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Two-stage TEVAR yields lower mortality and more protection against spinal cord injury

A two-stage endovascular repair of type II thoracoabdominal aortic aneurysms protects against spinal cord injury, according to a new study. This approach, with patients being intentionally treated in two separate procedures, was also associated with a decreased mortality rate.

Adrian O'Callaghan, Department of Vascular Surgery, Cleveland Clinic, Cleveland, USA, presented the results of the study at the Society for Vascular Surgery Annual Meeting (5–7 June, Boston, USA).

"Neurological dysfunction remains a devastating complication of thoracoabdominal aneurysm repair, and the risk of spinal cord ischaemia parallels the extent of aortic repair, with an incidence of 20% following open surgery approaches," O'Callaghan said.

"We hypothesised that staged repair might provide time for collateral development and lessen the surgical insult, thus mitigating the incidence and severity of spinal cord injury."

The investigators, led by Matthew Eagleton, conducted a retrospective study of patients undergoing endovascular fenestrated/branched repair of type II thoracoabdominal aortic aneurysms. Staged repair was defined as intentional completion of the endovascular repair in two temporarily separate procedures, with the intention

Matthew Eagleton

of promoting collateralisation.

Extent of aortic cover was calculated using 3D imaging. Primary outcome measures were incidence and severity of spinal cord ischaemia and mortality. The study included the following definitions: single-stage repair was a complete repair performed in a single procedure, with no prior aortic surgery; two-stage repair was a repair performed in two intentionally separate procedures; and unintentionally stage repair was when there was prior aortic surgery (without the intention for further aortic repair).

From January 2008 to July 2013, 574 fenestrated/branched repairs were performed. Of these, 95 were of type II aneurysms. Twenty eight patients with prior aortic surgery were excluded, and 32 single-staged and 27 two-staged repairs were performed. Both groups were equivalent in terms of demographics and risk factors.

The two-stage group had significantly greater percentage of the aorta covered (94% vs. 86%, p=0.001). Median time to the second stage repair was five months (1–60).

Rates of spinal cord ischaemia were 37.5% (single stage repair) and 11.1% (two-stage repair, p=0.03). All neurological injuries in staged repair were temporary, but resolved in only 58% of the single-stage repair group. Thirty-day mortality rates were 18.8% (single-staged repair) and 0% (two-stage repair), and these differences persisted during follow-up (p=0.03).

In conclusion, O'Callaghan said, primary staged repair is protective against spinal cord

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Endovascular repair of popliteal aneurysm maintains significant sac shrinkage at five years

Endovascular repair of popliteal artery aneurysm provides successful aneurysm exclusion with good long-term patency, excellent limb salvage, and survival rates, according to a study published in August in the *European Journal of Vascular and Endovascular Surgery*. At five years of follow-up, limb salvage was 98%, survival rate was 84% and mean sac volume shrinkage decreased from 45.5mL to 23mL.

The authors, led by Michele Piazza, Vascular and Endovascular Surgery Clinic of Padova University, Italy, stated that the aim of the study was to evaluate long-term outcomes and sac volume shrinkage after endovascular popliteal artery aneurysm repair. The study was a retrospective review of all endovascular repairs of popliteal aneurysm cases between 1999 and 2012. Sac volume shrinkage, long-term patency, limb salvage, and survival were evaluated using Kaplan-Meier estimates. The association of anatomical and clinical characteristics with patency was evaluated using multivariate analysis.

Forty-six endovascular repairs of popliteal aneurysms were carried out in 42 patients (mean age 78 years, 86% male; mean sac volume 45.5±3.5mL). In 93% of cases (n=43), the procedure was elective, while in 7% of

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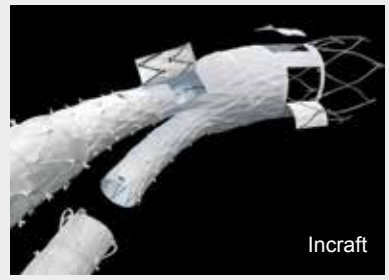
Incraft low-profile endograft launched in Europe and Canada

Cordis announced on 10 September the launch of its Incraft AAA Stent Graft System, an ultra-low profile device for use during endovascular aneurysm repair (EVAR) for patients suffering from infrarenal abdominal aortic aneurysms. The Incraft System is cleared for use and is now available in Europe and Canada. According to Cordis, the device is an advancement in the EVAR field and provides a new option for patients and physicians seeking a less invasive treatment approach for abdominal aortic aneurysms.

