

vascularNEWS

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I N T E R N A T I O N A L

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CRITICAL LIMB ISCHAEMIA

Setback for gene therapy in TAMARIS

Although earlier trials were promising, the TAMARIS trial showed that an experimental gene therapy growth factor failed to prevent death or amputations in patients with severely blocked lower limb blood vessels. Is there a future for gene therapy in the treatment of peripheral arterial disease?

Gene therapy did not prevent amputations or death among patients with severe obstruction in leg arteries and resulting foot ulcers, according to a clinical trial presented at the American Heart Association's Scientific Sessions 2010, in Chicago, USA.

Despite encouraging data from the phase 2 trial, patients treated with the experimental gene therapy growth factor NV1FGF did not fare better than those given a placebo among participants in the TAMARIS (NV1FGF gene therapy trial on amputation-free survival in critical limb ischaemia) phase 3 randomised trial. NV1FGF was designed to stimulate new blood vessel growth to increase blood

flow to save the legs and prolong the lives of patients with peripheral artery disease.

"Overall, it is a very disappointing result," said William R Hiatt, co-author of the study.

Hiatt, professor of medicine and cardiology at the University of Colorado School of Medicine and president of CPC Clinical Research, told *Vascular News*: "In terms of the analysis of TAMARIS, I would say that we have the final data from the trial and it was definitely negative on the primary endpoint of amputation and death. No other secondary analyses identify a signal of benefit. The only active component of the trial that goes forward is an obligation to monitor patients for any



William Hiatt

safety issues over the next two years."

Patients enrolled in the trial suffered from critical limb ischaemia and had exhausted available options. They were highly likely to have a leg amputated or die from the disease. Because of the severe lack of blood flow in their legs, many patients had severe leg and foot pain and painful foot ulcers.

"Gene therapy was a promising option in the treatment of coronary and peripheral disease in the last decades," Hiatt said. "We hope that the next phase of stem cell-based therapy will have better results."

In the 12-month study, researchers randomly assigned 259 patients to receive an inactive placebo treatment, while 266 patients received the gene therapy growth factor. The patients, who came from 30 countries, had foot ulcers as well as low blood pressure in the ankle or foot and were not good candidates for surgical revascularisation.

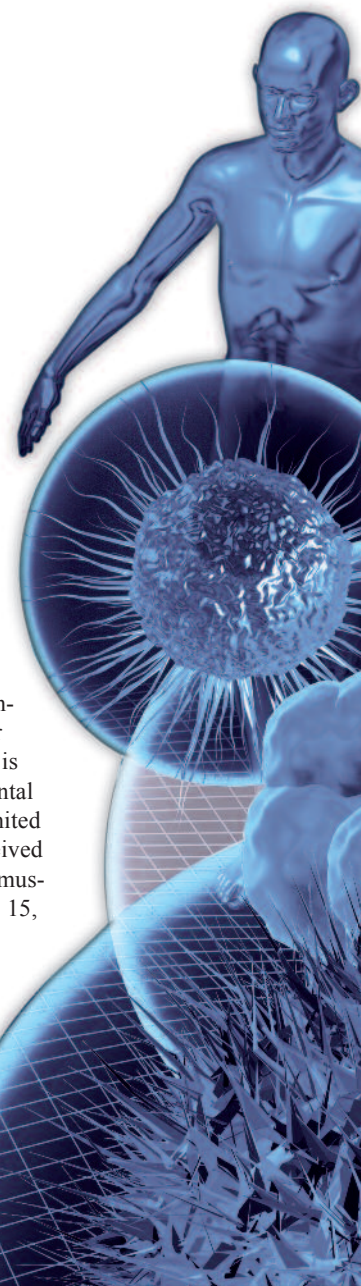
More than half the patients had diabetes. "Diabetes predisposes you to ulcers, so this is not

unexpected," Hiatt said.

The patients and their doctors did not know if the eight injections they received contained placebo or NV1FGF, which is still an experimental therapy in the United States. They received injections in leg muscles on days one, 15, 29 and 43 of the study.

Of patients on placebo, 21% suf-

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New EVAR devices presented at the VEITHsymposium

Two new EVAR devices were shown at the VEITHsymposium, in New York, USA.

