MEDICAL DEVICE DAILY™

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FIRST-OF-KIND PROCEDURE

Vbloc used as adjunctive treatment in two patients who had previous gastric surgeries

By Amanda Pedersen, Senior Staff Writer

Two veterans who had previously undergone sleeve gastrectomies but failed to achieve sufficient weight loss and diabetes control were recently treated with Vbloc Neurometabolic Therapy, representing the first time the device has been used as an adjunctive treatment to a previous gastric surgery.

Enteromedics Inc., of St. Paul, Minn., introduced the Maestro rechargeable system and Vbloc procedure last year. The system includes an implantable pacemaker-like device designed to intermittently block signals between the brain and the stomach using high-frequency, low-energy electrical impulses. It was the first FDA approval for a device to treat obesity in more than a decade. Since then, several other U.S. device

See Vbloc, page 3

COMMITTING TO IMPROVEMENT

Chinese adverse events rate continues to climb with increased hospital use

By Pearl Liu, Staff Writer

HONG KONG – The number of adverse events related to medical devices in China continues to rise as more patients tap into hospital services and the reporting system itself becomes more reliable.

China published its 2015 medical device adverse event report. A total of 184 reported deaths were caused by medical

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OCT MARKET TO REACH $1.1B BY 2017

Perimeter to establish itself in OCT market with FDA nod for Otis

By Omar Ford, Staff Writer

While the optical coherence tomography (OCT) market is filled with a number of prominent and well established players, there is still room for smaller companies to obtain market share. Perimeter Medical Imaging Inc., one of the newer entrants into the space, is hoping to make a significant impact with its 1.0

See OCT, page 5

SHRINKING TECHNOLOGY FOOTPRINT AND COST

Israeli technology could make proton therapy more accessible

By Cornelia Zou, Staff Report

HONG KONG – For decades, proton beam therapy systems for cancer treatment have been expensive and bulky, which affected their accessibility. Israeli company HIL Applied Medical Ltd. is developing a cost-effective and more accessible proton therapy system utilizing nanotechnology and an ultra-high-intensity laser beam.

"The biggest problem with proton therapy is that it's too expensive and too large," HIL's CEO Sagi Brink-Danan told *Medical Device Daily*. "Our aim is to bring proton therapy to every patient and every mid-size hospital."

HIL acquired Nevada-based Nanolabz Inc. on May 26 to help develop its ultra-compact proton beam therapy system. Nanolabz specializes in the development and

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ORTHOPEDICS EXTRA

Executive Editor Holland Johnson on one of med-tech's key sectors

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PRODUCT BRIEFS

Bioventrix Inc., of San Ramon, Calif., received IDE approval to initiate its pivotal clinical trial, named American Less Invasive Ventricular Enhancement. The trial is designed to demonstrate the safety and effectiveness of the Revivent TC Transcatheter Ventricular Enhancement System; a hybrid closed-chest transcatheter procedure to treat patients suffering from ischemic cardiomyopathy by reshaping and restoring the left ventricle. The trial will enroll 120 patients at up to 20 sites nationwide with a primary endpoint analysis at one year.

Exact Sciences Corp., of Madison, Wis., said that it is now an in-network provider of Cologuard with Anthem Blue Cross and Blue Shield in the states of Indiana, Ohio, Kentucky, Missouri and Wisconsin.

Integrity Applications Inc., of Ashdod, Israel, has set a conference call with the FDA, expected to take place in July 2016, for further discussion regarding the pre-submission supplement (including clinical trial protocol) for its Glucotrack Model DF-F device submitted to the FDA for review on May 10. Following the July discussion and subject to FDA approval of the company's clinical trial protocol, the company plans to initiate the pivotal clinical study in 3Q16.

Luminex Corp., of Austin, Texas, said it has received CE-IVD status for the Aries Flu A/B & RSV assay. Designed for use with the FDA cleared and CE-IVD marked Aries System, the assay is a rapid and accurate method for the detection and differentiation of three key respiratory pathogens: influenza A virus, influenza B virus, and respiratory syncytial virus using a sample to answer platform.