The Incraft System, which features an ultra-low profile endovascular stent graft system with innovative technology designed for durability, conformability and sealing without the need for polymers, is intended to reinforce the lower part of the aorta to prevent an aneurysm from rupturing. The device is the lowest profile EVAR system now available in Europe and Canada with a 14F outer diameter, including the integrated sheath, which is equivalent to a 12F catheter sheath introducer profile.



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Two-stage TEVAR yields lower mortality and more protection against spinal cord injury

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ischaemia development and severity. "In addition, the staged approach lowered 30-day and long-term mortality. Further investigations will be directed towards understanding the physiology of this benefit."

Matthew Eagleton, senior author of the paper, spoke to *Vascular News* about the study.

When is a two-staged procedure indicated for endovascular repair of thoracoabdominal aneurysms?

We have applied a two-staged approach to those patients with extensive aneurysmal disease who are going to undergo endovascular repair. The method we use to repair them in a staged fashion is predominantly reserved for those patients undergoing endovascular repair of a group II thoracoabdominal aortic aneurysm. We have sporadically used this approach for those getting repairs of group III thoracoabdominal aortic aneurysm, but it is not used as frequently in that scenario.

What did the two procedures in the staged repair consist of?

The first procedure is placement of a thoracic endograft. We cover the aorta with a TEVAR from the proximal landing zone (which is frequently either incorporated into an elephant trunk graft or landed at or proximal to the left subclavian artery). If an additional adjunctive procedure, such as an iliac conduit or left carotid-subclavian bypass, is necessary we will perform it at operation too. The second stage of the procedure is placement of the branched aortic endograft and complete exclusion of the thoracoabdominal aortic aneurysm.

What was the percentage of fenestrated vs. branched procedures?

As these were extensive aneurysms (type II thoracoabdominal aortic aneurysm), and all devices were custom-made branched endografts.

What will the next steps in the study be?

With the implementation of "off-the-shelf" grafts we will be interested in understanding what time frame is necessary to wait before performing the second phase. There is always the risk of the aneurysm rupturing in between the two stages, so the quicker we can complete the repair, the better. Animal studies suggest the timeframe may be as short as five days, but this has not been studied in humans.

Endovascular repair of popliteal aneurysm maintains significant sac shrinkage at five years

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cases it was for rupture (n=2) or acute thrombosis (n=1). Of the 43 patients who underwent elective repair, 58% were asymptomatic and 42% symptomatic (14 claudication, three rest pain, and one compression symptoms).

Technical success was 98%. Mean duration of follow-up was 56±21 months. Primary patency at one, three, and five years was 82%, 79%, and 76%, while secondary patency was 90%, 85%, and 82%, respectively. At five years, there was 98% limb salvage and an 84% survival rate.

During follow-up 11 limbs had stent graft failure: six required conversion, one underwent amputation, and four continued with mild claudication. Of those with graft failure, 63% (7/11) occurred within the first year of follow-up. The mean aneurysm sac volume shrinkage between preoperative and five-year post-procedure measurement was significant (45.5±3.5mL vs. 23±5mL; p<0.001). Segment coverage >20cm was a negative predictor for patency (HR 2.76; 95% CI 0.23; p=0.032).

