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# Myriad Innovations At MedFIT, But Graphene Wound Dressing And Back Pain Relief Exoskeleton Get The Votes

by

The first edition of the European medtech partnering conference MedFIT provided a showcase for early-stage innovations emerging from the R&D labs of start-ups and tech incubators, all poised to be taken to the next level of clinical evaluation or even commercialization. *Medtech Insight* attended the event's Start-Up Slam where eight medtech innovations vied to win over the jury of potential investors and industry experts, as well as the audience.

Home to eight of France's major research organizations and ranked by *Forbes* magazine in 2013 as one of the top five most inventive cities in the world, Grenoble seemed a fitting location for the inaugural MedFIT partnering conference organized by the French economic development agency Eurasanté. The aim of the two-day meeting, held on June 28-29, was to build R&D collaborations between academia, start-ups and Big Medtech in order to accelerate entry into market for viable innovations, and the Start-Up Slam on the second day provided a platform to highlight some of these innovative projects that were on offer.

Eight technologies – all at a pre-commercial stage but some further down the development/clinical pathway than others – were pitched to a jury comprising medtech industry veterans, serial entrepreneurs, experienced product developers and investors. The technologies ran the gamut in terms of therapy areas but all appeared to be targeting potentially lucrative markets.

Defymed, for example, was one of the Start-Up Slam competitors targeting the billion-dollar diabetes market. More specifically, the Strasbourg-based company's *MailPan* bioartificial pancreas for type 1 diabetes would compete in a product sector dominated by medtech giants like Medtronic and Johnson & Johnson, among others.

Unlike current artificial pancreas systems that would typically comprise a closed, feedback loop between a mechanical insulin pump with a blood glucose monitor, MailPan is more a biological product, consisting of an implantable pouch for housing insulin-secreting cells. This pouch has non-biodegradable, biocompatible membranes with selective permeability; while they allow glucose and insulin to enter and leave the pouch, the membrane is impermeable to cells of the immune system like white blood cells and antibodies and cannot penetrate the pouch.

When the MailPan is first implanted in the patient, the pouch is implanted in the abdomen empty and without the cells to allow vascularization around the bag. Once vascularization is optimal, the cells are then implanted via one of two catheters which link the pouch to two ports implanted under the skin. The catheters act as channels for flushing out the cells from the pouch and injecting new ones in when they approach the end of their life span and need to be replaced. The MailPan acts like a biological pancreas with the cells autonomously regulating the level of glucose in the blood and releasing the required amount of insulin.

In December last year, Defymed forged a partnership with Boston, MA-based biotech company Semma Therapeutics, in which the latter will supply the French firm with stem-cell derived differentiated insulin-secreting cells. Richard Bouaoun, director of operations at Defymed, told *Medtech Insight* that Defymed is in advanced preclinical studies of MailPan and plans to enter clinical trials in Europe in 2018. The first has raised around €3.2m in equity funding to date and €6.5m in public grants. IT is looking to raise a further €10m to advance MailPan to CE mark and through clinical trials.

The winner of the Jury Prize for the most innovative start-up was Japet Medical Device, is also targeting a significant market, chronic low back pain, which affects 80% of the population in Western countries. The firm is further ahead than Defymed in its business plan and is planning to start clinical trials of its *Atlas* exoskeleton within the third quarter of this year.

Lille-based Japet was started by CTO Damien Bratic and CEO Antoine Noël, who worked together in medical robotics for five years before founding the firm. The Atlas exoskeleton, which looks like a corset and worn around the patient's waist, is designed for sufferers of debilitating chronic low back pain caused by excess pressure on the lumbar region. The device, said Noël, is the first of its kind to help bring immediate pain relief to these patients while they are undergoing physical therapy to retrain their muscles and bring back some functional strength.

Many chronic low back pain sufferers have to undergo physiotherapy, but the exercises are often very painful and difficult for the patient. In order to get the needed pain relief to do these exercises, patients would have to take pain medication.

The concept of the Atlas exoskeleton is to help patients through their physiotherapy by decompressing the spine – thus relieving the pain caused by the pressure – whilst they are

performing the exercises. The exoskeleton has four rod-shaped micromotors to apply traction to the spine, as well as a set of embedded sensors to follow and adapt to the patient's movements and ensure they are performing their physical activities safely and comfortably.

The Atlas therapy is not a cure for chronic low back pain, Noël acknowledged, but it helps to make the rehabilitative exercises easier to perform, which in turn should lead to better adherence of the physiotherapy and higher chances of resolving their back pain over the longer term.