Optovue Inc., of Fremont, Calif., reported immediate availability of Angiovue Retina, an imaging system that provides retina specialists with a non-invasive, dyeless way to quickly visualize blood flow in the retina, the light sensitive portion in the back of the eye.

Tissuemed Ltd., of Leeds, U.K., has been granted regulatory approval of its Tissuepatch range of ultra-thin surgical sealant films by the Chinese FDA The approval comes at the end of an exhaustive two and a half year program and importantly covers all surgical applications for Tissuepatch sealant film technology, allowing Tissuemed to extend its product reach beyond the traditional Neuro and Thoracic spaces.

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BUSINESS OFFICE

Donald R. Johnston (Senior Director, Current Awareness), Penney Holland (Web Production Manager)

Vbloc

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companies have emerged with weight loss devices including a variety of balloon-based products, devices designed to improve sleeve gastrectomies, a suture anchor system and a technology intended to imitate gastric surgery without cutting or removing parts of the stomach. The market potential for obesity devices is estimated to reach $137.5 billion by next year. (See *Medical Device Daily*, May 21, 2015 and Nov. 25, 2015.)

Surgeons who have used the Vbloc technology have previously expressed interest in using it as an adjunctive treatment, but Enteromedics has not had any data or case examples to comment on until now, Paul Hickey, the company's senior vice president of marketing and reimbursement, told *Medical Device Daily*.

"There really is no silver bullet for obesity and it does potentially take several weapons to help patients fight through it," Hickey said.

Both of these Vbloc procedures were performed recently at the VA North Texas Health Care System by Sachin Kukreja, director of bariatric surgery. The patients included a 64-year-old male and a 55-year-old female, both with a body mass index (BMI) of between 35 and 40, and both suffering from diabetes. Each had lost and maintained significant weight loss with their sleeve gastrectomies, but remained with class 2 obesity and diabetes. Each were offered the option to proceed to duodenal switch, gastric bypass or Vbloc, and both opted for Vbloc. Their surgeries were performed without incident and the patients are both recovering well, according to Kukreja.

Hickey said the hope is that, because Vbloc is designed to work differently than gastric surgery, the addition of this therapy will provide an extra boost to these patients' initial weight loss procedures.

Though this was the first time Vbloc had been used as an adjunctive treatment, Hickey said the procedures were fairly routine otherwise for the therapy. Using the device in this way is within the company's FDA indications, he said, so if other surgeons were interested in using the technology in this way it would not require additional regulatory clearance.

"It's just a matter of supporting the physicians with our learnings as we go," he said.

These two cases also provide validation that the therapy is attractive to patients, Hickey said, because both of these patients chose Vbloc over their other options for adjunctive treatment.

Dan Gladney, president and CEO of Enteromedics, said there are more than 100,000 gastrectomies performed each year in the United States and up to a third of these patients will not achieve or maintain meaningful weight loss after five years. Gladney said the company's experience with the VA and other U.S. centers will provide an important foundation for the company's commercial progress and expanded use of the Vbloc therapy.

"Obesity is a chronic disease that often requires chronic treatment," Gladney said. "Vbloc used as an adjunctive therapy may play an important role for many."

COMPANY FACES REIMBURSEMENT HURDLES

Like many companies in this space, reimbursement is an ongoing concern for Enteromedics, given that its device is estimated to cost between $15,000 and $30,000. Making the technology widely available to patients is the company's primary focus, Gladney said during a call Wednesday to update investors on the company's commercial strategy, which he said consists of three main parts. The company is targeting patients in select markets through a direct-to-consumer advertising campaign in an effort to build near-term commercial experience with cash self-pay patients, which will be used to support the reimbursement process, he said.

Enteromedics partnered with American Healthcare Lending last year to provide financing options for self-pay patients, but early commercial trends indicated the self-pay market may not be as robust as anticipated, according to Chris Lewis of Roth Capital Partners. Lewis said in a recent report on the company that he expects its commercial traction over the next year or so to be limited until more widespread reimbursement is established.

Gladney said the second key part of the company's strategy is to partner with institutions to promote the Vbloc therapy to their patients and drive demand, a plan that he said goes "hand in glove" with the direct-to-consumer campaign.

