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P4P demonstration project offers hope for U.S. healthcare

By MARK McCARTY
***Medical Device Daily* Washington Editor**

WASHINGTON – The phrase "quality of care" has achieved the dubious fate of buzz-phrase status in modern healthcare, but an interim report on a demonstration of the value of pay for performance (P4P) – another phrase in danger of drowning in buzz – may show that quality improvements may actually be had without leaving the U.S. economy in shambles.

The hospital quality incentive demonstration (HCID) project, undertaken by the **Centers for Medicare & Medicaid Services** (CMS; Baltimore) and **Premier** (Charlotte, North Carolina) – a group of hospitals that also has a stake in the group purchasing industry – has rounded up the figures from the first year of the three-year effort, and come up with numbers that are encouraging.

Additionally, those promoting the P4P effort clearly are

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Henry Schein adds Darby units; Sirona/Schick merger complete

A *Medical Device Daily* Staff Report

Henry Schein (Melville, New York) yesterday reported that it would acquire the assets of **Island Dental**, **Darby Medical Supply** and **Darby Dental Laboratory Supply** from **Darby Group Companies** (Jericho, New York) for about $51.5 million in cash.

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"The acquisition of these three businesses is an excellent match with Henry Schein's U.S. operations, and affords deeper penetration in our Dental and Medical divisions," said Stanley Bergman, CEO and chairman of Henry Schein. "Furthermore, Island Dental, Darby Medical Supply and Darby Dental Laboratory Supply share with Henry Schein a customer-focused culture, with a commitment to personalized service and attention to detail . . . We look forward to offering new products, services and programs to our new customers and sales representatives."

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Report from Europe

Limited European release seen for FlexPLUS spinal system

A *Medical Device Daily* Staff Report

SpineVision (Paris) reported that it has initiated a limited European release of FlexPLUS, a posterior lumbar pedicle screw-based system that is the first new product developed by its wholly owned subsidiary, **FlexSpine** (Singapore), spun off from SpineVision's New Technologies Business Unit in December 2005 for the purpose of developing innovative motion preservation technologies.

The FlexPLUS product addresses what SpineVision cited as two critical clinical needs – the dynamic stabilization of the spine without fusion and protection of the adjacent levels in a lumbar fusion.

FlexPLUS offers various degrees of stabilization – rigid, hybrid and dynamic – and is complementary with the recently launched X-PLUS instrumentation system. The FlexPLUS system enables spine surgeons to apply FlexSpine's Selective Segmental Stabilization technology during the procedure and therefore adapt to multiple disc-degeneration stages.

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IIP-Technologies sees results with wireless retinal implant

By KAREN YOUNG
***Medical Device Daily* Staff Writer**

IIP-Technologies (Bonn, Germany), which initially unveiled its "first-in-man" plans for its retinal implant in September 2005, has now marked up to 27 weeks of the device implanted in the eyes of four patients, none of whom have had any problems with cell proliferation.

Furthermore, these four patients – all of whom are blind – have been enabled to see light, as well as simple patterns – via a wireless transmission of data and energy using the device, called the Learning Retinal Implant. The company said it is the first time in the history of the development of artificial vision that completely wireless transmission of data and energy into an implant in the eye of long-time blind persons has resulted in pattern recognition.

The company presented results of its early clinical data last week at The Eye and The Chip: World Congress on Artificial Vision, held in Detroit.

Hans-Jurgen Tiedtke, CEO of IIP-Technologies, a subsidiary

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IIP-Technologies

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of **Intelligent Medical Implants** (Zug, Switzerland) told *Medical Device Daily*. "[The device] is extremely well-tolerated by the body, and we don't see any biocompatibility issues."

"It is our intention that the Learning Retinal Implant System, along with rehabilitation, will facilitate patients' recognition of objects by allowing them to identify their size, as well as their position, movements and shapes," said Gisbert Richard, professor of ophthalmology at **University Medical Center Hamburg-Eppendorf** in Germany. "Our study concludes that it is possible to provoke pattern recognition by electrical stimulation. The wireless data and energy transmission into the implant allowed totally unrestricted eye movement and is therefore considered suitable as a long-term solution for blind persons."

