Podcast Feature

Courtesy: 2013 Spine Technology Awards

THE TEN BEST NEW SPINE TECHNOLOGIES FOR 2013

Robin Young • Sun, November 10th, 2013

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The winners of the 2013 *Orthopedics This Week* Best New Technology award for spine are Benvenue Medical, Inc., Globus Medical, Inc., Johns Hopkins University/Siemens Healthcare, AFcell Medical, Inc., Orthozon Technologies, LLC, OsteoMed, Paciera Pharmaceuticals, Inc., PhDx Systems, Inc. and Trakya University in Turkey.

This annual award rewards inventors, engineering teams, surgeons and their companies who've created the most innovative, enduring and practical products in 2013 to treat back pain. To win the *Orthopedics This Week* Best New Technology for spine care, a new technology must meet the following criteria:

1. Be creative and innovative.
2. Have long-term significance to the problem of treating the diseases of the spine. Does this technology have staying power?
3. Solve a clinical problem. To what extent does this technology solve a current clinical problem or problem that is inadequately solved today?
4. Does it have the potential to improve standard of care?
5. Is it cost effective?
6. I would use it.

Our panel of surgeons scores every submission on a scale of 1 to 5 (5 being the highest score) for each of the above criteria.

We and our panel of surgeons were impressed that inventors—despite ever growing hurdles to innovation and entrepreneurism in spine—still managed to create a solid group of more than 40 new products to submit for the 2013 *Orthopedics This Week* Spine Technology Awards.

We offer our thanks and deep appreciation to the engineering teams, surgeon inventors and the following companies for submitting their best ideas this year:

Aesculap, Inc.
Aspen Medical Products, Inc.
Aurora Spine Corporation
AFcell Medical, Inc.
Benvenue Medical, Inc.
Biomet, Inc.
Expanding Orthopedics, Inc.
Globus Medical, Inc.
J2 Medical, LP
Johns Hopkins University/Siemens Healthcare
K2M, Inc.
Lanx, Inc.
Medacta Internatinal SA

Medtronic, Inc.
NLT Spine
Orthofix Biologics/MTF
Orthozon Technologies
Osseon Therapeutics, Inc.
Osseus Fusion Systems
OsteoMed Spine
Pacira Pharmaceuticals, Inc.
PhDx Systems, Inc.
Prism Surgical Designs Pty, Ltd
Thompson MIS
Trakya University, Edirne-Turkey
Vertebral Technologies, Inc.

Our intrepid and detailed panel of surgeon judges were:

- **Dr. Thomas Zdeblick:** Dr. Zdeblick is the chair of the Department of Orthopedics and Rehabilitation and a member of the faculty at the University of Wisconsin School of Medicine and Public Health.
- **Dr. Daniel Riew:** Dr. Riew is the Mildred B. Simon Professor of Orthopedic Surgery. Dr. Riew is a professor of neurological surgery and Chief of the Surgical Spine Center and Director of the Cervical Spine Institute at the Washington University School of Medicine.
- **Dr. Sigurd Berven:** Dr. Berven is Associate Professor in Residence at the University of California, San Francisco. Dr. Berven is a prolific researcher and clinician with particular interests in pediatric and adult deformity, degenerative conditions of the spine, spinal tumors and spinal trauma. He is also at the forefront of investigating biological regeneration technologies.
- **Dr. Alex Vaccaro:** Dr. Vaccaro is a Professor and Attending Surgeon of Orthopaedics and Neurosurgery at Thomas Jefferson University Hospital and a partner at the Rothman Institute in Philadelphia, Pennsylvania. He is the Vice Chairman of the Department of Orthopaedics.
- **Dr. Stephen Hochschuler:** Dr. Hochschuler is one of America's leading spine experts and co-founder of the Texas Back Institute and Chairman of the Board of TBI Holdings, Inc. Dr. Hochschuler has published numerous research papers in international spine journals and is past-president and board member of the Spine Arthroplasty Society.