The third part of the strategy is to establish the need for this procedure and early commercial traction through clinical and medical society support as well as physician and patient demand for the procedure.

"We have begun to aggressively position Vbloc with payers as not just an obesity treatment device but as a cost-effective care delivery model that yields pharmaco-economic benefits and longer-term savings achieved through Vbloc's lower complication rates," Gladney said. However, he added, "it will take time for our direct-to-consumer advertising campaign to gain momentum and fill the funnel with potential cash pay patients." **//**

APPOINTMENTS AND ADVANCEMENTS

Cardiodx Inc., of Redwood City, Calif., appointed Khush Mehta as president and CEO and a member of the board. Mehta succeeds company founder David Levison, who has been named the chief strategy officer of the company. Previously he served as the global head of health care enterprise solutions at Siemens as well as other executive roles at Siemens Healthcare. Levison, in his new role as chief strategy officer, is expected to lead the company in business development, health payer coverage and next-generation technology.

China

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devices in the country last year, almost twice the number of 2014. The CFDA issued its Medical Device Adverse Event Monitoring Annual Report on May 27. The report shows that there were 321,254 suspected medical device adverse events last year, or 240 cases for every million people, up 21.4 percent from 2014.

The 47,065 cases involving serious and the 184 deaths represented an increase of 15.2 percent compared with the year before.

"The many adverse events related to medical devices in China is not something we would like to see, however as long as there is a system of such cases being exposed, in the long-term perspective, we are heading in the right direction," said Li Zhaohui, Director of APAC Sales, NAMASA China, a medical device science and technology consulting company.

The number of reported adverse events started increasing in 2003, when only 366 such cases were reported across the country. The same trend can be seen in terms of cases involving death and serious injuries caused by medical devices. The numbers dropped significantly between 2010 and 2011 but were still at a whopping 20,610.

The CFDA issued its initial guidelines for medical device adverse event monitoring, the Medical Device Adverse Event Monitoring and Re-evaluation Management Practices (trial), in 2008. Prior to that, the country, which had more than 10,000 medical device companies, reported less than 10,000 cases every year.

In 2010, the medical device adverse event monitoring network and reporting system officially came into effect. One year later, the guidelines and other relevant regulations, were also implemented.

The CFDA made a few revisions to further modify existing rules since then, aiming to standardize monitoring procedures and expand as well as improve monitoring coverage.

"We should not just see the number growing. One important reason is that the monitoring system has been improved and the omission rate has gone down," said Wang Baoting, former director at the medical device supervision department of the CFDA. "The CFDA, as well as provincial authorities, have devoted a lot of effort to creating such a system that can accumulate and coordinate adverse event data. It is one major step to improve our medical device industry."

Another reason for the ongoing increases is that more Chinese patients are using more medical devices, Wang added.

"Before, a lot of Chinese chose to just take pills if they thought it was just a minor illness. We've seen a growing population of people going to the hospitals in recent years, thus more medical devices are being used for treatment," he explained. "Plus, more new and advanced equipment, for example, heavy ion medical accelerators, have emerged. The downside is that they are associated with a higher level of risks."

Irene Lu, global regulatory manager with Qualtech, a regional medical device regulatory consulting company, agreed and told *Medical Device Daily* that, "safety awareness of device users, including doctors and patients, has risen and we've seen more reporting from them."

According to the CFDA, adverse events reporting still mainly come from the user side, rather than the manufacturer side, which only contributed 1.7 percent of all reported cases. The authority urged in the annual report that, "equipment makers, who are the first-hand responsible party of medical device safety, should improve their level of consciousness."

Medical polymer materials were most commonly involved in adverse events, accounting for 67,629 cases. Syringes and puncturing instruments came in second at 41,936, medical dressings had 39,231 reports, physical therapy instruments 26,173, implants and artificial organs 21,307.

"Polymer materials have been largely used in surgeries, for example, infusion devices and drains are all categorized under it," said Lu.

The consultant believes that tightening the supervision of medical device safety could push the country's sector to a higher level.

In December 2015, the CFDA proposed some further changes to the framework of medical device adverse event monitoring.

One important change is the creation of serious adverse events (SAE) category, which will require a much quicker response mechanism.

