work, and is potentially dangerous. The government needs to spearhead an effort to create an organized central command dedicated to relief."*

> *"What, after all, did we learn from Katrina?"*

company news

## Alphatec Scient'x Merger Nearing Completion

A key condition for closing the acquisition of Scient'x by Alphatec has been met. The Hart-Scott-Rodino (HSR) review period has expired with no action by the United States Federal Trade Commission (FTC). That, in turn, sets up March 16th as the date for the special shareholder's meeting to approve issuance of shares to purchase Scientx. Shareholder's of record as of February 9, 2010 are eligible to vote.

Alphatec's management is proposing to issue 24 million shares of common stock, which as of last Friday, was priced at $5.11 per share for a total price of $123 million. Alphatec is purchasing Scient'x with, in effect, 46% of its current voting shares outstanding and, post transaction, will have issued 31% of its total voting shares.

The combination of the two firms has been proceeding quickly. From announcement (last December 17th) to special shareholder meeting (March 16th), just under three months will have passed. The purchase is an all stock transaction and when it's completed, Alphatec will own 69% of Scient'x. The remaining 31% will be held by Scient'x current shareholders.

Combined, the two companies should be generating approximately $187 million in annual revenues and be distributing products into more than 50 countries. Scient'x brings to Alphatec approximately 250 sales

Alphatec'x
Dynamic Solutions for the Aging, Global Spine

reps worldwide, 75% of which are exclusive. Scient'x is the #2 spinal implant company in France and the fifth largest overall in Europe. Clearly, Alphatec CEO Kuyper is eyeing all the new markets he can use for his growing line of innovative spinal implant products.

*—RRY (February 27, 2010)*

## NuVasive Sales Jump 43%. Stock Soars

NuVasive, Inc. reported on February 25 that sales for the full-year ended December 31, 2009 jumped 43%, which was higher than management had previously guided and higher than consensus Wall Street estimate.

For the fourth quarter, NuVasive reported that sales of its spinal implants and biologic products had reached $106.9 million, up 43% from the same period a year earlier and higher than analysts expected by about $4 million. In absolute terms, NuVasive increased overall sales by $32.3 million from the prior year.

## company news

For the full year 2009, NuVasive shipped $370 million in spinal implants and biologic products. That was a whopping 48% increase from the full-year 2008 results and also slightly higher than the analysts' expected target of $367 million. In absolute terms, NuVasive added $120 million in new sales.

In commenting on the year's performance and the year ahead, NuVasive Chairman and CEO, Alex Lukianov, said, "We achieved outstanding revenue growth of nearly 50%, a record non-GAAP operating margin of approximately 13% and more than $45 million in operating cash flow in 2009. We look forward to 2010 as the next step in NuVasive's evolution toward the #4 global spine company with $1 billion in revenue with even stronger profitability." In terms of market share in the spinal product industry, NuVasive is currently the #5 company behind Medtronic, Inc., DePuy Spine, Inc., Synthes, Inc., and Stryker Spine.

Looking ahead, Lukianov said that he expects sales will rise 30% to 35% for the full-year ending December 31, 2010 to reach $480 million to 500 million. The company's stock price remained almost the same on the day of the announcement (a $0.35 or 1% increase), but jumped $10.31 or 34.73% on February 26, the day after the announcement. Analysts commenting on stock prices said the jump was due to the fact that Aetna Inc., a San Diego insurance company, changed its policy to include coverage for anterior interbody fusion with NuVasive's XLIF device.


For a comprehensive update on the spine product industry at the close of 4Q09, keep reading next month for *OTW's* report from Matt Menze, PearDiver Technologies Senior Analyst.

*—DK (February 26, 2010)*

## biologics

### Augment: Final PMA Module Submitted

Champagne all around… BioMimetic Therapeutics, Inc. has submitted the third and final module of its Premarket Approval (PMA) application for marketing of Augment Bone Graft in the U.S. This module contains a comprehensive review of the clinical data related to Augment.

In June 2009 the company filed the pre-clinical pharmacology/toxicology and quality/manufacturing modules with the FDA. Now the FDA begins its 45-day filing process as the first

biologics

*Niklas Bildhauer / Wikimedia Commons*

step in the formal review of the PMA. BioMimetic expects the agency to schedule an advisory panel review sometime later in the year.