So, without further delay, here are the ten best new spine technologies for 2013 arranged in alphabetical order by category:

Category: Biomaterials, Biologics and Pharma

Two Winning Technologies

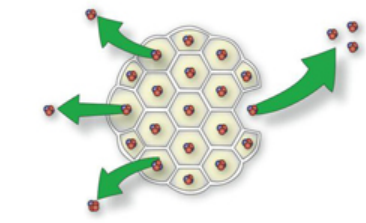
EXPAREL
Company: Pacira Pharmaceuticals, Inc.

Description: EXPAREL is a new, single administration drug (a liposomal formulation of bupivacaine) which reduces post-operative pain and opioid requirements up to 72 hours. EXPAREL's formulation is flexible which means it can be used across either minimally invasive small incisions or larger open incisions.

Kimberly Wilkinson and Robin Young

Traditional bupivacaine HCl only provides up to 8 hours of non-opioid analgesia while EXAREL, which encapsulates the bupivacaine in DepoFoam, lasts up to 72 hours.

DepoFoam is a matrix of microscopic aqueous chambers that encapsulate the bupivacaine without altering its molecular structure and then releases it over time.



Opioids are highly effective analgesics but they come with a range of potential adverse events. Studies show that the worse postsurgical pain occurs 24-48 hours post-op. Since EXPAREL lasts up to 72 hours, patients can begin their recovery process with less pain and reliance on opioid rescue medication. Also, there's no need for catheters, pumps, or other external delivery devices when using EXPAREL.

EXPAREL has been used in many spine procedures including lumbar, cervical and interbody fusions; microdiscectomies; and laminectomies. Patients receiving EXPAREL have demonstrated decreased pain scores, opioid use, and PACU time, as well as faster discharge readiness. Some

early adopters have converted their standard of care for postsurgical pain from PCA (IV opioid administration) for their opioid-naïve postsurgical patients.

AmnioClear Amniotic Tissue Allograft
Inventors / Engineers: Alex Canonaco and Howard Wolek
Company: AFcell Medical, Inc. and MTF

Alex Canonaco, David Buche and Robin Young

Description: AmnioClear is a graft collagen sheet of human placental tissues which may be placed over the surgical site to cover and protect it during healing. The patent-pending tissue graft technologies provide surgeons with a unique placental collagen three-dimensional matrix that is a superior covering for the surgery site.

Because of the unique form of placental collagen matrices and the particularly high levels of endogenous proteins and beta defensin peptides, the grafts are able to transfer many of the same protective capabilities of the placenta to the surgical site.

Recent advances in understanding the biologic mechanisms of action underlying tissue growth and differentiation (i.e., stem cells and other progenitor biologics), scientists have been able to unravel the mechanisms of action surrounding fetal development and the critical role that placental material plays in ensuring that the fetus is protected from external threats such as infection or maternal rejection.

In human studies, the method used to process and deliver AmnioClear has resulted in a more effective and natural covering than bovine, porcine or polymer based synthetic coverings. In a canine laminectomy model, animals treated with amnion tissue coverings had reduced post-operative fibrotic scarring.

Important Note: I'm the founder of AFcell, which created an obvious conflict of interest. That relationship had no bearing, I think, on scoring. The judges are independent surgeons with zero financial or other interest in RRY publications. And each judge is very independent and objective. All are volunteers—there is no compensation. Finally, I don't ever learn the scores until all judges have voted and the results are compiled by a third party.

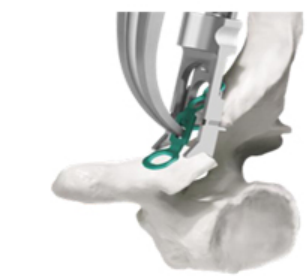
Category: Cervical Care

One Winning Technology

CANOPY Posterior Decompression System
Inventors / Engineers: John Suh
Company: Globus Medical, Inc.