Treovance, Bolton Medical

Bolton Medical presented its new abdominal aortic device, the Treovance abdominal stent graft with the Navitel delivery system. The device aims to reduce the potential for limb separation and limb thrombosis and provide accurate delivery with ease of use.

"We will pursue a higher degree of angulation and a longer neck of 15mm. We are going to try to push the limits and

get something out to help us do things we cannot currently do," said Mark A Farber, University of North Carolina, USA.

The Treovance stent graft with Navitel delivery system is a three-piece modular system with a broad range of sizes, and active fixation featuring suprarenal and supplemental infrarenal barbs.

Additional device features include flexible main body and legs, telescopic limbs enabling variable limb overlap and step-wise user controlled deployment.

"The device has been designed as a

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MEDTECH
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More information on page 6

In association with **Vascular News**

Towards vascular access consensus



ERIC CHEMLA

COMMENT & ANALYSIS

The CX St George's Vascular Access Course will see even more debate and seek consensus in 2011

This year St George's vascular access days will be hosted again at the Charing Cross Symposium. Our successful meeting in April 2010 has enticed us to reinforce our collaboration with Charing Cross and we have decided to make a two-day meeting in 2011 with more time for debates, questions, abstract and poster sessions. At our last edition the room was full and it is clear that the main European vascular meeting being held at the same time has had a massive impact

on our success. Vascular access, although a proper specialty of its own right, is more and more connected with vascular surgery, the number of patients in need of access is in constant augmentation while the number of transplant centres and transplant surgeons remain the same. It was only natural that the specialty turned towards vascular surgery when overwhelmed by the demand for more and more complex accesses needed by a frailer, older population that presents with

more co-morbidity. It is estimated that number of type 2 diabetes patients could reach a record 350 millions in the world from 2015 onwards!

Vascular access has evolved dramatically in a very short period of time; the first ever created fistula was performed in New York City by Dr Apple, general surgeon, 1966, although all credits went to the nephrologists Brescia and Cimino. We do now perform complex access for patients with multiple access failure and central venous stenosis, also we can rescue and re-open successfully up to 85% of the clotted fistulae that present in haemodialysis.

It is time for us to think of a better structure for our discipline which still remains niche with few randomised trials and therefore weak evidence levels, unlike our colleagues in vascular surgery who only accept very robust well documented evidence.

In 2011, we have decided to follow exactly the pattern of the main meeting: 'Vascular access – evolving towards a consensus'. We will examine over a two-day meeting each of the main topics and discuss whether we could agree on a common approach on steal syndrome, high inflow fistulae, rescue, endovascular

operations or open surgery etc.

We will again accommodate a split session on Monday afternoon for the nurses where specifics will be discussed towards a consensus (or not): Early cannulation, direction of the needles, how to monitor access efficiently, infection control etc.

We will of course and for the second year in a row have an abstract and a poster session. As it is a two-day meeting we will have more time to listen to more abstracts but also to question, debate and dialogue with one another. I am also very pleased to be able to bring the access community to the vascular community as we need to grow bigger and to get to know each other. Our faculty will be as usual very well known and international with a mix of speakers coming from the USA, Europe and of course, the UK. We will have some sessions on innovations so as to keep up to date on what is new and hot at the moment in our world.

I am sure our second meeting will be a success and I sure hope that you will be coming in numbers.

Eric Chemla, St George's Hospital, London, UK, is director of the St George's Vascular Access Course

Hold the date!

CX St George's Vascular Access Course
11–12 April 2011, within the CX Symposium

The 6th St George's Vascular Access Course – under the auspices of the Vascular Access Society – is an integral part of the Charing Cross Symposium. The main topic is "Towards Vascular Access Consensus"
Web: www.cxsymposium.com/vascularaccess
Email: info@cxsymposium.com

First Optiflow anastomotic connector cases performed in the UK

A team from St George's Hospital, London, UK, led by Eric Chemla, consultant renal transplant and vascular surgeon, chair of the Division of Medicine and Cardiovascular Sciences Renal Transplantation, performed the first four UK cases with the Optiflow anastomotic connector (Bioconnect Systems)

The device replaces hand-sewn suturing for arteriovenous fistula creation. All patients were treated with the Optiflow, which recently received CE mark approval.