The proposal divides all adverse events into two categories, normal and serious. SAEs are classified as events that cause death or permanent damage to the human body, endanger human life or cause circumstances that could lead to an injury or death.

Health care providers or device manufacturers must report a SAE within 15 days of its occurrence. If the SAE resulted in death, it must be reported within five days.

Regulatory authorities, including provincial monitoring institutions, will monitor devices that frequently cause severe adverse events more closely. //

APPOINTMENTS AND ADVANCEMENTS

Miami-based **Erba Diagnostics Inc.** amended the employee agreement with CEO Mohan Gopalkrishnan, which extended Mohan's term for seven months. His employment contract will now expire Dec. 31. The company also appointed Hayden Jeffreys to its board of directors. Jeffreys is the commercial director for the molecular diagnostics division and the head of business development and strategy for Erba Diagnostics Mannheim Gmbh, which beneficially owns about 83.3 percent of the company's outstanding shares.

OCT

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OCT system - or Otis. Funded by a $5.5 million series A round, the Toronto-based, company, which was founded in 2013, just received FDA clearance for the imaging system.

Otis is Perimeter's flagship product, and provides high-resolution, real-time imaging of the periphery of excised tissue, enabling clinicians to visualize sub-surface structures up to 2 mm below the surface. The company said sub-surface structures would otherwise not be evident for days - and often weeks - later when conventional histology slides are available for review.

The device can be used in a variety of different tissue types, but the company gave breast lumpectomy procedures as an example. The company pointed out about 25 percent of patients requires a second surgery because of cancer cells left behind. It said Otis can help in reducing these surgeries by providing surgeons with the ability to assess whether there are any areas that require additional attention during the initial surgical procedure.

The device can be used in a variety of different tissue types, including in breast lumpectomy procedures. The company noted that about 25 percent of breast cancer patients require a second surgery because undetected cancer cells are left behind. Otis can help in reducing these surgeries by providing surgeons with the ability to assess whether there are any areas that require additional attention during the initial surgical procedure.

"The reasoning for developing this device is that we saw a clinical need that wasn't being satisfied by other technologies," Elizabeth Munro, engineering operations lead, regulatory representative for Perimeter, told *Medical Device Daily*. "Right now clinicians have great access to preoperative imaging techniques and have great access to postoperative pathology, but when a clinician is in the operating room performing a tissue removal surgery, they really don't have any tools to let them excise the tissues they are removing from the patient's body."

Previously-cleared devices required the clinician to move their hand to collect "point-by-point" images, increasing operator workload and generating images from only a small number of points on the specimen. Otis doesn't have this limitation because of its ability to automate the image capture in the operating room.

But even with the automated imaging collection features on Otis, the company still faces stiff competition from larger players in the space.

A little more than a year ago, Tokyo-based, Nikon Corp., made a $400 million acquisition into the OCT market through its acquisition of Dunefermline, Scotland-based Optos Group. (See *Medical Device Daily*, March 2, 2015.) At the time of the acquisition, Nikon said Optos' ultra-wide field technologies with OCT imaging technology had the potential to be combined with other technology to create minimally invasive medical devices.

Earlier this year, the medical technology business group of Carl Zeiss Meditec AG received CE mark approval for its OCT Plex Elite 9000 technology. The Jena, Germany-based company's device is used to examine the critical retinal microstructures and microvasculature of the eye at any depth of interest.

EXPANDING OCT FIELD

OCT is a non-invasive imaging technique that is analogous to ultrasound. However, instead of using reflected sound to create an image, OCT uses reflected infrared light - a key feature that has attracted researchers.

Two years ago, a team at the University of California Davis demonstrated how OCT can simultaneously measure blood flow and blood oxygenation in vessels, without the need for contrast agents. (See *Medical Device Daily*, June 11, 2014.) Researchers noted that for device manufacturers, these findings might play a role in the development of add-on devices for existing technologies or possibly completely new devices because of advances in imaging hardware and imaging speed.

Another area where OCT is being studied is in precision-guided epidurals.