(Left to right) Scott Stanton, Kelly Quick, Robin Young, Jason Cianfrani, Sean Cranston

Description: The CANOPY Laminoplasty Fixation & Posterior Decompression System uses spinal fixation plates and screws in laminoplasty procedures. CANOPY implants, which come in various sizes and geometric options, are inserted through a posterior cervical or thoracic approach. Surgeons can use CANOPY's fixation plates with bone graft material. They may also use the hinge plates to stabilize weakened or displaced lamina. The system's screws, which are used to attach the plates to bone, are available in a variety of lengths and diameters. CANOPY also offers graft chambers in radiolucent polymer.



CANOPY is intended for use by the surgeon in the lower cervical and upper thoracic spine (C3 – T3) for laminoplasty procedures. It can hold bone allograft material in place in order to prevent the allograft from expulsion or impinging the spinal cord. CANOPY is a comprehensive posterior decompression system and provides the surgeon with a variety of plate options including a polyaxial screw hole plate design which enables the connection of a screw and rod system. This helps to preserve the posterior elements, protecting the canal and leaving the interspinous ligaments intact, for stability and to help promote fusion through traditional fixation.

Category: Diagnostics and Imaging

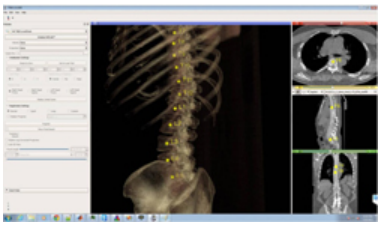
One Winning Technology

Automatic Labeling of Vertebrae in Intraoperative Images Using *LevelCheck*: A Tool against Wrong-Level Spine Surgery
Inventors / Engineers: Y. Otake, J.H. Siewerdsen, A. J. Khanna and Z. Gokaslan (Johns Hopkins University, Baltimore, Maryland); G. Kleinszig and S. Vogt (Siemens Healthcare, Erlangen, Germany)
Company: Johns Hopkins University/Siemens Healthcare

(Left to right) A. Jay Khanna, M.D., Gerhard Kleinszig Dipl. Ing., Robin Young

Description: "LevelCheck" reduces the risk of wrong-level surgery, improves clinical workflow, and reduces the time and cost for the preoperative process by offering an independent check using intraoperative fluoroscopy.

"LevelCheck" is based on a robust geometric alignment of preoperative 3D images and intraoperative 2D images and is possible because of recent advances in high-speed computing. With LevelCheck, the surgeon can accurately localize any structure defined in the preoperative 3D image using intraoperative fluoroscopy. LevelCheck operates without any additional tracking or navigation equipment and can compute registration in as little as 1 second.



Wrong-level surgery (subject to variation and possible under-reporting) occurs, according to some analysts, once in every 3,110 spine surgeries, implying that approximately 50% of spine surgeons will encounter a wrong-level error at least once in their career, with an approximate monetary cost of $55,000 per case according to The Joint Commission.

The challenge in spine level localization arises from the difficulty of correctly identifying target vertebrae in the radiographic/fluoroscopic scene and/or via direct visualization. Despite preventative measures in the current standard of care, the incidence of wrong-level surgery persists as the second-most common category of wrong-site surgery. LevelCheck corrects that while also reducing time and cost.

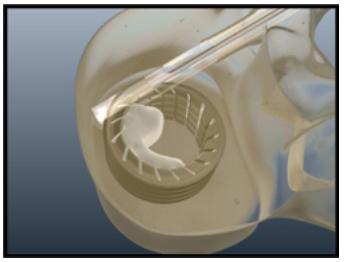
Category: Minimally Invasive Spine Care

Five Winning Technologies

Kiva VCF Treatment System
Inventors / Engineers: Laurent Schaller, Steve Golden, Ryan Connelly, Jeff Emery, Tim McGrath, James Lee
Company: Benvenue Medical, Inc.

(Left to right) Robert Weigle, Laurent Schaller, Eric Gilbert, Robin Young

Description: The Kiva VCF Treatment System is a new treatment of painful vertebral compression fractures (VCFs). The Kiva VCF system features a proprietary flexible implant made from PEEK-OPTIMA. Kiva functions as a mechanical support structure and a reservoir to direct and contain the flow of bone cement. It is delivered percutaneously in a continuous loop into the vertebral body through a small diameter, single incision. The amount of the Kiva implant delivered can be physician-customized during the procedure to adjust to various fracture types. Delivered over a removable guidewire, the implant stabilizes and supports the vertebral body and directionally controls and contains bone cement.