Piazza *et al* write that although

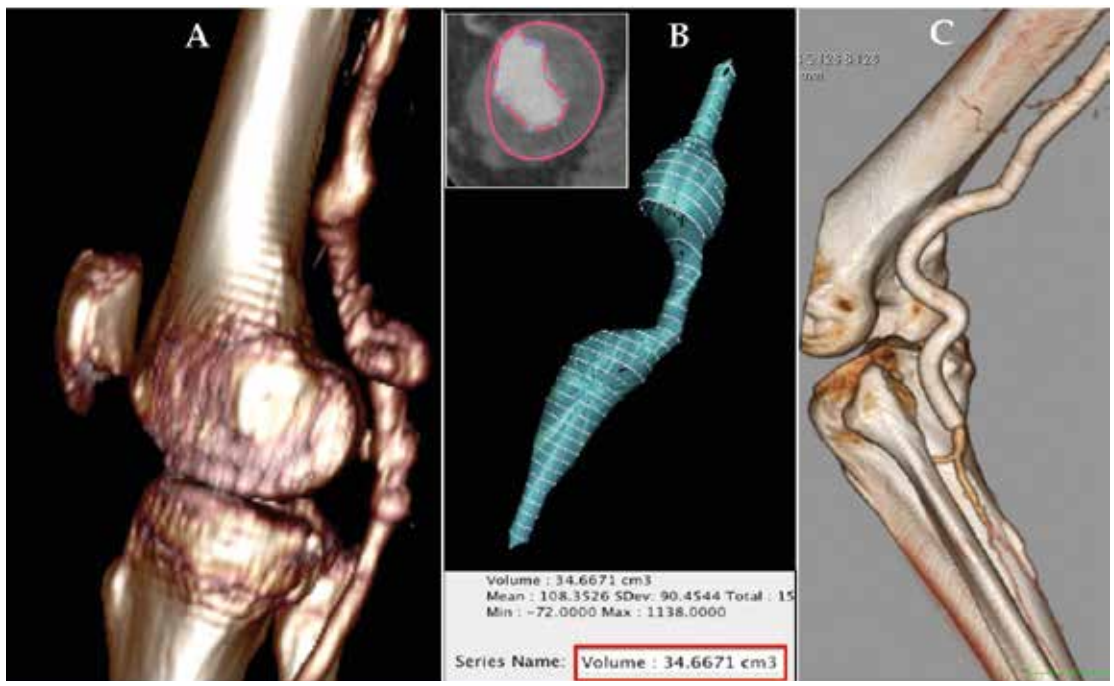
Michele Piazza

the results were positive for patency, limb salvage and survival, "close surveillance is nevertheless required, particularly during the first postoperative year". They added that patients requiring long segment coverage (>20cm) may be at increased risk for failure.

He commented: "Endovascular treatment of popliteal aneurysm in our institution has been traditionally performed using the Gore endoprostheses. From 1999 to 2003 we used first generation endograft (Hemobahn, n=15); from 2004 to 2009 second generation endograft (Viabahn, n=25) and from 2010 to date, the heparin-bonded Viabahn (n=6). The type of endograft used did not appear to influence long-term primary patency in our multivariate analysis model."

Speaking to *Vascular News*, Piazza said that no other study has focused on the long-term patency rate and the efficacy of endovascular popliteal artery aneurysm repair in aneurysm sac exclusion. He notes that this single-centre experience demonstrates that this procedure is durable and guarantees effective aneurysm sac shrinkage over time. However, he said, when selecting patients for endovascular approach, the length of coverage and the need for close surveillance—especially during the first year of follow-up—should be carefully evaluated.

"In the future we aim to identify other reliable anatomical predictors of patency, in order to guarantee a more precise and effective patient selection for of endovascular popliteal artery aneurysm repair. Furthermore, the role of endovascular repair in emergency cases still needs to be better defined," he said.



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Endoleak does not predict reduced long-term survival, but is associated with less sac shrinkage

An analysis of the OVER trial presented at the Society for Vascular Surgery Vascular Annual Meeting (SVS, 5–7 June, Boston, USA) shows that endoleaks were common in patients treated with endovascular aneurysm repair (EVAR) in the study, with an incidence of 31%.

Wei Zhou, professor of Surgery, Stanford University and VA Palo Alto Health Care System, Stanford, USA, who presented the results of the analysis, said that 53% of the endoleaks seen in the trial resolved spontaneously.

The OVER trial randomised 881 patients at 42 Veteran Affairs centres in the USA and 439 of the patients received successful EVAR. The study showed a lower perioperative mortality rate for EVAR (0.5%) vs. open repair (3%, p=0.004), but there was no significant difference in mortality at two years (7% vs. 9.8%, p=0.13). The objective of the analysis presented at the SVS meeting was to identify risk factors and long-term outcome of endoleaks in patients who received successful EVAR in the OVER cohort.

