

Chronic Wound Diagnostic Aids: Revisiting Several New Products on the Horizon

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Treating chronic wounds has been described as an art, new diagnostic aids provide opportunity for accurate treatment and reduced overall costs.

Chronic Wound Diagnostic Aids

Key opinion leaders including William Ennis DO, Keith Harding CBE and Tom Serena MD, have all preached the need for chronic wound diagnostic aids as an alternative to the current methods of diagnosing a wound via the paper ruler and a digital camera. Last year's SAWC and EWMA meetings featured several innovative companies showcasing new chronic wound diagnostic aids that were not yet introduced to the US market but were definitely on the forefront. However, to date, none of these products received US FDA approval or were launched in the US. BioMedGPS wanted to report on whether these devices were still moving forward and if so, what were the specific plans and timelines, especially related to the US market.

Bruin Biometrics

At last year's EWMA meeting in London, Bruin Biometrics (BBI) a California-based, privately held company, founded in 2009, featured its SEM Scanner designed for early-stage pressure ulcer (PU) detection. Although the company first launched the product in the UK, the technology originated and was licensed from several UCLA research groups including: the UCLA Wireless Health Institute, UCLA David Geffen School of Medicine, UCLA School of Nursing and the UCLA Henry Samueli School of Engineering and Applied Science. Dr. Barbara Bates-Jensen, a well-known name in pressure ulcer prevention, is the lead inventor. The SEM Scanner, short for sub-epidermal moisture (SEM) Scanner, uses biosensor technology to measure interstitial fluid associated with localized edema in the inflammatory phase—the body's first response to tissue damage. A deviation in SEM values of >0.6 suggests the presence of underlying pressure-induced tissue damage and potential PU formation within 3 to 10 days

following the measurement. This early-stage detection allows preventative measures to take place to reduce tissue damage and the incidence of hospital-acquired pressure ulcers (HAPU). In the US alone, the Agency for Healthcare for Research and Quality (AHRQ) estimates the total cost of all PUs at \$9.1 - \$11.6B, per year.

BioMedGPS reached out to BBI and talked with CEO, Martin Burns regarding the status of the Company and the SEM Scanner. The SEM Scanner is CE Marked, has been available in the UK and Ireland since 2014, and was recently launched in Canada. BBI is utilizing both a direct and distribution model as they launch in various countries: the UK has a direct sales organization with clinical specialists, while Ireland and Canada each employ a key distributor. The Company is being flooded with inquiries from other European countries for distribution of the SEM Scanner; however, BBI is taking a conservative approach by not only looking at the qualifications of potential distributors but also whether PU prevention policies exist in the country. BBI plans to launch in several other European countries by year-end 2016.

The interest in the SEM Scanner can be attributed to its mounting clinical evidence and the associated high costs of PU treatment, which AHRQ estimates annually, between \$20,000 to over \$150,000, per ulcer, depending on classification as a Stage 2 or Stage 4. In Sept 2015, at the 18th Annual Meeting of the European Pressure Ulcer Advisory Panel, an independent 47-pt study completed by the Royal College of Surgeons in Ireland's School of Nursing was presented. The study found the SEM Scanner improved the time to detection by, on average 4 days, and up to 11 days, earlier than the gold standard of care—the skilled nurse. Earlier in March 2015, a study of the SEM Scanner at the NHS

England's Wrightington, Wigan and Leigh Trust determined use of the SEM Scanner reduced HAPUs to zero during a 3-month period.

BBI has been working closely with the US FDA to determine the appropriate pathway and the best clinical study approach to validate its product claims. Accordingly, the SEM Scanner will follow a de novo path as the base impedance technology is currently FDA cleared but the product will be used for a new application. BBI will soon initiate a large 400-pt trial with 2 sites in the UK and 8 in the US to support the claim that the SEM Scanner provides information to accurately detect early-stage PUs. The study will begin in March with completion targeted for Q316, and US product launch planned for early 2017.