The Kiva VCF system is investigational in the United States and in an approved IDE (investigational device exemption) study—the KAST clinical trial, sponsored by Benvenue Medical.

The Kiva VCF Treatment System is designed to:

- Preserve cancellous bone structures
- Reduce bone cement usage
- Support and stabilize the nucleus
- Direct cement flow and act as a barrier against extravasation
- Maintain intra-operative height

A European randomized trial of Kiva and balloon vertebral augmentation was recently published in the February edition of *Spine* (2013; 38:292-299). This Level I data demonstrated Kiva's superiority over balloons in many key

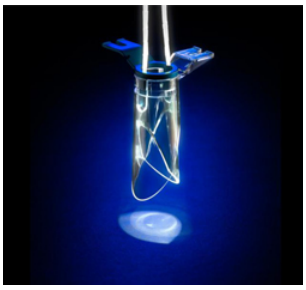
areas:

- Significant restoration of the Gardner angle in patients treated with Kiva (p=0.002) whereas balloon kyphoplasty did not meet significance (p=0.067)
- Lower cement extravasation rates (3% for Kiva and 9.8% for balloon kyphoplasty, p<0.05)
- Lower cement volume (1.8 mL for Kiva and 2.8 mL for balloon kyphoplasty, p <0.001)

Lumiere Retractor System
Inventors / Engineers: Joseph Aferzon, M.D. and Jeffrey Bash, M.D.
Company: Orthozon Technologies, LLC

(Left to right) Joshua Aferzon, Madubuike Okafor, Robin Young

Description: Lumiere is a state-of-the-art minimally invasive surgical retractor that provides superior access and visibility for physicians. Lumiere uses a powerful built-in fiber optic lighting, translucent retractor blades and full medial access to give surgeons an expandable field of view and greater comfort and flexibility when performing micro endoscopic surgery. Patients who have undergone surgery with the Lumiere minimally invasive technique as opposed to open discectomy have shown a drastic reduction in pain, blood loss, surgical duration, and faster recovery time.

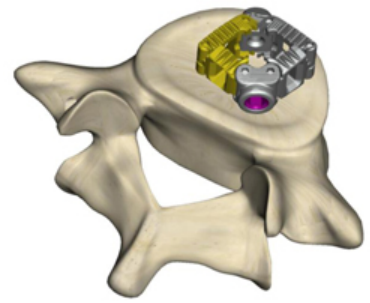


The Lumiere Retractor is recommended for minimally invasive discectomies, laminectomies, foraminotomies, transforaminal interbody fusion surgeries and similar techniques. It provides surgeons with maximal access and visibility in tough-to-reach areas. Current tubular retractor technologies suffer from limited visibility and access due to their complex, bulky, and outdated designs. For MIS surgeons looking to access deep anatomy with an easy-to-use tool, the Orthozon Technologies retractor includes rotatable blades to facilitate medial exposure and powerful fiber optic lighting to illuminate the surgical pathway.

LATIS MIS Expandable Lumbar Interbody Spacer
Inventors /Engineers: Jonathan Perloff, Brian Garvey, Jason Pastor, Robert Wriggins, Christopher Saville
Company: Globus Medical, Inc.


(Left to right) Scott Stanton, Sean Cranston, Robin Young, Jonathan, Perloff, Conor Fleming, Mark Fromhold

Description: The LATIS Spacers are lumbar interbody fusion devices which provide structural stability in skeletally mature patients following discectomy. What sets the LATIS Spacers apart is their linked segments which allow the spacer to take a new configuration once implanted and are available in a variety of sizes to accommodate patient anatomy. For example, the Spacers allow lateral expansion that changes the footprint of the device from a narrow rectangle to a diamond. The design also allows insertion through a posterior, transforaminal, or lateral approach with a final footprint equivalent to spacers inserted through an anterior approach.



