
Executive Summary
In a panel discussion, neurosurgeons forecast a bright future for robotics spine surgery and a wish list for technological improvements.

Companies that develop advanced technologies and robotics that can help neurosurgeons improve their workflow, create efficiencies and improve outcomes will catapult spine surgery capabilities to a higher level, according to an expert panel at this year’s virtual North American Spine Society meeting.

During a panel on 8 October, neurosurgeons from different US institutions offered their perspectives on the current state and future of robotic spine surgery, new applications for navigation systems, 3D printing technologies and augmented reality in the operating suite. (Also see “Device Week, 9 October 2020 – Updates From NASS And The Virtual MedTech Conference” - Medtech Insight, 9 Oct, 2020.)

Srinivas Prasad, a neurosurgeon at the Jefferson University Hospitals in Philadelphia, PA, said that companies that have developed medical robots such as Medtronic plc (Mazor), Zimmer Biomet Holdings, Inc. (ROSA) platform and Globus Medical Inc. (Excelsius GPS system, which Prasad uses), are all exploring ways to make robotic systems more meaningful for institutions, patients and surgeons.

MAZOR Robotics Ltd., which was acquired by Medtronic in 2018 for $1.7bn, pioneered the spine robot SpineAssist, which was approved by US regulators in 2004.

Prasad said while there are many applications for surgical robotics in spine surgery, his bias is toward developing robots and solutions that solve procedures.

“It’s not as useful to have a device that you bring in to fulfill one part of the procedure, but really something that enables you to fulfill all parts of that procedure,” Prasad said. Every case is different and needs to be individualized for each patient. There are many techniques and tools available.

“What we are trying to do is to find the most effective technique for achieving the goals in that patient – minimizing morbidity without compromising effectiveness and finding something that is efficient and works well for the surgeon,” he said.

Accuracy in pedicle screw placement has been studied most with respect to navigation and robotics. In his presentation, Prasad pointed to a meta-analysis of 130 studies with 37,337 pedicle screws that compared the accuracy of placements with or without using navigation. The study found a general improvement of pedicle screw placement with navigation of about 95.2% versus 90.3% without navigation.

“That’s a reasonable number to take away, given the size of this meta-analysis,” he said.

Another study, published in the Journal of Neurosurgery Spine in 2014, showed that not all navigation systems are created equal.

The study compared accuracy differences for pedicle screw placement between 3D fluoroscopic navigation methods, 2D navigation, and conventional fluoroscopic image guidance systems. The researchers found that the more sophisticated 3D fluoroscopic image guidance
systems significantly improved pedicle screw placement accuracy compared with conventional fluoroscopy or 2D fluoroscopic image guidance methods.

“We are really looking for technologies and the role that they have for specific cases and might make a different decision depending on the case,” he said. In general, he said, robotic pedicle screw accuracy in the thoracolumbar spine has been advantageous with an accuracy rate in the high 90s.

It is also not clear that robotics reduces radiation exposure to patients and surgeons.

Prasad cited a study published in Robotic Surgery: Research and Reviews in 2019, that looked at multiple papers evaluating, among others, the role of radiation exposure to patients and surgeons. It showed that some robotic-assisted devices, including Zimmer Biomet’s ROSA Brain Robot and Beijing Tianzhihang Medical Technology Co.’s TiRobot, actually increased radiation exposure.

“The value (of robots) from a radiation standpoint is a little bit more controversial,” he said. “It’s not clear that robotics saves radiation exposure.”

A comparison between operative times using a robotic-assisted device versus conventional freehand studies also showed variations between robotic-assisted devices.

A study of Medtronic’s Mazor robotic-assisted device showed no difference in operative time compared to conventional surgery while Zimmer Biomet’s ROSA BRAIN robot showed it increased operating time.

Prasad said, in his own experience, operative times are longer with robotics, which is significant for overhead costs. That is part of the reason why he is not using robotics routinely now.

There is a need for better pre-operative planning software that allows surgeons to better define anatomy and goals, multi-modal intra-operative navigation and tracking and a more versatile robotic platform that goes beyond just doing pedicle screw placement and can do full procedures, such as decompressions, and other technically challenging maneuvers, he said.

He feels that robotics is “not there yet,” but has a bright future ahead. “It is up to us to really define the direction that robotics goes in spine surgery,” he said. (Also see “Role Of Digital Surgery Will Continue To Grow Despite Cost Constraints” - Medtech Insight, 8 Oct, 2020.)

Medtech companies are paying attention.

Medtronic’s vice president of global product marketing, Jason Eckhardt, told Medtech Insight that the company’s goal has always been to use robotics and navigation to help ensure that surgeons can execute their pre-operative plans exactly as they intended with precision and confidence.

