

INSIDE

BION Stimulators

A new device could stem muscle atrophy in stroke patients, pg. 3

New Partial Breast Irradiation Devices Increase RT Choices



Source: Biolucent Inc.

New features could enhance dose conformality, widen patient pool, pg. 4

SCCM Update

Highlights from the Society of Critical Care Medicine conference 2007, pg. 6

DEPARTMENTS

- FDA Approvals** 3
- Business Briefs** 3
- Reimbursement**..... 5
- Clinical Briefs** 5
- Director's Column** 8

TECHNOLOGY INDEX

- APBI 4
- Atavi Spine Surgery System..... 4
- BION Neurostimulators 3
- Cannulated Screw Delivery System... 4
- ClearPath HDR 4
- COR Analyzer I 3
- ICU Automation 6
- MammaPrint..... 3
- MammoSite RTS..... 4
- Mechanical Ventilation..... 6
- PillCam 1
- Pulse Oximetry 6
- Remote ICU Monitoring..... 6
- SAVI Applicator..... 4
- 'Smart' IV Pumps..... 6
- Teleradiology 3
- Theken eDisc..... 7
- TITLE 2 Pedicle Screw System .. 4
- Upright Multi Position MRI 4
- Virtual Colonoscopy 2

ORTHOPEDICS

One company's quest to design a 'smart' implant heralds a new wave

Chronic osteoarthritis and other hard-tissue degenerative conditions are the cause of many of the major hip, knee, and spine surgeries in the US, but a systemic cure to prevent their underlying causes is a distant dream. Tissue engineering – tissue and joint regeneration using a patient's own cells – is another promising therapy, but is another elusive goal. Obviously, innovation in these areas is being closely watched. In the meantime, innovative device manufacturers hope to improve on the existing standard-of-care technology – implants made of synthetic materials.

Indeed, endowing implants with the ability to record physical activity, monitor surrounding body tissue, and perhaps adjust *in vivo* according to biological activity, seem within reach given the current state of technological know-how. Already, small changes are underway to make implants collect and communicate information while providing structural support.

Making implants 'smart'

While orthopedic and spine implants have fairly high rates of survivorship, aseptic loosening, dislocation, mechanical failure, and infection of sur-

rounding tissue and are some of the primary causes of revision surgery.

The question is how synthetic implants can mitigate these complications. Some innovators argue that they can help quite a bit, because currently these implants are mute and immutable—that is, they do not communicate any information and cannot change once implanted. One solution could be to apply developments in nanotechnology to recognize the dynamics of physical changes and adjust for those changes. For example, one may conceive of an implant that hardens with tough physical activity like running but softens when walking. Given the state of nanotechnology research, however, this is a longer-term application. In the near-term manufacturers are focusing on developing an implant that recognizes when it needs to prepare to bear extra stress. Implants with the ability to communicate body load, flexion and torsion would allow physicians to recalibrate physical therapy according to individual needs. However, adjustments to better fit an individual's load profile would necessitate invasive surgery. The next step would be devices that not only communicate information but also can be maneuvered remotely. This

(Continued on page 7)

GASTROENTEROLOGY

PillCam COLON promises non-invasive imaging, but lacks interventional advantage

An experimental new device that uses an ingestible camera to capture images of the colon is an exciting non-invasive technique but is unlikely to replace conventional optical colonoscopy, which has the potential to perform biopsies. Unlike regular colonoscopy PillCam is not invasive and requires no sedation potentially making it a preferable option.

PillCam COLON, expected to debut in the U.S. later this year, is a video capsule endoscope similar to the PillCam already marketed for small bowel (PillCam SB) and esophagus (PillCam ESO). The pill-size capsule includes an embedded camera. The device is orally ingested, passes through the GI tract and images the colon. It records and transmits images to a data receiver worn by the patient. Gastroenterologists can later view and interpret the images at a workstation screen.



Source: Given Imaging

The PillCam COLON is non-invasive; by virtue of that fact, it cannot perform biopsies. It is important to remember however, that two-thirds of colonoscopies performed annually do not require intervention.

Given Imaging, the maker of PillCam, is in the process of developing an advanced PillCam capsule that can analyze secretions, polyps and tissue characteristics using different wavelengths of light in the hope of differentiating malignant from benign tissue. That said, these features are still in very early stages of development and will not be incorporated into the device for a few years.