In the analysis, logistic regression was used to identify predictors for endoleaks and secondary interventions. Of the total of 439 patients treated with EVAR, 134 (31%) developed 187 endoleaks over a mean follow-up of 62±2.4 years and five aneurysms ruptured.

Zhou, speaking on behalf of the OVER Study Group, noted that the results showed that there was no difference in survival between patients who developed endoleaks and those who did not.

She explained that the 187 endoleaks included 76% type II leaks, 12% that were type I, 3% that were type III, 3% that were type IV and 6% that were indeterminate. Age >75 years predicted the presence of endoleaks on univariate analysis, but did not show significant on the multivariate model. Neck length and angulation were not associated with the development of endoleak in the OVER cohort with relatively good anatomy. The presence of endoleak was significantly associated with less sac shrinkage (p<0.001).

Fifty three per cent of endoleaks resolved spontaneously. Of those that did not resolve Medtronic's endograft appeared to have less than half (35) the endoleak rate of Cook Medical (74) and Gore (76), but the time from endoleak detection to resolution was not significantly different among the endografts.

The initial aneurysm size independently predicted a need for secondary intervention (p<0.001), and 32% of patients with endoleak received secondary intervention (10% of all patients), Zhou said. She added, "Delayed type II endoleak (detected more than one year following EVAR) was significantly associated with sac enlargement compared to type II endoleak detected early. There was no difference in aneurysm size or length of survival between type II and other types of endoleaks."

Summarising the results, Zhou stated that in the study, endoleaks were common and did not affect long-term survival, and that the presence of endoleaks was significantly associated with less sac regression; large aneurysms predicted future secondary interventions; type II endoleaks had similar effects on aneurysm size over time compared to other types; and delayed type II endoleak was significantly associated with late sac enlargement.

She explained that the analysis had some limitations: endoleak detection and classification were not centrally adjudicated, there was no randomisation between devices, and the decision for endoleak interventions was made by individual surgeons.

Zhou told delegates at the SVS meeting, "The presence of an endoleak does not predict reduced long-term survival, but negatively impacts sac regression. In addition, delayed type II endoleaks behave more aggressively than their earlier counterparts. Long-term surveillance is essential."

IMPROVE trial morphology analysis: The answer lies in the neck

An analysis of aneurysm morphology in the IMPROVE (Immediate management of the patient with rupture: open versus endovascular repair) trial presented at the British Society of Endovascular Therapy (BSET) Annual Meeting in June showed that for long aneurysm necks, mortality after EVAR and open repair was very similar. Surprisingly, the investigators said, there was "a very strong inverse association between neck length and mortality after open repair". The analysis on aortic neck length and survival after repair of ruptured abdominal aortic aneurysm was presented by Janet Powell and Rob Hinchliffe on behalf of the trial investigators.

"Aneurysm morphology indicates whether a patient with ruptured abdominal aortic aneurysm is eligible for EVAR and may influence the outcome of both EVAR and open surgical repair. In the emergency setting, the morphological criteria for EVAR (IFU, instructions for use) may be relaxed, but by how much?," they wrote in an abstract.

Patients with a proven diagnosis of ruptured abdominal aortic aneurysm, who underwent repair and had their admission CT scan submitted to the core laboratory, were included in this analysis of 30-day mortality and re-interventions, according to a pre-specified plan, focusing on liberal IFU (neck diameter ≤32mm, neck length ≥10mm and proximal neck angle <60°) and six morphological variables: maximum aortic diameter, neck diameter(s), neck length, proximal neck angle, neck conicality and maximum common iliac diameter.

Four hundred and fifty eight patients (364 men), mean age 76 years were included, with EVAR commenced in 177 and open repair in 281 cases, with 155 deaths and 88 re-interventions. The mean maximum aortic diameter was 8.6cm. There were no important correlations between the six morphological variables.

Patients within liberal IFU (58%) had lower mortality, although this narrowly failed to achieve statistical significance, p=0.054. Only aortic neck length (mean[SD] 23.2[16]mm) was associated significantly (inversely) with 30-day mortality both for open repair (p<0.001) and overall (p=0.007). A short aneurysm neck was the commonest reason for a patient being unsuitable for EVAR. For re-interventions, only iliac diameter showed a borderline association but this will be reassessed after 12 months of follow-up.