"The Augment PMA submission is an important milestone for BioMimetic and our commitment to advance first-in-class, innovative biologics that stimulate tissue regeneration in bone, ligaments and tendons," said Dr. Samuel Lynch, President and CEO of BioMimetic Therapeutics, in the news release. "We are very encouraged by the results seen to date in Augment's clinical development program and look forward to working with the FDA to facilitate the review and approval of this novel therapeutic."

Providing background on the data, Dr. Lynch told *OTW,* "In October of 2009, BioMimetic Therapeutics released positive top-line data from its Augment Bone Graft North American pivotal trial comparing the company's fully synthetic, off-the-shelf bone growth factor product to autograft for use in hindfoot and ankle fusion surgery. The results demonstrated non-inferiority to autograft, which was the primary study goal. For the primary endpoint, the percent of subjects achieving fusion as defined by 50% or greater bone bridging on CT scans at 24 weeks, patients treated with Augment experienced a similar fusion rate (61.2%) compared with those receiving autograft (62.0%), which met non-inferiority (*P*=0.037; n=397 patients). Since many patients had multiple joints treated, analysis was also performed on a per joint basis. Non-inferiority was also established on a per joint basis, with 66.5% of joints treated with Augment fused on CT scans compared to 62.6% of joints treated with autograft (*P*=<0.001; n=597 joints)."

He also commented to *OTW,* "These positive top-line results indicate that, with the use of Augment, patients can expect a comparable treatment outcome while being spared the pain and potential morbidity associated with traditional autograft bone harvesting and transplantation. We have now submitted the PMA application to the FDA and look forward to working with them to facilitate the review and approval of this novel therapeutic. We believe we have prepared and submitted a strong package for the FDA's review. Of course the schedule of the upcoming panel meeting is determined by the agency, but we do expect it to be scheduled for later this year with product approval in early 2011."

*—EH (February 23, 2010)*

## New Stem Cell CLI Data

Last Week Aastrom Biosciences released interim results and analysis from the company's multi-center, randomized, double-blind, placebo-controlled U.S. Phase 2b clinical trial to measure the effects of autologous stem cells in patients with critical limb ischemia (CLI).

CLI is the result of a severe obstruction of the arteries and decreased blood flow to the extremities (hands, feet and legs) and

biologics

has progressed to the point of severe pain, skin ulcers or sores. Most patients who present with CLI have one or more of the following conditions:

- Pain or numbness in the feet
- Shiny, smooth, dry skin of the legs or feet
- Thickening of the toenails
- Absent or diminished pulse in the legs or feet
- Open sores, skin infections or ulcers that will not heal
- Dry gangrene (dry, black skin) of the legs or feet

The incidence rate of CLI is increasing in the United States as a result of the general aging of the population but is accelerating due to ever rising cases of diabetes, obesity, high cholesterol and high blood pressure. Approximately 1 million patients in the U.S. have CLI and approximately 160,000 patients endure an amputation each year from CLI.

Aastrom's interim data from its RESTORE-CLI trial showed, first, that using the patient's concentrated progenitor cells was safe. Specifically, the safety profile was similar between the treatment and placebo arms. Second, the interim data showed that, in terms of the study endpoint of assessing time to treatment failure (including major amputations, wound size and gangrene), Aastrom's autologous vascular repair cells (VRCs) were more effective than placebo (P<0.05).

*Photo courtesy of: Geschwür am diabetischen Fuß eigenes Foto 2007-01-06 Papa1234*

There were 46 CLI patients in the trial who had at least 6-month follow up, including 33 patients who went out for 12-month follow up.

This is the largest blinded, randomized cell therapy study currently being conducted for CLI. With this good safety and efficacy data, the company concluded enrolling new patients and will complete the study as soon as possible. Aastrom is now turning to planning the pivotal trial and further conversations with the FDA.

Aastrom's other endpoints in the trial (e.g., major amputation rate, complete wound closure) approached but did not reach statistical significance at interim analysis.