(Continued on page 2)

Automated, adaptable respiratory assistance headlines innovation in mechanical ventilation

Perhaps less alluring than telemedicine, but equally worthy of attention, are innovations in mechanical ventilation. The most recent and significant technical jump in this area is systems that can continuously monitor a patient's breathing and process real-time data to calculate appropriate ventilator responses. Historically, ventilators are programmed to provide a preset level of respiratory support, without taking into account the changing needs of the patient or the most effective level of support for a given respiratory state. Ventila-

tors from major vendors including Viasys Healthcare (SensorMedics), Maquet, Hamilton Medical, Dräger (Siemens), and Puritan Bennett can adapt their respiratory assistance to match the patient's own breathing by indirectly measuring flow or diaphragm movement and automatically adjusting support. The recently-approved Neurally Adjusted Ventilatory Assist (NAVA) feature from Maquet, which tracks brain signals sent to the diaphragm in order to appropriately adjust ventilation settings is particularly interesting. NAVA requires hard- and software upgrades to the company's existing Servo-i ventilator. It is imperative for hospitals looking to

replace their mechanical ventilators—an effort that tends to occur on average every 8 to 15 years, depending on utilization rates—to keep this feature in mind for improving dynamic patient-ventilator synchrony, patient comfort, and potentially reducing time on ventilation and ventilator length of stay.

Other notable ventilation-associated technologies shown at SCCM 2007 included mobile ventilation (Viasys Vela), non-invasive vibrational response imaging (VRI) for diagnosing lung abnormalities, and non-invasive electrical impedance tomography (EIT) for assessing respiratory function.

'Smart' Implants

(Continued from page 1)

would allow automatic diagnosis and device adjustment without surgery.

Theken's eDisc

A first in the field of devices with the ability to communicate information to clinicians – Theken's experimental artificial lumbar disc, eDisc – will have an electronic module to collect body load information and will be made from polyurethane rubber bonded to titanium upper and lower end plates with force sensors. So, unlike first generation artificial discs, which are composed of a metal or plastic ball between plates, it will mimic the natural movement of the spine and, when bent, spring back to an upright neutral position. Even more interesting, an electronic device housed in the disc will record the distance and pressure between the force sensors and will communicate this data to surgeons. This recorded data will help do two things: assist patients to moderate activity during the crucial post-operative period; assist in recommending when a patient is ready to return to work.



Source: Theken Disc.

Inside view of eDisc spinal disc

In a small percentage of cases too much physical activity too soon after surgery leads to implant dislodgement; the disc's force sensors aim to prevent this by giving patients real-time information when they put too much strain on their spines. The plan is to have patients wear a programmable belt that can download information from the disc and even beep to signal too much or too little activity. So, overactive patients can be warned to slow down, and inactive patients could be asked to step up their exercise routines. Physicians could use the information to monitor healing and bone formation around the implant and tailor a graduated scale of physical activity. One nifty feature – eDisc also records the direction in which force is exerted, allowing physicians and patients to know exactly which type of activity triggers too much stress. The device will be able to record high-load events yielding data that could corroborate decisions about resumption of normal activities, a more scientific approach than subjective pain feedback from patients.

Data collection could encourage more insurance companies to provide coverage since it could potentially speed recovery and even cut losses in workers' compensation benefits by eliminating patients who may not want to return to work despite having recovered. eDisc will also record temperature, so localized inflammation can be caught early.

Theken says the device can lay safely dormant within the body for years and be activated at any point, so later complications or pain can be recorded as well. Battery life can vary from a few weeks to a few months, depending on frequency of use and could potentially be recharged at the physician's office.

Theken hopes to begin phase I clinical trials for the disc by the end of this year after receiving approval of its Investigational Device Exemption application. The



Source: Theken Disc.

eDisc artificial spinal disc

trials will compare the electronic and non-electronic versions of eDisc to Johnson&Johnson's Charité artificial disc. The company's goal to obtain market approval by 2011 is very ambitious given the ponderous pace of FDA approvals.

The big question – cost

So, the technology is exciting, but how affordable will it be? The price is yet to be decided, but Theken says it will likely be comparable to other artificial discs, because the electronic component is not particularly expensive.

“For the disc to be commercially viable it cannot be valued at twice or more the price of other artificial discs,” Richard Navarro, Vice President for research and development at Theken, said. The company plans to sell discs with and without the electronic component so surgeons can choose patients likely to benefit from electronic monitoring. “So it won't add unnecessary cost for every patient, it will benefit patients who are likely to be active too soon,” continued Navarro.

Although eDisc may not be overly expensive, it is hardly the final iteration of a

(Continued on page 8)

“smart” implant. It will communicate but will essentially be static. One could speculate that the next generation of implants, with the ability to adjust *in vivo*, will pose a greater financial challenge.

A more functional (and costly?) future

So can “smart” implants include other features on surgeons’ wish lists: monitoring healing, bone growth, and local inflammation? By adding electronic components, implants could be used as built-in diagnostic tools. Theken has received requests from hip and knee companies that want to include the electronic component in their products to monitor whether a fracture is healing and measure the speed of healing.