LATIS comes in three starting footprints: 10x32mm, 10x37mm, and 10x42mm. Each narrow rectangular spacer can be opened in vivo to the desired shape, reaching a square configuration of 23x23mm, 26x26mm, and 29x29mm, respectively, at maximum expansion.

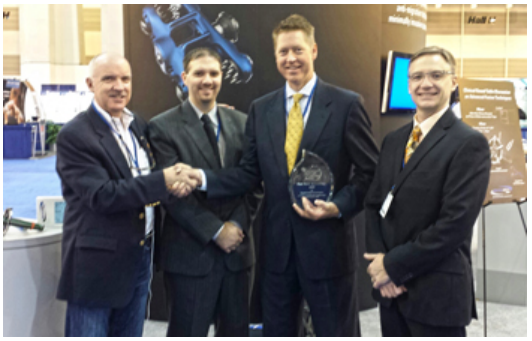
LATIS can be implanted alone or in pairs depending on the surgical need, approach, and anatomical requirements.

LATIS implant consists of 6 links (green) joined by 6 pivot pins (gray) and a locking set screw (purple) contained within link 6.

The interior of the spacers are open and may be packed with autogenous bone graft material following expansion to promote fusion. Graft material is injected through the hole in the posterior wall of link 6 using a funnel tube which is passed by the surgeon through the holder. Once graft is injected, the holder is removed from the implant. LATIS Spacers are offered with or without a lordotic option and in various sizes to accommodate patient anatomy.

PrimaLIF Lateral Lumbar Interbody Fusion (LLIF) System
Inventors / Engineers: Corbett Stone, Ephraim Akyuz, Stuart Goble, Bryan Howard, Daniel J. Triplett, Charlie Forton, Nathan Erickson, Andrew Fauth, Jason Glad

Company: Osteomed



(Left to right) Robin Young, Charlie Forton, Doug Schmierer, Scott Nelson

Description: PrimaLIF LLIF is an innovative and unique lateral access lumbar interbody fusion system which features a radial blade retractor expansion design, independent blade length adjustment, and both direct and fluoroscopic visibility. The PEEK implant has an anatomically matched shape to maximize endplate contact as well as a self-distracting tip for easy insertion and tantalum radiographic markers for optimal placement confirmation.

PrimaLIF is a complete system and includes a full set of disc prep instruments, retractor and table mount, insertion and trialing instruments as well as all implant sizes and footprints.

One of the problems with current methods of lateral access is that it requires dilation of the access space prior to the insertion of the retractor. As a result, the tips of the dilation tubes and retractor blades are exposed to soft tissue structures and exiting nerve roots. These gaps between the distal ends of the dilation tubes and retractor blades as they twist and tear through the psoas muscle subsequently expose the patient to soft tissue and potential nerve damage, further elevating the need for continuous intra-operative monitoring during the entire sequence.

By contrast, the PrimaLIF retractor radially dilates from the inside out by nesting the retractor blades to the size of an initial probe, then expands them simultaneously using dilators. This unique method of lateral access allows the retractor blades to be placed before dilation occurs, not after.

By dilating from within the retractor, the outwardly expanding blades provide a protected channel through the psoas, allowing for sequential dilation in an environment designed to protect the soft tissue and nervous plexus. While other retractors will have gaps between retractor blades in their final position, a final access ring placed between the blades in the PrimaLIF retractor holds them in position. This ring provides an enclosed circular surgical site without any gaps, greatly reducing tissue creep. With improved access and a reduced risk of nerve injury, users can easily deploy the PrimaLIF retractor and focus on their discectomy and interbody insertion.

TrackMyBack app
Inventors / Engineers: Geoff Mather and Ian Cowgill
Company: PhDx Systems, Inc.

(Left to right) Geoff Mather, Ian Cowgill, Robin Young

Description: The new TrackMyBack app is a patient and physician tool to better engage and evaluate spine patients' health status pre- and post-treatment. The app utilizes the convenience of a smartphone to obtain continuous spine patient outcomes data with increased accuracy.