CLI is typically identified as the end stage of peripheral arterial disease. People with CLI face a high risk of amputation and in some cases death. Approximately 1 million patients in the U.S. suffer from CLI. The disease results in more than 160,000 amputations each year.

## biologics

"Based on these results, we can now move ahead with plans to advance this program into Phase 3 clinical testing," said Tim Mayleben, President and CEO of Aastrom. "We look forward to presentation of the full data at an appropriate medical meeting and initiating the next phase of testing as soon as possible."

*—RRY (February 27, 2010)*

## extremities

### Compression Socks for DVT

Pick up your socks…and put 'em on. Ames Walker International, manufacturer of graduated support hosiery, diabetic shoes and socks, and accessories, is drawing attention to the problem of deep vein thrombosis (DVT), a potentially fatal blood clot that can form in the lower leg. Physicians often recommend wearing graduated compression products, which, when applied to the lower extremities, accelerates the velocity at which the blood flows through the deep veins placing the greatest compression at the ankles.

As indicated on the American Academy of Orthopaedic Surgeons web site, "The risk of developing DVT extends for at least three months after joint replacement surgery. The risk is greatest two to five days after surgery; a second peak development period occurs about 10 days after surgery, after most patients have been discharged from the hospital."

*Microfiber Firm Support Travel Socks*
*Ames Walker International*

"A silent killer is among us," said John Mauriello, MD, FACPh, American College of Phlebology President-elect, in the news release. "It is a disease that the population in general needs to take more seriously. For many, this illness can strike without warning because the symptoms are difficult to detect or thought of as minor leg pain and ignored."

Commenting on what orthopedists should know about DVT, Dr. Mauriello told *OTW,* "Along with anticoagulant therapy, leg compression and ambulation is better than bed rest for the treatment of acute deep vein thrombosis. This can help reduce pain and swelling as well as slow clot progression. This can also have beneficial longer-term effects such as helping to prevent the development of post-thrombotic syndrome."

Ames Walker offers its Microfiber Firm Support Travel Socks, as well as a new patient resource, A Lighter Vein—a blog which offers news, expert insight and information about leg health and the benefits of compression socks. Patients can also access the "Ask a Doctor" feature to find answers to any leg/vein healthy concern.

*—EH (February 26, 2010)*

### Distal Radius Fractures: New Guidelines

An (evidenced based) hand up for those who have fallen… The American Academy of Orthopaedic Surgeons (AAOS) has just released an evidence-based clinical practice guideline on the treatment of distal radius fractures (DRT). This common fracture usually occurs as a result of a fall.

The physician volunteer work group examined more than 4,000 journal articles. Only prospective, randomly controlled clinical trials with enough patients to establish clinical and statistical significance could earn the highest grade.

"The Academy created this clinical practice guideline to improve patient

extremities

*Displaced Distal Radius Fractue/Wikimedia Commons*

care for those sustaining a distal radius fracture," stated David Lichtman, M.D., chair of this guideline workgroup, in the news release. "This serves as a point of reference and an educational tool for both primary care physicians and orthopaedic surgeons, streamlining possible treatment processes for this ever-so common problem," he added. "While a wide range of treatment options are available, they should always be tailored to individual patients after discussions with their orthopaedic surgeons."

Some of the 29 evidence-based recommendations are:

- The research suggests that a rigid cast is better than a splint if the fracture was displaced.
- If a fracture was not displaced—as in a hairline crack—a removable splint can be worn.

Due to the current studies lacking evidence-based support the group suggested that DRTs treated without surgery should have repeated X-rays for three weeks and when the use of a splint or cast is discontinued. Also, patients should perform active finger motion exercises following diagnosis of DRT. Finally, they advise patients with distal radius fractures and unremitting pain to be re-evaluated promptly by their physician.

Concerning evidence-based information, Dr. Lichtman told *OTW,* "There are reasons, of course, that reliable evidence for surgical treatment is generally lacking. The logistical difficulties and ethical concerns in conducting placebo-controlled studies of operative interventions compromise the reliability of these studies. To improve the reliability of future studies of operative treatments, the use of active, non-placebo control groups should be considered. Investigators should develop rigorous patient inclusion criteria to ensure that patients that typically receive the surgical intervention in clinical practice are adequately represented in the study population."