“We’re on our eighth generation navigation system now, so we have the most experience of navigation in the market,” Eckhardt said. In the next few months, Medtronic plans to release new capabilities for the Mazor including incorporating the Stealth-Midas high-speed drill into the robotic system to create the initial pilot holes that allows for a more precise screw placement.

In a clinical study, led by Duccio Boscherini at the Neuro Orthopedic Center in Switzerland, researchers are comparing the fluoro-registered Mazor X Stealth in terms of pedicle screw placement and radiation exposure to O-arm and navigation as the institutional gold standard in 36 participants. The trial is expected to be completed in February of 2022.
AR For Spine Surgery

Chetan Patel, an orthopedic surgeon and spine specialist at the AdventHealth Medical Group in Altamonte Springs, FL, also foresees great opportunities for using augmented reality (AR) in the operating suite. He defined augmented reality as seeing the world, while adding virtual information or virtual objects to it.

Patel gave an overview of multiple AR systems that are available today and pointed to some of the pros and cons.

He pointed to a 2019 cadaver lab study that compared pedicle screw placement using the Microsoft Corporation HoloLens AR device versus fluoroscopy. Of the 38 pedicle screws placed in the study, 21.1% screws were placed with less than 2mm breach with HoloLens compared to 94.7% with fluoroscopy.

“Unfortunately, the error rate was significantly high,” he said.

Automatic registration and real-time active tracking of instruments may increase the accuracy rate, the paper noted. The HoloLens was also found to be relatively heavy, causing surgeons pain after about 40 minutes of use. The newer HoloLens 2 has addressed some of these issues, he added.

Another study from 2017 that compared pedicle screw placement using Google Glass with navigation AR versus traditional navigated screw placement found that placement was faster using the AR device – 4.13 min/screw navigation with AR versus 4.86 min/screw navigation without AR – and that the device was comfortable to wear in the operating room

On the downside, the author of the study, Jang Yoon, found that the display was suboptimal and the resolution of the original Google Glass also was not adequate, which Patel said was also his experience with using Google Glass.

The author also noted that the most common disadvantages of head-up displays included limited battery life, display size and discomfort, which are also among Patel concerns.

An ideal AR device for spine system would fulfill the following requirements: It would be lightweight and comfortable to wear for three to four hours rather than 40 minutes, offer HD resolution and a 3D binocular display, minimize opacity and have good battery life.

Patel said his ideal device would allow for clear vision of the operating field, work with systems he already uses, including X-ray, navigation, robotics and surgical loops, while not adding time to the procedure. It also should be cost-efficient. Patel said he first started using Epson’s Movario glass in the operating suite this May and found that this device fits many of his requirements.

Overall, Patel believes that using AR in spine surgery offers surgeons several benefits.

“The main benefits I see in terms of outcomes for patients is the ability to not look away from the patient,” he said. “I think it’s really important in terms of patient safety and avoiding those inadvertent errors.” While there are a lot of things that have yet to be proven using this technology, he remains excited about its future.

“Even with the relatively early systems being out today, I’m already finding it is an asset in my operating room,” he said.

3D Printing

Eric Nottmeier, a neurosurgeon at the Mayo Clinic at Jacksonville, FL, talked about various applications for 3D-printing technologies.
He discussed how the Neurosurgery Simulations and Innovations Lab at the Mayo Clinic uses 3D printing, synthetic creation and advanced technologies to enable neurosurgeons to practice an operation before the surgery.

“Perhaps the most exciting part of the 3D principle simulation is for education and training,” Nottmeier said. The technology allows residents to essentially reproduce cadaver simulations with materials that are low cost. The material cost of these models is .002% the price of using a human cadaver and they are easily transportable and disposable.

The properties of the material can be manipulated so that the resident gets tactile stimulation feedback when practicing pedicle screw placement, which is an advantage over a regular cadaver simulation, he said.

“It’s really simulation beyond just bone. You can simulate skin [and] muscle tendon. You can even have active bleeding with the simulator,” Nottmeier said. This allows residents to master a technique before they operate on a patient.

The technology can also be used for surgeons who want to learn a new technique.

“If you have a big scoliosis case coming up, you can actually print the patient’s entire spine with the 3D printer and practice instrumentation placement on the patient’s anatomy prior to entering the operating room,” he said. Another big advantage as compared to using cadavers for education is that the models can be taken anywhere where there is a classroom, such as hotel room or even be shipped to a physician’s office to be used for multiple practice sessions.

“There is no biohazard associated with these models ... they are polymer so there is no disclosure risk,” he said. They can be simply be disposed in the trash.
**NASS 2020: Medtronic Announces First Patient Implant With InterStim Micro, Adaptix Interbody System Launch**

**Executive Summary**

Medtronic’s next-generation InterStim Micro system for overactive bladder is more competitive with Axionics’ r-SNM system, according to an analyst. Medtronic continues to innovate as its former CEO announces retirement.