The fact that IIP-Technologies' solution is wireless is critical and makes the company unique vs. competitors that also are developing implants, Tiedtke said, noting that he thinks that a wireless product is "a must" for this technology to work for patients.

In addition to being chairman and head of the department of ophthalmology at the University Medical Center Hamburg-Eppendorf, Richard serves as general secretary of the **European Society of Retina Specialists**. The first IRL implant occurred in late November, under Richard's direction (*MDD*, April 10, 2006).

And while this generation of the implant allows patients to see patterns and distinguish light, IIP-Technologies already is planning for clinical studies to begin in August for the next-generation of the implant.

The system is made up of three subsystems. First, there is a stimulating device, which is implanted in the eye. Secondly, there is a pair of glasses that is worn by the patient that serves as a transmitter of wireless signals to the implanted stimulator. And thirdly, connected to the glasses by a cable is a processor worn on the waist. The processor sends programmed signals to the glasses, which are then delivered to the implant so as to stimulate the act of seeing.

For the next study, a camera will be added.

The initial targeted patients for the implant are those with retinitis pigmentosa (RP), one of the two most common causes of vision loss in persons over the age of 50 by hereditary degenerative retinal diseases. More than 1 million persons worldwide are affected by RP, which causes the light-sensitive cells of the retina to slowly degenerate and die. However, in many patients, even those who are blinded, certain adjoining nerve cells remain intact and can be stimulated by a retinal device like the Learning Retinal Implant.

Tiedtke told *MDD* that "the full system will not only provide the patient with patterns, but, let's say, real calculated data from images."

"I think they might be able to recognize simple objects, like a door in the room, or a big chair or something like that," he said. "That will enable them to move around in their own house, at least."

Whether it would enable patients to live independently is another question, because, as Tiedtke noted, "Independently is a huge word. It depends a little bit on the mentality of the patient." He added, "Some of them might be able to live independently to the greatest extent, depending on how well they adapt the artificial information the retina receives from our implant. And others may be restricted to their own home environment."

The current technology now implanted in four patients will continue to remain in their eyes for up to 18 months to allow the company to develop long-term data, Tiedtke said. However, IPP-Technologies already has enough data to begin the next phase of the trial.

In April, Tiedtke told *MDD* that the company had begun discussions with the FDA, discussions that allowed IPP-Technologies to forego further pre-clinical study. Application for an investigational device exemption is expected in the second half of 2007.

There are competitors to IIP-Technologies, including **Second Sight** (Sylmar, California), **OptoBionics** (Naperville, Illinois), **Retina Implant** (Tubingen, Germany) and researchers at the **Stanford School of Medicine** (Palo Alto, California) with funding from refractory surgery player **VISX** (Santa Clara, California).

As for how far the retinal implant by IIP-Technologies can be developed – and what those implanted with the device ultimately may able to see – is hard to predict, Tiedtke said. Much of it, in fact, depends on advances in technologies other than the implant itself.

"Technology never stops," he said. "So if there's a new chip technology available, if there's new manufacturing technology available, we can downsize the thing to make more pixels, increase the number of electrodes and resolution might increase." ■

Roundup

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payments up to the low double digits based on annual sales of any drugs commercialized from the program.

Celera's cathepsin S inhibitor, CRA-028129, entered a Phase I trial in September 2005 in a single-center study being conducted at the **Christchurch Clinical Studies Trust** (Christchurch, New Zealand).

In an unrelated transaction, Celera also reported that it has sold an undisclosed, early-stage preclinical small-molecule program to an undisclosed venture capital investor for $250,000, plus an equity stake of 5% in a new company formed to move the program forward.

If the program meets certain milestones and results in the approval of a drug, it may generate milestone payments to Celera of up to $15 million. Additionally, Celera will be entitled to single-digit percentage royalty payments on annual sales of any drugs commercialized from the program. ■