Bioengineer Yu Chen of the University of Maryland and his colleagues have developed a way to integrate an OCT device with an 18-gauge epidural needle. Epidural administration is traditionally done blindly, using anatomical landmarks. But the team's hand-held device is designed to let anesthesiologists see tissue from the perspective of the tip of the epidural needle, which could help doctors to deliver spinal anesthetic to patients with less pain and fewer complications.

Perimeter is still working on OCT-related research of its own. Muro told *MDD* that Perimeter is developing a reference atlas of tissues including thyroid, skin, breast, cervical, prostate and ovarian, to demonstrate a correlation between Otis images and histology, which is considered the gold standard. The goal of the imaging atlas is to boost adoption of OCT by clinicians.

Last September, Perimeter entered into a data sharing agreement with Columbia to further strengthen its efforts in developing the imaging atlas.

"We've been very diligent in collecting OCT images from excised tissue and working with our pathologists to [review the images,], Munro told *Medical Device Daily*. "Part of the challenge of a new medical imaging modality is that unless you can take that modality and relate it back to something the clinician already trusts and believes in, it's very difficult to convince them to adopt that imaging modality."

The ongoing research bolsters the ever-growing OCT market. According to BBC research, the worldwide market for OCT will increase to about $1.1 billion by 2017, at a CAGR of 10.4 percent from 2012 to 2017. //

Proton Therapy

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fabrication of smart nano-engineered targets for the short-pulse laser R&D sector.

"The acquisition immediately doubles HIL's patent portfolio, thus further fortifying our already-strong IP position in the field. It also adds strong, complimentary talent to our team, and provides a strong base for HIL's U.S. operations," said Brink-Danan.

Proton beam therapy has been a controversial treatment for tumors since its invention more than 80 years ago because of its low cost-effectiveness. It delivers positively charged proton particles to cancer patients to kill the tumor cells. Accelerators and magnets are the two major components of the proton beam therapy system. The existing proton therapy centers worldwide all use the same technology first developed in the 1930s.

There's a significant difference between X-ray radiation and proton beam therapy. High dose of standard X-ray radiation can damage healthy tissues as easily as it hurts tumor cells. So, often, less-than-desired doses of radiation are given to patients to avoid side effects. Unfortunately, it is harder to control cancers. The benefits of using protons is that the radiation can be programmed to focus mainly in tumor cells instead of the surrounding tissue. So it can be used at a higher dose without hurting vital organs, which is also why it's more beneficial to young cancer patients. However, the better outcomes of proton therapy often cannot make up for its massive cost.

Brink-Danan said the existing therapy centers are often of the size of football courts and can cost up to $250 million. "Because they're so large, expensive and complex, there are very few of them, so they are not accessible to 95 percent or more of the world population," he said.

But there is a big unmet market need. According to radiation health care intelligence firm Medraysintell, the world's proton therapy market is expected to reach $1 billion by 2019 with 330 proton therapy rooms. It will further grow to at least $3.5 billion by 2030 with 1,200 treatment rooms. HIL said only 10,000 patients in the U.S. received proton therapy last year, less than 4 percent of the 300,000 potential patients. There are only 19 active proton therapy centers in the U.S. compared with over 2,700 traditional X-ray radiation therapy centers.

LOOKING TO LOWER TECHNOLOGY COSTS

In order to increase the accessibility of the therapy, companies have to reduce the size and the cost of the system.

"We do that by means of high intensity lasers and nanotechnology for the acceleration of protons," Brink-Danan explained. "On the accelerator side, we use those technologies, at the same time, we are also developing smaller magnets to replace the heavy ones."

So the combination of these two much smaller parts lead to a new system that is about half the size and one third of the cost of the traditional ones.

"We're in R&D mode, it's still quite a few years away from commercialization but Israel and the U.S. would be our first choices for marketing," said Brink-Danan. "There's no proton therapy center in Israel which is why I want to build the data system here. Several hospitals are already interested."

Little data collection is also an issue for the further development of proton beam therapy and its comparison with X-ray treatments simply because there are not enough centers that practice this technology.

"Little research is being done because the system doesn't exist in many places, once they are made available and affordable, there will be more research data to solve this problem," said Brink-Danan.

It's interesting that as much as the therapy itself is very complicated and requires many resources, the regulations for it are pretty simple. The FDA classifies the proton therapy system as a class II medical device that is typically exempt from clinical trials.