By using an expansive spine patient outcomes database of over 15,000 patients and procedures, the app utilizes data modeling algorithms to set patient and physician expectations for how the patient's health may improve over time.

In the future, management plans to add motion sensors and geolocation to further understand spine patients' functional status over time. The app provides patient education and sets expectations for how ones pain and function may improve over time. The clinician will benefit by:

1. Seeing early follow-up data collected outside of the standard clinical follow-up intervals
2. Evaluate how a patient progresses in relation to a large population of patients with similar demographics, diagnosis, and procedure.

Currently, patient reported outcomes (PRO) data for spine procedures is collected at standard clinical visits (ex, 6 weeks, 3 months, 6 months, 1 year, 2 year, etc.). Important PRO data elements such as Visual Analog Scale Pain (VAS), SF-36, Oswestry Disability Index (ODI), and Euro-QOL (EQ-5D) are often used to evaluate new products and procedures for regulatory approval and policy decisions.

With this app, data may be collected at earlier and more frequent time periods. By using a smartphone app such as TrackMyBack, the resulting rich data stream eliminates the potential for data variability while also increasing user compliance.

Category: Thoracolumbar Care

One Winning Technology

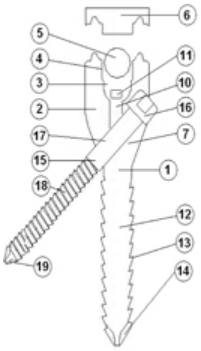
Interlocked Double Sacrum Screw System

Inventors / Engineers: Cumhur Kilinçer, M.D., Ph.D., TRAKYA UNIVERSITY, Edirne-TURKEY and Tasarimmed Tibbi Mamuller San. Tic. Ltd. Sti.

Cumhur Kilincer, M.D., Ph.D.

Description: The Interlocked Double Sacrum Screw System is a sacral anchor and consists of one primary (thicker) screw aimed to purchase the sacral body, and a secondary (thinner) screw which passes inside the neck of the primary screw and purchases the sacral ala (sacral wing). The two screws are locked inside with a nut. The design is elegant, very simple, and intuitive.

Pedicle screw is the most frequently used spinal implant. Sacrum has notoriously high rate of screw loosening (pullout), especially in long-segment instrumentations. This design aims to overcome the infamous problem of sacral screw loosening by purchasing the sacral body and the ala simultaneously. There were historical attempts to obtain combined purchase of both sacral body and ala regions. Those designs failed due to their bulky designs and difficulty of applications. The Interlocked Double Sacrum Screw System enables the surgeon to increase the pullout resistance of sacral screws in a simple and efficient way.



Loosening of sacral screws is a frequent problem with serious consequences. To prevent this problem, surgeons frequently prefer to support the sacral screws with interbody fusion procedures, which may require an additional surgery such as anterior lumbar interbody fusion (Alif) or Axialif. Although the Interlocked Double Sacrum Screw System may still be used in combination with these solutions, it may obviate the need for an additional surgery in selected cases, and decrease the rate of screw loosening greatly comparing to regular screws. The implant has major advantages comparing to regular pedicle screws:

1. Triangulated two screws has much more holding power comparing to one screw
2. The system can be used as a part of ordinary pedicle screw system.

In closing, thank you to all of the companies that submitted their technologies for the 5th annual Best Spine Technologies award. Every year the judges surprise us with their insights and preferences. Clearly this year, MIS was the strongest category. Who knows, a new category will emerge. Until then, keep innovating.

Comments (2) | Share

2 Responses to "The Ten Best New Spine Technologies for 2013"

1. *Mika Rei* says:
November 13, 2013 at 10:36 am
Is the last one of the Ten Best New Spine Technologies for 2013, Interlocked Double Sacrum Screw System, very similar to a Japanese Patent in 2001(JP 2001-252283 A)?
It can be seen on the webpage given.

Best regards.

Reply

2. *sravanthi* says:
December 20, 2013 at 12:29 pm
I'm suffering from spine from 8 years…when I consult a doctor they say there is no problem persist….please help me how do i treat this problem

Reply

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