Medtronic plc kicked off this year’s virtual North American Spine Society (NASS) conference with clinical trial news on its next-generation InterStim Micro sacral neuromodulation (SNM) device for overactive bladder, the launch of the first 3-D printed titanium implant, and announced the final exit of former long-time CEO Omar Ishrak.

Medtronic announced on 6 October, the first day of the four-day NASS meeting, that the first patient has been treated in the post-market ELITE study to evaluate the safety and performance and long-term outcomes of its recently approved InterStim Micro System for treating overactive bladder.

The rechargeable SNS system includes all SNS indications for symptoms of overactive bladder – urinary urge incontinence, urinary frequency, non-obstructive urinary retention and fetal incontinence.

“Millions of adults in the US suffer from bladder and bowel disorders,” said Keith Xavier, a founding partner of Urology Partners of North Texas, who implanted the patient. “Through the Elite study, our goal is to further validate existing data that sacral neurostimulation is a safe, long-term solution for patients who are limited professionally, personally and socially by their condition.”

The Elite study will enroll 160 subjects across 40 sites in the US, Europe, Australia and Canada, Medtronic said. The endpoints of the study include patient reported outcomes, disease specific quality of life questionnaires and symptom diaries. Patients will be followed for two years.

Medtronic said Elite is the first rechargeable SNS study to include fetal incontinence, which affects nearly 20 million adults; about 11.5 million adults suffer from both, overactive bladder and fetal incontinence.

Medtronic pioneered the sacral neuromodulation market with its InterStim device but has been facing rising competition.

Medtronic filed a lawsuit against Axonics in November 2019 asserting claims for infringement of seven patents related to the neuromodulation technology. Medtronic announced on 25
September that the Patent Trial and Appeal Board (PTAB) of the US Patent and Trademark Office has decided to review the validity of six of the seven Medtronic patents in question.

“Contrary to Axionics’ assertions, the PTAB has not made a final determination that any of Medtronic’s patent claims are invalid,” said Brooke Story, vice president and general manager of Medtronic’s Pelvic Health and Gastric Therapies business, part of the Restorative Therapies Group. He noted that the full inter partes review process will start now and that the PTAB will make a decision within the next 12 months. (Also see “FDA Expands Indication For Axonics’ Incontinence System; Medtronic Claims Patent Infringement“ - Medtech Insight, 15 Nov, 2019.)

**Fierce Competition**

In a note following the FDA’s approval of Medtronic’s Interstim MicroStim system in July, Wells Fargo’s analyst Larry Biegelsen wrote that the next-generation InterStim Micro system is more competitive with Axonics r-SNM system from a size standpoint – Axonics’ r-SNM is 5cc whereas Medtronic’s InterStim Micro is 3cc and the Interstim II is 15cc. Both systems have 1.5T and 3T magnetic resonance imaging-conditional labeling, he added.

“However, Micro was approved without clinical data and Axonics now has best-in-class data out to two years,” Biegelsen wrote on 3 August. He said that some clinicians will be swayed by Axonics’ clinical data. He also noted that the charge burden of the InterStim Micro remains unknown.

Medtronic said on 6 August that patients can choose how and when they want to charge the device from once a week or as infrequent as once per month, depending on preference or device settings. The battery life is 15 years.

“Axionics recently received approval for their next-generation device, which decreases how frequently a patient needs to recharge their implanted device to once a month for about one hour versus the current recharging interval which is one hour every two weeks,” Biegelsen wrote.

He also noted there is uncertainty how InterStim Micro’s patient remote controller compares to Axonics’.

“We have heard that in Europe, Micro’s patient remote controller requires two separate devices versus one for Axionics,” he said.

Medtronic said that its InterStim systems have been implanted in more than 325,000 patients. Biegelsen believes that the approval of “newer and better devices will expand the sacral neuromodulation market like we saw when Nevro’s Senza was approved in the spinal cord stimulation market.”

**Adaptix Launch**

On 7 October, Medtronic also announced the US launch of its Adaptix Interbody system, the first 3-D printed titanium implant developed in-house by Medtronic engineers that incorporates the Titan nanoLOCK Surface Technology. Titan Spine, which Medtronic bought in 2019, first developed the surface technology that incorporates elements of nanotechnology for spinal devices as outlined in the FDA nanotechnology guidance document, Medtronic said.

Interbody implants are spacers that surgeons insert between the vertebrae during spinal fusion surgery to help relieve pressure on the nerves and hold the vertebrae in place while fusion occurs.

**Retirement**

This week, Medtronic also announced that its former long-time CEO, Omar Ishrak, will retire as executive chairman and chairman of the board of
directors on 11 December.

The company said on 6 October that Geoff Martha, Medtronic’s CEO, will succeed Ishrak as chairman of the board.