Noël said Japet will be first targeting rehabilitation centers and physiotherapy clinics, which he estimates account for a market worth over €8m in Europe and the US combined. The bigger and more lucrative market would be for Atlas to be used for rehabilitation at home, where the patient could rent the system. This home care market is estimated to be worth around €25bn, according to the CEO.

If the clinical trials of Atlas go well, the company is expecting to CE mark the Class IIa system in the first quarter of 2018 and it hopes to enter the US market in 2020.

The Atlas exoskeleton applies traction to the spine to provide pain relief to chronic back pain sufferers so they can undergo physiotherapy more easily and comfortably.

Source: Source: Japet Medical Devices

While it may not have won the vote of the official jury, the *Grapheal* wound care technology – incubated under the auspices of French tech transfer and start-up building company Linksium – got the thumbs-up from the audience and walked away with the Audience Prize for the most innovative medtech start-up.

Grapheal is a wound healing platform exploiting the features of graphene, a thin layer of pure carbon that not only has heat- and electro-conductive properties, but is also 200 times stronger than steel. Vincent Bouchiat, who invented Grapheal in the labs of CNRS (Centre national de la recherche scientifique) and is managing the project, explained to *Medtech Insight* that these specific properties of graphene enable the technology to be advanced from a passive wound dressing to a smart wound healing technology that not only has a therapeutic effect but also diagnostic capabilities.

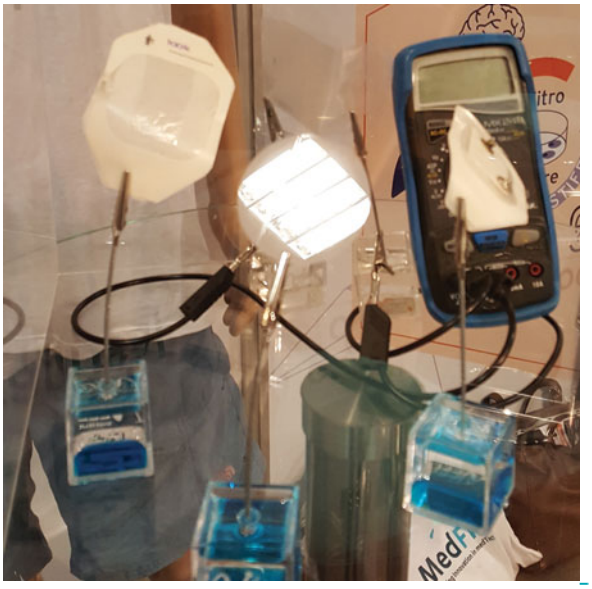
The first-generation Grapheal bandage is a graphene-based scaffold that looks like a very thin, transparent plaster. The graphene layer of the scaffold will be in contact with the wound – "cells see it as a good support to build new tissue", said Bouchiat told *Medtech Insight* – to encourage

cellular growth in advanced wounds and speed up healing. This first-gen bandage is currently undergoing clinical trials.

The second-generation Grapheal, which is not too far behind and is expected to be launched next year, will be an "active" bandage by taking advantage of graphene's electro-conductive properties. The bandage would be designed so that electrostimulation can be applied to the dressing and this electrical charge should help enhance the healing process.

The third-generation Grapheal, expected to be launched in 2019, will be a "smart" wireless bandage. While the graphene helps to heal, its electrical properties can be developed so that the bandage is designed to also monitor and detect possible infections as they're developing.

Bouchiat said he is now looking for a serial entrepreneur with the commercial expertise to spin out Grapheal as a start-up – hopefully in 2018 – that will focus on taking the product from bench to market.



Prototypes of the three generations of the Grapheal graphene-based wound healing technology. On display in the Linksium stand at Eurasantés MedFIT 2017 event in Grenoble, France.

Photo: Tina Tan

Aside from diabetes, back pain and wound care, other product markets that the remaining contestants in MedFIT's Start-Up Slam were targeting include: noninvasive imaging of melanoma and carcinoma; dual-drug delivery; stress urinary incontinence; transcatheter mitral valve repair; and single cell analysis for cancer.