According to CEO Burns, the overall cost savings potential for the SEM Scanner for HAPU reduction is substantial and will far outweigh the cost of the device. A solid strategy combined with the potential opportunities for the SEM Scanner continues to bring in new investments. In Jan 2016, BBI raised an additional \$9MM with the round financed by existing and new investors bringing total investments just under \$25MM. Proceeds from the \$9MM will be used to accelerate the commercialization of the SEM Scanner including the upcoming clinical trial.

Kent Imaging

Kent Imaging, a privately held company from Canada, exhibited at SAWC Spring 2015 in San Antonio, promoting its Kent Imaging device utilizing near-infrared (NIR) technology licensed from the National Research Council of Canada. The original non-invasive device (mounted on a rolling cart with a monitor to view images) operates similar to a point and shoot camera and provides real-time images of blood oxygenation in the imaged tissue. In discussion with CEO Donald Chapman at SAWC, BioMedGPS learned the Company was in the process of developing a smaller Handheld Imaging device, significantly less expensive—\$20,000 compared to \$60,000—which they expected to have FDA approved by year-end 2015.

With no FDA clearance in sight for the new Handheld Device, BioMedGPS circled back with Chapman to obtain the status of the new product. Exhibiting at SAWC Spring was valuable to Kent Imaging as they obtained feedback from numerous clinicians which led to incorporating additional features to enhance the current design of the device. In upgrading the device, they also identified new intellectual property that resulted in new patents being filed last year. Today, they are in the process of initiating clinical trials to compare the new improved Handheld Imaging device that provides the advantage of imaging an entire tissue area to traditional transcutaneous tissue oxygenation (TCOM) measurements that obtain a single value for the tissue oxygenation level. An added benefit is that this comparison to TCOM offers the advantage of using current reimbursement codes.

The Company now expects FDA clearance for the new Handheld Imaging device by mid-year 2016 and is in the process of filing for a CE Mark, as significant interest has been expressed by parties from Europe and Asia. To raise funds for commercialization, the Company had planned to go public earlier this year but pulled back from taking action based on stock market conditions. Kent is currently seeking \$5MM to \$10MM as a private placement to boost its commercialization and development efforts.

MolecuLight

MolecuLight, a Canadian-based company, was founded in 2012 by Dr. Ralph DaCosta, a molecular imaging scientist at the Princess Margaret Cancer Centre and the Techna Institute for the Advancement of Technology for Health (UHN). The Company's i:X imaging device utilizes a handheld imaging platform, allowing instantaneous visualization of bacteria and tissue (in wounds) based on autofluorescence imaging. Bacteria emit intrinsic fluorescence signals that are captured in real-time allowing clinicians to quickly and easily visualize the presence of critical levels of bacteria on the skin or in a wound. No patient contact is required or use of contrasting agents. BioMedGPS contacted CEO, Craig Kennedy to learn more specifics regarding the commercialization plan for the

MolecuLight i:X device.

The targeted application and initial clinical research for the MolecuLight i:X device is chronic wound care, especially those suspected of being infected with bacteria or having clinically relevant levels of bacteria. Visualizing bacteria has multiple benefits including identifying critical levels of bacteria, aiding the removal of bacteria through debridement, and more accurate wound sampling. In 2015, the Company completed a clinical validation study of the technology which demonstrated autofluorescence imaging to accurately guide wound sampling, validated against blinded, gold standard swab-based microbiology. Additional studies are underway including an 80-pt study to determine effectiveness of the i:X device in tracking of pathogenic bacterial presence, contamination and infectious status in complex wounds over time. The study is planned for completion mid-year 2016.

The i:X fluorescence imaging device was approved by Health Canada in October 2015 and is currently on track for receiving US FDA 510(k) clearance by the end of Q216. CE Mark for the device is expected about the same time and the Company is currently in discussions with potential distributors in Europe and North America. With the cost of i:X device at roughly \$6,000, the Company is exploring reimbursement options and is in discussion with payers to determine appropriate pathways. MolecuLight will be exhibiting at the two major advanced wound care meetings in 2016, SAWC Spring and EWMA, to create awareness for the i:X scanner and provide a foundation for commercialization in 2016.