The Optiflow is an implantable conduit that replaces suture for vascular anastomoses. The initial indication is creation of arteriovenous fistulae for dialysis access. The same technology could eventually be used for peripheral and coronary bypass surgery.

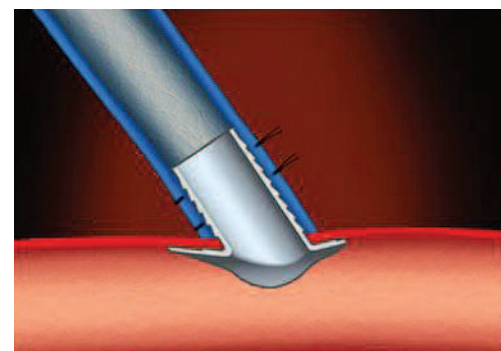
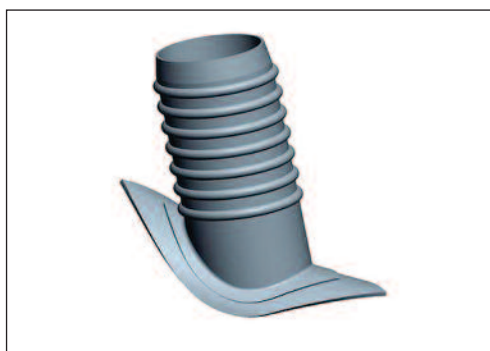
The potential benefits of Optiflow include standardising procedure technique and results, reduced procedure time, and improved patency and maturation.

Preclinical chronic animal studies of the Optiflow demonstrated a more anatomical anastomosis with increased flow ver-

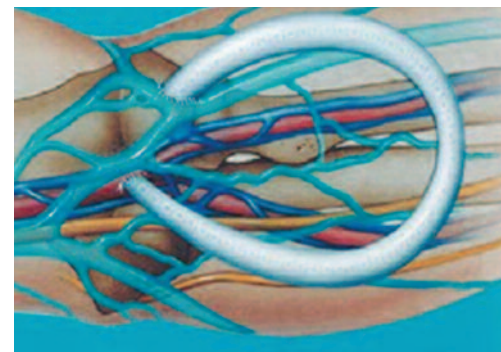
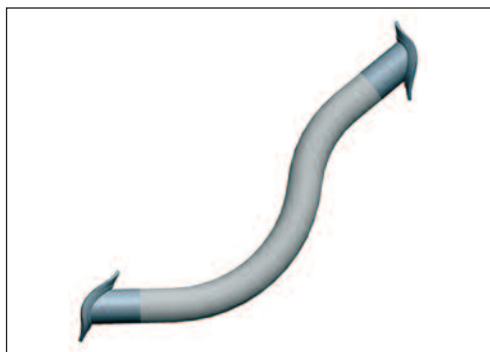
sus suture. The device provides a mechanical scaffold which does not change overtime and shields the vessel lumen from adverse remodelling.

Vascular access is considered as the Achilles' heel of haemodialysis. The Dialysis Access Consortium (DAC) study on the effect of clopidogrel on early failure of arteriovenous fistulae for haemodialysis: a randomised controlled trial showed 60% of fistulae were not suitable for dialysis at 4–5 months and a 20% acute thrombosis rate at 42 days. The results were published in the *Journal of the American Medical Association* 2008.

Lajos Matyas, chief of Vascular Surgery, BAZ Megyei Hospital, Miskolc, Hungary, recently presented interim results from an on-going study



Optiflow anastomotic connector and arteriovenous fistula



The Optigrift synthetic graft is the next product in Bioconnect's pipeline

of Optiflow at the Symposium on Vascular Innovations, Budapest, Hungary, in November 2010. The data demonstrated 100% (25/25

patients) patency at 14 days, 92% (22/24) at 42 days and 83% (20/24) at 90 days. There were no long-term safety issues. Follow-up is on-going.

A study based in the UK, which includes St George's Hospital and Manchester Royal Infirmary, will start enrolment in early 2011.