"You just need to prove your system can produce a beam of protons that live up to certain specifications," said Brink-Danan.

Based in Jerusalem, HIL originated in the physics lab of Hebrew University. It focuses on the development of a new class single-room add-on proton therapy solution that will eventually be made accessible worldwide. //

FINANCINGS

Earlysense has completed a $25 million round of funding, led by Israel's largest bank, Bank Hapoalim, with participation from Pitango Venture Capital, JK&B Capital and other previous investors. The Ramat-, Israel-based Earlysense's contact-free monitoring system is FDA-cleared and CE-approved. The system enables health care professionals to track patient heart rate, respiratory rate and movement constantly through a sensor placed under the mattress. To date, Earlysense has raised $100 million from investors, including Samsung, Welch Allyn and Mitsui.

Mount Olive, N.J,-based **Flowonix Medical Inc.** has obtained financing totaling approximately $15.5 million. The transaction included $10.5 million investment, led by insiders including Clarus Ventures and other existing Flowonix investors. Additionally, the fundraising included $5 million in venture term debt financing, adding to its existing debt arrangement with Hercules Capital Inc. The company plans to use the proceeds to further its investment in sales and marketing infrastructure to support the continued commercial ramp of its Prometra II programmable infusion pump system and expand its manufacturing capacity.

Nexpoint Capital Inc., of Dallas, will commence a voluntary tender offer for up to 2.5 percent of its outstanding common stock at a price equal to 90 percent of the offering price per share.

Second Sight Medical Products Inc., of Sylmar, Calif., has completed its previously announced rights offering to shareholders of record on May 13, 2016. The rights offering was oversubscribed. Net proceeds, after deduction of fees and expenses, are expected to be about $19.4 million.

Spine Wave Inc., of Shelton, Conn., reported an $11 million round of new financing. The round was led by existing investors New Enterprise Associates (NEA) and Acadia Woods LLC. Other participating investors include Compass Global Fund, Industry Ventures, Collinson, Howe and Lennox, California Technology Partners and MB Ventures. The proceeds will be used to fund the largest product portfolio expansion in the company's history.

OTHER NEWS TO NOTE

Cnoga Medical Ltd. reported a distribution agreement with **Artech srl** to distribute Cnoga's Tensor Tip devices in Italy. Cnoga, of Or Akiva, Israel, said its MTX device, which is part of its Tensor Tip family, is designed to monitor 14 parameters such as blood pressure, pulse, blood carbon dioxide, oxygen, oxygen saturation, blood pH, hemoglobin, hematocrit, red blood cells, stroke volume, cardiac output and more, as well as live Waveforms of blood pressure and pulse, in one compact portable device. Artech, of Cavezzo, Italy, distributes devices in the field of interventional cardiology and cardiac surgery.

Amsterdam-based **Royal Philips** said that as part of its existing research agreement with the Yale School of Medicine, it has entered into a new research program led by Jeff Geschwind, chair of radiology and biomedical imaging at Yale. Philips said it will collaborate with Geschwind and his team on a multi-year cancer research program to explore new concepts in image-guided therapies, as well as diagnostic imaging and informatics. The research program also involves further research groups at Yale School of Medicine.