An implant could also be engineered to sense biochemical reactions like the loosening of bone in-growth, a key indicator of implant stability. Including electrical stimulation capability could potentially help stimulate bone growth (there is some skepticism about this because implants would likely not generate enough power for bone stimulation). On a similar note, electrical stimulation from an electrode attached to an implant could stimulate a painful nerve, thereby providing effective pain management. Evidently, the possibilities are endless once an energy source and computing platform have been established.

The bad news for hospitals is that “smart” implants could contribute to a steep increase in the price of musculoskele-

tal implants, raising the question – will they be able to plan for it? Currently spine and orthopedic procedures offer comfortable margins. These procedures are a mainstay for hospitals and profits from these procedures allow hospitals to pay for other, less-profitable practices. Hospitals may very well find that greater sophistication in implant design allows them to take on more cases than they previously did, even if they do not make as much per case. However, a steep increase in prices could create a window of pain for hospitals while payers play catch-up. And, if they do not, hospitals could be looking at hard times. How long will the stretch last? It’s difficult to predict, but we will continue to track the development of “smart” implants.’

DIRECTOR’S COLUMN

A Conversation with Lisa Bielamowicz, MD

TI Director Kyle Rose sat down with Dr. Lisa Bielamowicz, Director of Diagnostic Imaging Research at the Advisory Board Company and Technology Insights’ Senior Clinical Advisor. Dr. Bielamowicz attended Baylor University Medical School, trained in radiology at the Johns Hopkins University School of Medicine, and was a Fellow at the National Institutes of Health in Bethesda, MD. During her tenure at the Advisory Board, Dr. Bielamowicz has been tracking national and regional trends in diagnostic imaging, including reimbursement, innovation, and physician practice patterns.



Kyle Rose

Kyle Rose: Over the last two years of Technology Insights operations, Diagnostic Imaging has been our most popular service line in terms of project requests by far. What is driving these requests?

Dr. Bielamowicz: Imaging technology has been evolving at an extremely rapid pace over the past several years; the number of potential investments, both large and small, reaching administrators and planning committees is increasing annually. Of course, the amount of capital involved is daunting. Diagnostic imaging is easily divided into six or seven modalities or sub-service lines, and hospitals could be considering multi-million dollar acquisitions in each of these. Fortunately, there is potential to offset these costs with adequate volumes and fairly generous reim-

bursement. Increasingly, diverse physician specialists – cardiologists, vascular surgeons, oncologists, gastroenterologists – want to be involved in imaging purchase decisions. Tech Insights is often called upon to help hospitals navigate potential turf wars.

Rose: With regard to technology-driven developments, which do you think have been the most significant across the last several years? And what can we expect over the next few years?

Dr. B: As in the last three or four years, premium CT remains on the forefront for hospitals and vendors alike. The rate of development in this space continues to be unprecedented, with each major vendor currently offering or planning to field scanners over the 64-slice capability. Hospitals, large and small are struggling to keep up, and several are considering the newest scanners. Hospitals that just acquired a 64-slice CT are now wondering if that is adequate. As hospitals consider investments in CT and other premium modalities like MR over the next few years, they should take stock of their capacity needs. Bread-and-butter exams will drive volumes and profits for at least the next five years, and hospitals don’t need a 64-slice CT to do these exams at or beyond standard of care. They may be better off spending resources on two 16-slice scanners instead of one 64-slice scanner, which would give them the needed capacity for high-quality service. We find that freestanding imaging centers have caught on to this idea more quickly.

It may also be well worth paying attention to women’s imaging. Tomosynthesis

could be the first high-impact new technology in women’s imaging, replacing a huge portion of mammography. Early research is very positive, and CMS tends to reimburse anything that touches breast cancer quickly, so expect tomosynthesis to come on quickly once products are available.

Rose: And now the fun part. In keeping with the mission of the Horizon Scan Monthly, what are your broad-brush predictions for the future of Diagnostic Imaging? Where will the service line be in 10 or 20 years?

Dr. B: New technologies and improvements will come on the scene every year, but as I said earlier, bread-and-butter exams will continue to fuel diagnostic imaging for the next five to ten years. In the long run, imaging will surely see the true advent of molecular diagnostics. Both MRI and advanced nuclear medicine will be used for enhanced diagnosis as well as for imaging the delivery of therapeutics. But we need to be realistic about the timeframe – we’ve been talking about molecular imaging for the last decade, and it’s not here yet.

For Technology Insights clients: If you would like to follow-up with Dr. Bielamowicz regarding these or any other topics, please contact your institution’s Dedicated Advisor to schedule a conference call.