When asked about future research, Dr. Lichtman commented to *OTW,* "High quality trials that we would like to see addressed in the future include studies to better define the minimally

## extremities

clinically important improvement (MCII) in an upper extremity specific disability measure for patients recovering from a fracture of the distal radius. This MCII will be the basis for power calculations for clinical trials addressing methods of treatment for fractures of the distal radius. Also, prospective randomized clinical trials comparing operative treatment with non-operative treatment, separating articular and non-articular fractures, and separating older, infirm, low demand patients from younger, active patients. Consideration should be given to whether withholding operative treatment in younger, active patients in whom comparative effectiveness trials might be more appropriate, is ethical."

*—EH (February 26, 2010)*

## large joints

### Group Therapy for Arthritis Fears?

Talk about pain…German researchers, in a controlled study, set out to determine if brief group psychotherapy would help eliminate fears of disease progression (FoP) in patients with chronic arthritis or cancer. The work, published in the current issue of ***Psychotherapy and Psychosomatics,*** involved either cognitive-behavioral group therapy or supportive-experiential group therapy.

*Lakota Storyteller / Wikimedia Commons*

A total of 174 chronic arthritis patients, along with the same number of cancer in-patients, were randomized to receive one of the two interventions. The patients provided data before intervention, at discharge, and at 3 and 12 months of follow-up. FoP was the primary outcome; secondary outcomes were anxiety, depression and quality of life. A control group provided data on the primary outcome.

The investigators found that patients with chronic arthritis indicated higher levels of FoP than cancer patients. The results revealed that, compared with no specialized intervention, both group therapies were effective in reducing dysfunctional FoP, but only among cancer patients. The interventions were not differently effective in reducing the secondary outcomes.

Professor Peter Herschbach, the study's lead author, told *OTW,* "Orthopedists should be aware of the importance of the fear of disease progression (as a main source of distress) and talk about that with their patients."

*—EH (February 22, 2010)*

### IOF: Record Number of Abstracts

Those carrying the torch of osteoporosis knowledge are flocking to Florence this year. According to the International Osteoporosis Foundation (IOF), more than 850 abstracts have been received for the 2010 meeting, to be held in the center of Florence, Italy, from May 5 - 8, 2010.

An expected 5,000 researchers and clinicians from around the globe will have access to clinically focused Meet-the-Expert Sessions, restricted in size for maximum interaction between lecturers and participants.

Providing details on these sessions was Professor Cyrus Cooper, IOF Chair of Scientific Advisors, who told *OTW,* "These sessions are among the most popular aspects of the scientific programme. In Florence, they'll cover 19, primarily clinically oriented topics, including several of specific interest to orthopaedists. The sessions are led by the world's top international experts with a restricted number of attendees to offer opportunity for informal discussion. Attendees are encouraged to ask questions and to provide feedback about their own experiences."

Other topics to be covered include:

- Assessing Fracture Risk: The Future for Designing New Therapies;
- Growth and Development of the Skeleton;

large joints


*Manuscript Book mural in Evolution of the Book series, John White Alexander/Wikimedia Commons*

- Subtrochanteric Fractures After Long-Term Use of Bisphosphonates;
- Rare Bone Disorders: Impact in Drug Development, among others.

As for the large number of abstracts, Professor Cooper told *OTW,* "The IOF WCO-ECCEO 10 meeting is regarded as one of the premier osteoporosis meetings in 2010 and this is one reason why we have attracted a record number of abstracts this year. It will be an excellent opportunity to showcase research from young scientists as well as experienced clinicians. We have developed a really diverse and exciting programme that is attractive to many of the disciplines in the bone arena-from orthopaedics and radiology, right through to rheumatology, geriatrics, endocrinology, nutrition and science."

*—EH (February 25, 2010)*

# The Picture of Success: Dr. Mininder Kocher

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


A child is not a little adult—and a general orthopedist isn't a pediatric sports medicine specialist. But Dr. Mininder Kocher, Associate Professor of Orthopedic Surgery at Harvard Medical School, is.