MolecuLight has raised just under \$10MM at various stages during product development and validation from several sources: venture capital firm, iGAN Partners, the Ontario Centres of Excellence, Canadian Institute for Photonic Innovations, Health Technology Exchange and Canadian Institutes of Health Research and Cancer Care Ontario. The goal of MolecuLight for the i:X device is to be used as ubiquitously as the stethoscope--a huge win for the company should they succeed. With the i:X device expected to be used on all

stalled wounds where bacteria is suspected to be an issue, the market opportunity is tremendous for MolecuLight.

WOUNDCHEK Laboratories

WOUNDCHEK Laboratories exhibited at 2015 EWMA last year and was featured in a SmartTRAK Start-Up Spotlight article in 2014. WOUNDCHEK's development efforts are focused on addressing two key clinical questions: "Does the wound have elevated protease activity?" and "Is there an active infection?" — key pieces of data needed to direct treatment of chronic wounds. At the time of the article in 2014, The WOUNDCHEK Protease Status (for elevated protease detection) was launched in Europe and was expected to launch in the US in H115, while the WOUNDCHEK Bacterial Status (for active infection) was to launch in Europe in late 2014 and in the US in 2015. Since neither product had been FDA cleared, BioMedGPS circled back with Louise Digby, VP Sales & Marketing, to learn the status of these products for commercialization.

The delay in the US has been primarily due to the extensive clinical data required by the FDA for both the Protease Status and Bacterial Status indicator tests which are undergoing a de novo 510(k) approval process in the US. Although, the scale of the FDA clinical data requirements has delayed the launch of the Protease Status indicator, it has better prepared Management for the clinical requirements needed for the Bacterial Status indicator. The Company is currently running a clinical trial in the US on the Protease Status test for detection of elevated human inflammatory protease activity in chronic wounds which will be used for their FDA filing. In addition, a study is in process for the Bacterial Status indicator for bacterial pathogenesis as indicated by the presence of bacterial protease activity.

Its initial product, The Protease Status test is CE Marked and Health Canada approved, with US FDA 510(k) clearance expected in 2017. The Bacterial Status indicator is targeted for CE Mark in Q316 with FDA approval also anticipated in 2017. With the

approval of both products converging on the US market, the Company is currently reviewing reimbursement options including point-of-care CPT reimbursement codes. Current pricing for the disposable test in Europe is 35 Euros (\$38.5) with one to two tests estimated per patient.

Clinical data continues to mount for the WOUNDCHEK Protease Status increasing its adoption in the EU market. A pilot across 9 wound care clinics in Germany addressing 107 chronic wounds found when wounds were evaluated for elevated protease activity using the WOUNDCHEK Protease Status to guide treatment, at 12 weeks 52% of the wounds healed in the test group while only 36% healed in the non-test group. Total savings amounted to ~\$2275 per wound for those having elevated protease activity. WOUNDCHEK will be at several upcoming 2016 meetings to promote the clinical and economic value of Protease Status, including EWMA and several wound meetings in Canada and the UK.

WOUNDCHEK was challenged the last few years after the spin-out from Systagenix which coincided with the Acelity/KCI acquisition of Systagenix in 2013, and the termination of the Acelity/KCI distribution agreement in March 2015. The Company has had to scramble to enlist new distribution partners and now has the capability to launch more broadly in Europe, Canada, the US, Saudi Arabia, Australia and Mexico. The Company touts a healthy financial position attributed to funding provided by private investors, company management and Alere, the manufacturer of its products. With the global launch of both the WOUNDCHEK Protease Status and Bacterial Status in 2017 accompanied by strong clinical data and experienced distribution partners, the Company is poised for success moving forward.

An Untapped Market

Treating chronic wounds is sometimes described as an art due to the multiple co-morbidities of patients, along with the limited availability of diagnostic aids to quickly and accurately assess a wound. Introduction of new technology for diagnostic aids is occurring

globally but progress is slow with products initially being introduced in countries outside the US, due to the more rigorous FDA clearance process. Once approved for regulatory clearance and reimbursement in the US, the market opportunity is enormous for these products.