ORTHOPEDICS EXTRA

Keeping you up to date on recent developments in orthopedics

By Holland Johnson, Executive Editor

Preterm babies with low birth weight may be at increased risk of osteoporosis

Adults who were born prematurely or at a below average weight are more likely to have weaker bones and an increased risk of fracture and osteoporosis later in life. This research, presented at the European Congress of Endocrinology, could lead to recommendations that high-risk individuals follow diets rich in calcium, vitamin D and protein, and undertake weight-bearing exercise. Worldwide, about 10 percent of babies are born preterm and are subject to multiple health risks later in life. The human body concentrates calcium for bone development during the third trimester of pregnancy; if this is interrupted due to premature birth, babies may risk suffering poor bone health later in life. This study, by researchers at the Norwegian University of Science and Technology, examined the bone mass of 186 adults, of both genders. Peak bone mass is achieved between 20 and 30 years of age and is a good indicator of fracture risk; the sample was therefore made up of adults of 26-28 years of age. Of these 186 individuals, 52 were born prematurely with very low birth weight (1265g) and 59 were born at term but with low birth weight (2950g). The further 75 - who were born at term with average birth weight (3700g) - formed a control group. The researchers found that both low birth weight groups had a lower peak bone mass than controls. However, once height - a factor which greatly influences bone mass - was adjusted for, this lower bone mass was accounted for in the group born at term; the research showed that low bone mass in this group was partly due to smaller body size. This was not the case in the preterm, very low birth weight group where body size alone could not account for the low bone mass, highlighting this group as particularly high risk. Differences in physical activity and calcium intake were also adjusted for, and differences in bone mass between groups still persisted. Smoking habits did not differ between the groups, and the occurrence of previous fractures was also similar. Chandima Balasuriya, who led the study, said that follow-up of these children is important. "Ensuring children with low birth weight have a diet rich in calcium, vitamin D and protein, in combination with exercise regimes involving weight-bearing physical activities, will help reduce risk of bone fractures later in life." The next stage for the research will be to look at what causes babies to be born with low birth weights. The abstract is titled "Influence of Prematurity and Low Birth Weight on Peak Bone Mass."

Bonesupport reports on preclinical study

Bonesupport AB, of Lund, Sweden, reported the publication of a paper in *Nature Scientific Reports*. The paper, titled, "A Biphasic Calcium Sulphate Hydroxyapatite Carrier Containing Bone Morphogenic Protein-2 and Zoledronic Acid Generates Bone, " covers a preclinical study which demonstrated that Cerament loaded with a combination of recombinant human bone morphogenic protein 2 (rhBMP-2) plus zoledronic acid (ZA) in very low doses was able to quantitatively and qualitatively generate a higher amount of mineralized bone volume. The study also showed In vivo that the mineralized volume was significantly higher when Cerament was combined with rhBMP-2 and ZA (21.4±5.5mm^3) as compared to Cerament in combination with just rhBMP-2 (10.9±2.1mm^3). The company said the findings highlight the potential utility of Cerament as an injectable carrier material that can mimic natural bone matrix. The authors of the publication noted that, "The results that we have published shows that it could be possible to develop a single stage method based on the unique properties of Cerament BVF to deliver a combination of the rhBMP-2 and ZA locally at the site where significant new bone formation is needed."

Pinnacle launches Infill ALIF device for spinal fusion surgeries

Dallas-based **Pinnacle Spine Group LLC.**, launched its Infill anterior lumbar interbody fusion (ALIF) interbody device. This device is designed to maximize wall thickness and graft chamber volume, ensuring optimal contact with the vertebral endplates by both the interbody device and bone graft material. The Infill ALIF device is compatible with Pinnacle's Infill graft delivery system, which allows surgeons to deliver the optimal volume of graft material to the implant in situ without disrupting the interbody device's placement, providing an opportunity to achieve maximum bone graft-to-endplate contact. Pinnacle Spine's Infill fusion systems include a full line of interbody fusion devices engineered for easier insertion, reduced subsidence through maximum contact with the apophyseal ring. The backbone of the technology is based on controlled and precise in situ placement of bone graft material Pinnacle recently reported its first international patent, a Chinese patent, which followed receipt of three U.S. patents on the Infill Fusion System.

Anika reports European launch of Cingal for osteoarthritis pain

Anika Therapeutics Inc., of Bedford, Mass., reported the commercial launch of Cingal, its third-generation viscosupplement, in the European Union. Cingal, which will be initially available in Hungary, the Czech Republic, Poland, Germany, and Italy, received CE mark approval in March 2016 to treat pain associated with osteoarthritis. It will be marketed and sold in Europe by a network of commercial partners under the terms of their respective commercialization agreements. The company said Cingal is the first viscosupplement approved for use in the European Union that combines triamcinolone hexacetonide, a steroid to treat inflammation, with sodium hyaluronate, the active ingredient in the company's viscosupplements, Orthovisc and Monovisc. Viscosupplements are injected by a licensed medical professional into synovial joints to replenish the natural cushioning within joints that depletes with age and degenerative orthopedic diseases, causing pain.