Born in Rochester, New York, there was no getting around science in this family. "My parents, originally from India, came to the U.S. in the 1950s to pursue their education. My dad, a professor of thermodynamics, and my mom, an elementary school teacher, pushed hard in terms of education and were especially interested in seeing me pursue the sciences. I spent time in my dad's lab when they were doing early computing work. We ended up designing a Pinewood Derby car on the computer, building it with his lab guys, and even testing it in their wind tunnel. I'm proud to say there was not a right angle on that thing."

Instead of thermodynamics, however, a young Minider Kocher approached the sciences from a different angle.

"It almost seems de rigeur for orthopedists to have suffered an injury in their youth. In keeping with this, yes, I tore my meniscus in high school, which led to my first exposure to medicine. The famed Dr. Ken DeHaven at the University of Rochester performed my surgery and stoked my interest in orthopedics. I thought it was amazing that a patient could injure something and lose something so important to them—in my case, basketball—and then have a competent person do an exam, determine what's going on, and then just fix it. They make it possible for you to regain what you lost."

## Finding His Groove in Medical School

After regaining the ability to play basketball and then attending Dartmouth as an undergrad in the same fraternity as Ken DeHaven, Mininder Kocher then headed to Duke University. "Not only did I revel in the OR, but under the guidance of Dr. John Feagin, I became amazed by the form and function of the knee. Dr. Feagin arranged for me to do a rotation in Jackson Hole, Wyoming, where he was running a ski clinic. It was thrilling to see the knee injuries right as they came off the mountain, and then learn from Dr. Feagin exactly how to do a thorough physical exam."

And what was the primary takeaway from Dr. Feagin? How to take down the walls. "To this day I use Dr. Feagin's suggestions about how to put patients at ease. It really helps

to distract them by talking about something that matters to them…that way their body/knee/shoulder relaxes and you can do a better exam. He also rightly stressed the importance of the pivot shift exam in measuring rotational instability."

For all of the science floating around him, selecting a specialty was anything but scientific. It had to do with jumping…for joy, that is. "After finishing medical school in 1993, I headed to the Harvard Combined Orthopaedic Residency Program, where I rotated through Massachusetts General, Brigham and Women's, Beth Israel and Children's Hospitals. My main sports medicine interest was the knee—until I rotated at Children's with Dr. John Hall. I was in awe of taking care of children, and my wife confirmed my enthusiasm when she said, 'Have you noticed that you jump out of bed in the mornings when it's time to go to Children's Hospital?'"

But knees made him jump as well. "I was in a quandary because I liked pediatric orthopedics and sports medicine. It was Drs. Jim Kasser and Lyle Micheli, both of Children's Hospital Boston, who made me realize I could do both. So I stayed at Harvard for an extra year, became chief resident, and did a fellowship in pediatric orthopedics. The fellowship gave me a solid understanding of pediatric orthopedics, as well as growth and development. It was becoming clear that if I wanted to do pediatric sports medicine I needed to have credentials within both disciplines."

And what better place to acquire the sports medicine credentials than Vail's Steadman-Hawkins Clinic? Dr. Kocher: "During my time at Steadman-Hawkins I developed arthroscopic skills and gained great insight into how to interact with patients. That experience cemented my interest in pediatrics and adolescent sports, and I was very excited to take emerging technologies and bring them to kids and adolescents."



## Leading the Field

Given the trends in youth athletics, he might even be using that emerging technology on a seven year old. "In prior years we thought that children didn't get major injuries, but that is changing. I do 675 operations a year, most of which are pediatric and adolescent patients. Youth sports have really changed as children are now playing with greater intensity and are physically bigger. Another shift is that kids are focusing on a single sport now, sometimes by middle school. They play one sport all four seasons, which has meant a skyrocketing injury rate…it's actually three times higher at games than at practices. While the old paradigm was a Michael Jordan who crosstrained in three sports, we now have a Tiger Woods paradigm where you take a three year old and have him or her focus on one thing."