“I’m excited about the future of the company and I am certain that under Geoff’s leadership and the collective guidance of the board of directors, Medtronic will reach new heights,” Ishrak said. (Also see “Medtronic ‘Plays Offense’ Despite Pandemic Challenges, Q1 Results Provide Optimism” - Medtech Insight, 26 Aug, 2020.)

“For the last nine years Omar has guided us, championed and operationalized our mission and re-established our leadership role in medical technology around the world,” Martha said. “We wish Omar all the best as he continues to pursue his personal passions and continued success advancing health care and technology innovation via the many other organizations he serves.”
Device Week, 9 October 2020 – Updates From NASS And The Virtual MedTech Conference

Executive Summary
On this week's podcast, Marion Webb has an update from the North American Spine Society meeting and Reed Miller reviews the panel discussions at AdvaMed’s Virtual MedTech Conference about the lasting impact of COVID-19 on surgery.

Salvia Scores $31M To Develop Neurostimulation Therapy

Executive Summary
The Dutch start-up will use the funds to finalize product design for a neurostimulation platform targeting chronic migraines.

Salvia Bioelectronics has received a $31m cash injection from investors to develop a bioelectronics therapy for people suffering from chronic migraine.

The series A round was led by Panakès Partners, INKEF Capital, SHS Gesellschaft für Beteiligungsmanagement with participation from BOM Capital, Thuja Capital, and Dolby Ventures.

Founded in 2017, the Eindhoven, Netherlands-based preclinical start-up has seasoned medical device executives at its reins. CEO Hubert Martens and others on Salvia's team led product development at neurostimulation firm Sapient Steering Brain Stimulation, which was acquired by Medtronic in 2014 for $200m.

“We've been active in this field for many years now,” Martens told Medtech Insight. “We are very proud of the team we have assembled – we are covering all angles across the business with a relatively small team which possesses multiple expertise in corporate and start-up ventures.”

According to Martens, the company’s technology will be uniquely matched to the needs of migraine patients. “We’ve learned a lot and are now focusing on a truly minimally invasive solution for the treatment of chronic migraine.”

Salvia's neurostimulator device applies small, electrical pulses to the nerves which help to calm the circuits in the brain causing the migraines.

“If you have a headache it is very natural to massage the forehead at the region of the temple. Why do we do this? Because just below the skin at those locations, there are nerves running that are related to the generation of the pain. By massaging those nerves, you help to relieve the discomfort,” Martens said.

The bioelectronic foil is inserted below the skin across the nerves in a minimally invasive surgical procedure that can be performed in an outpatient setting. After a recovery time of one or two weeks, the therapy commences and is administered daily for a set period.

Although the first line of treatment for chronic migraine is medication, Martens said there is a large group of patients whereby the medication is not effective or induce too many side effects. “While new drugs for migraine have recently been introduced on the market, a large majority of patients still don't get sufficient relief,” Martens said.

The new funds will be applied to finalizing Salvia's product development, to be followed by clinical studies in Europe and US to obtain regulatory clearance, he said.

The financing landscape has been challenging for some start-ups during COVID-19, but Martens said the team benefited from its earlier dealings in the space. “The advantage that we had was a lot of contact and experience already from our previous ventures so we could really build on our network and credibility.”

According to Martens, investors saw a large business opportunity for the technology. “The focus of the company today is delivering our promise in the migraine space but further along the horizon we can also imagine this technology could have broader applicability,” he said. “We are pleased that investors really see the potential and value our solution can bring.”
Infographic: Chronic Pain Market To Reach Almost $10Bn By 2024

Executive Summary
The market for devices to treat chronic pain is set to grow by 4.9% annually to 2024, with the US market expanding by 5.5% per year, according to the Meddevicetracker Dashboard.

Combined sales of devices to treat chronic pain – including spinal cord stimulators (SCS), electrical nerve stimulators, drug delivery patches, neurostimulation devices, external stimulators, implantable drug delivery pumps and magnetic nerve stimulators – totalled an estimated $7.87bn in 2019. These data are extracted from the beta version of our new Meddevicetracker Dashboard, a searchable dashboard combining news and analysis from Medtech Insight with market reports, pipelines, trials, events, catalysts and forecasts from Meddevicetracker.

Meddevicetracker Dashboard: CHRONIC PAIN

The market for chronic pain treatments, including drug delivery patches, spinal stimulation devices, electrical nerve stimulators, and other devices, has a five-year growth rate of around 5%.

Market Forecast

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$7,866.2m 2019 Sales
$9,981.7m 2024 Sales
4.90% CAGR
TOP PRODUCT TYPES

Greatest number of product approvals for spinal cord stimulators

DEVELOPMENT PHASE

Approved

Development

Suspended

Approved In Europe

IDE

Development

15

Suspended

5

Approved In Europe

11

IDE

2

Approved

68
Access the full article coverage on spinal devices from Medtech Insight here