Below are details of these five other companies:

Daidalos Solutions, based in Amsterdam, the Netherlands, is a medical device development company founded by cardiac surgeon Eric Berreklouw, who presented a transcatheter mitral *AnchorValve* to the audience. The TMV space is a crowded one, Berreklouw acknowledged, with both big names like Edwards, Medtronic, Abbott, Boston Scientific and LivaNova and smaller participants active in this field. However, there has not been a single solution that has met with a lot of success, due to the mitral valve being a more complex structure than the aortic valve and more challenging to repair. Daidalos' AnchorValve is a combination of a stent and a clamping ring; it is positioned between the left atrium and ventricle in a single transcatheter procedure,

and works by anchoring itself to the valve annulus only. This differs from competing products which use leaflet attachment like Edwards' *Fortis*, Medtronic's *Twelve* valve, Neovasc's *Tiara*, and products like Abbott's *Tendyne* valve that is fixed to the LV apex with a tether.

Diadalos has conducted extensive ex-vivo testing of AnchorValve as well as acute aortic and mitral animal studies, as well as longer 90-day aortic animal study of the device. Advantages demonstrated by AnchorValve include no leaflet immobilization, no need for anticoagulation and left ventricular outflow tract obstruction, a complication that could occur with other TMVR systems.

Diadalos is now seeking around €5m to optimize the design of the valve and delivery systems and to conduct clinical studies to obtain CE mark and FDA approval. It plans to do its first in man within two years.

Sencet is addressing the liquid biopsy market for cancer diagnosis and monitoring, an area in which investors' interest has ramped up in the last few years. Its *CellCet* single cell analysis system incorporates the *Silicon Nanotweezer* (SNT) technology for harvesting and characterizing circulating tumor cells (CTCs) and is the result of a 10-year research project between France's CNRS and Japan's IIS-University in Tokyo. The company Project leader Grégoire Perret told the jury that unlike current liquid biopsy technologies which require expensive and slow equipment, the SNT technology is designed to be affordable and fast, allows for several cancer types to be detected with one device, and can be integrated into lab-on-chip for ambulatory use. The so-called "tweezers" in this technology comprise a mechanical actuator to compress and immobilize single cells. Once the cell is captured, a proprietary characterization platform measures both the displacement of the actuator and the electrical properties of the immobilized cell, thereby enabling the differentiation between normal cells and circulating tumor cells. The company is seeking around €2m in funding to help launch the first version of CellCet, by the end of 2018, which will target the research use market. Sencet would also use the funds to develop the next generations of CellCet for use by pharma companies for drug discovery, potentially by 2020. The Lille-based firm would then need to seek more funds in order to advance a version of the technology that can be used as an IVD in hospitals.

Fizimed has developed *Emy* to help the 16 million women in Europe alone – and many more globally – who suffer from stress urinary incontinence. Emy is a home-use, "perineal reeducation" system for strengthening the pelvic floor muscle that might have been weakened by childbirth, vigorous sport or menopause. It comprises a tampon-like probe device that is connected wirelessly to the user's smartphone; the app on the smartphone controls settings for the therapy, including exercise and the data transmitted to the app will allow users to follow their progress in real time.

Fizimed CEO Emeline Hahn said the company plans to sell the device direct to consumers, distributing it via a dedicated website, or through partner pharmacies and other specialized third-party websites.

Ascil Biopharma specializes in injectable and locally acting therapeutics together with advanced drug delivery systems. Tabatha Bourgois medtech project leader at Ascil presented the company's combo connector, a device that allows injection of two or more drugs with a single needle shot. While there are other devices out that designed for the simultaneous delivery of more than one therapeutic, Bourgois claims that the combo connector is the only device that does not allow any contact between the drugs, and can deliver varying doses of drugs. the firm has conducted proof of concept and filed a patent. The product has the potential to be customized for specific needs, users and volumes. There are versions suitable for all market and reservoirs, say Bourgois.

The manufacturing process of the combo connector is standardized and scalable and entails a competitive cost of goods. The device is immediately available for licensing, either on a therapeutic application basis or on a geographic market basis. Ascil is looking for an industry partner or a device manufacturer or specialist with injectable combo needs

Damae Medical is developing *Octav*, a noninvasive technology for performing using linear confocal optical coherence tomography (LC-OCT) to detect melanoma and carcinoma. Octav does not seek to replace tissue biopsies; instead it is designed to give clinicians more confidence with diagnosis and reduce the number of unnecessary biopsies. CEO Anais Barut told the jury that the company believes Octav would also help dermatologists increase revenue because it is "a time-saving technology, which means that the dermatologist can have a higher patient throughput." The company closed its first financing round in May, raising €2m. Investors include Kurma Partners, Idinvest Partners, News Invest, Paris-Saclay Seed Fund and private investors.

*From the editors of Clinica.*