Go ahead, Johnny…you can do it. "Yes," says Dr. Kocher, "much of this solo sport issue is parent driven. He jokes,

> ***"I see about 120 patients a week and 119 of those are 'elite' athletes. I say to these parents, 'Look, I care about your child getting back to play, but we need to think about what he or she is going to be like five years from now.' Usually I can get parents to get on board with longer term thinking."***

Backing him up in these and other conversations is his extensive knowledge of epidemiology. "While in residency, Dr. Matt Liang, a rheumatologist-researcher at Harvard, got me interested in clinical research methods that weren't being used in orthopedics, namely prospective cohort studies, decision analysis and survivorship analysis. I began to take classes toward a masters degree at the Harvard School of Public Health, and focused on developing a prediction rule for the irritable hip in children to differentiate between septic arthritis and transient synovitis. Not only did

this work get me hooked on clinical research, but it was published in the *Journal of Bone and Joint Surgery* and won the Kappa Delta award."

Toe, tap, or tackles, Dr. Kocher is ready. "I am happy to have participated in the growth of our sports medicine division. This, the first pediatric sports medicine program in the US, was established by my partner, Lyle Micheli in 1974. We now have five orthopedic surgeons, 10 primary care sports medicine doctors, two sports podiatrists, a sports nutritionist, a sports psychiatrist, and three physician assistants. We manage to cover 50 high schools in the Boston area, several colleges, and organizations like the Boston ballet and USA Track and Field. In part we are able to do this because of our three fellows. They are part of our one year, combined sports medicine program that is focused on pediatric sports medicine. It is approved by the Accreditation Council for Graduate Medical Education and each year receives approximately 100 applications."

## Advice for Aspiring Physicians

For those interested in emulating such a path, Dr. Kocher advises, "It is vital to get the message out that young athletes are different than adult athletes. To do this you should be prepared to give ongoing presentations to other medical professionals, as well as parents. As for the structure, it is important to have the service be not just sports trauma surgery, but to be multidisciplinary within sports medicine. For example, we have a concussion clinic, a bone clinic, and a young adult female clinic, among other offerings. Orthopedic sports medicine groups tend to focus on surgery, but some are starting to have primary care doctors—a good thing because they are integral to things like patellofemoral pain and overuse injuries."

"Some of my other work involves looking at outcome instruments that are used in adults and adolescents, but not validated in adolescents. Interestingly, we have found that kids often don't understand the questions (the terms catching or locking, for example). I'm doing this work through the International Knee Documentation Committee of the American Orthopaedic Society for Sports Medicine (AOSSM); we will present our findings at AAOS this year."



There are advocates for slow food and slow living…Dr. Kocher champions slow orthopedics.

> ***"My team and I are involved in randomized trials of supracondylar elbow techniques, i.e., casting versus pinning. In addition to the cost challenges, it is hard to get patients to participate because they are not interested in being randomized. Another major issue is time…in this field we are adopting new technologies at a faster rate than we can document their effectiveness. In the middle of our randomized femur fracture trial there suddenly appeared new ways of fixing femur fractures. It is hard to keep up…and not necessarily good for patients either."***

On the society front, Dr. Kocher serves on the board of the American Orthopaedic Society for Sports Medicine and the Pediatric Orthopaedic Society of North America, and was elected as a member of the Herodicus Society. "Herodicus is a unique sports medicine think tank. So many meetings we attend involve presenting things, but this organization allows us space to discuss a concept or a problem. For example, now double bundle ACL reconstructions are a hot topic… six years ago the Herodicus members were talking about it in conceptual form."

And while his family is a hub of sustenance, it's not a source of

repose. "My wife Mich and I met on a Dartmouth biology study program in Costa Rica in which we lived in tents for four months. Our adventures only continued from there, as she went to Duke and obtained a masters in civil engineering and we went on to have five children: an 11 year old girl, a 10 year old girl, a 7 year old boy, a 5 year old girl, and a 9 month old boy. In the winter 'team Kocher' goes to the slopes where my wife, a former ski racer, engages in her passion. We also love taking the kids kayaking, hiking and camping."

"My activities are a bit more limited nowadays as I tore my achilles tendon two years ago and suffered a shoulder injury last year. These injuries meant that I had to stop playing adult league basketball; I do coach now, however."

Dr. Mininder Kocher…forging new paths for children.

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