In conclusion, the investigators said, the results showed that for long aneurysm necks mortality after EVAR and open repair is very similar "and explain the results of the Dutch and French trials, which only recruited patients suitable for endovascular repair". They added that there was a very strong inverse association between neck length and mortality after open repair. There were very few patients undergoing EVAR with aneurysm neck lengths between 10 and 14mm, so that it is difficult to assess whether EVAR might offer a clear advantage for these neck lengths.

"We hope that our agreed collaboration with the Dutch and French trials might enable us to provide some further information by the end of the year. The results also explains why observational studies, which 'cherry pick' long necked aneurysms for EVAR leaving all the short necked aneurysms for open repair, always show that mortality is lower after EVAR. Such observational studies are comparing apples and oranges," the investigators said.

The pre-specified analysis plan and more information about the trial can be found at www.improvetrial.org

Incraft low-profile endograft launched in Europe and Canada

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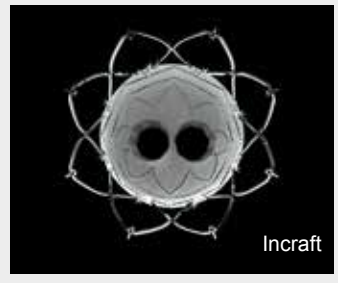
Most EVAR stent grafts have a system profile ranging from 16–22F in size.

This ultra-low profile device is designed for proximal and distal placement accuracy and allows for customisation during the procedure to accommodate a wide range of anatomical sizes. This broad anatomical coverage is offered with a minimal number of product codes for easier pre-procedural planning.

"The Incraft System is an attractive new EVAR device option because its ultra-low profile design and customisation allows physicians to consider this less invasive procedure for many patients, especially those with smaller vasculature who might otherwise be ineligible for EVAR," said Giovanni Torsello, of the University Hospital Münster, Münster, Germany. "The recently published two-year data on the Incraft System from the INNOVATION trial in Europe demonstrated excellent performance adding to the scientific data supporting the device."

The INNOVATION trial is a multicentre, open-label, prospective, non-randomised study designed to assess the safety and performance of the device in the treatment of patients with abdominal aortic aneurysm with investigational sites in Germany and Italy. At two years, results from the study demonstrated the device performed well in patients and showed no incidences of aneurysm enlargement, endoleaks (types I or III), device or procedure related major adverse events, stent graft migrations or stent fractures. One patient in the study developed a late graft occlusion unrelated to the device that was caused by shrinkage of the aneurysm. The two-year study results were presented at the 2014 Charing Cross Symposium and subsequently published in the July 2014 online issue of the *Journal of Vascular Surgery*.



The Incraft System is currently approved for investigational device use only in the USA and Japan and is being studied in a global pivotal clinical study in the US and Japan called the INSPIRATION trial, which completed enrolment in 2013.

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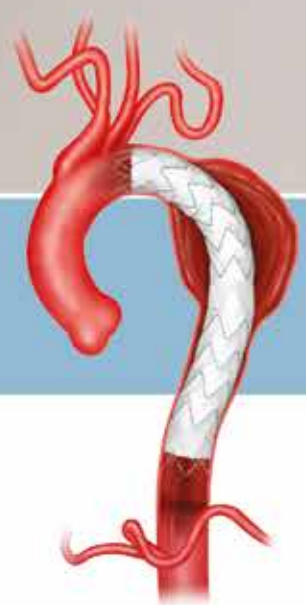

COOK MEDICAL

“Only operators and centres with the highest skillsets should be performing complex TEVAR”

With advances in technology, device availability and surgical skillsets the outcomes from endovascular repair of thoracoabdominal aortic aneurysms will continue to improve and become the treatment of choice for patients with the condition, according to Stéphan Haulon, Lille, France. He speaks to *Vascular News* about why he believes endovascular repair is the way forward.

Why, in your opinion, are fenestrated and branched grafts, rather than surgery, the optimal way to treat thoracoabdominal aortic aneurysms?

A large number of thoracoabdominal aortic aneurysm patients are unfortunately faced with significant comorbidities that decrease their ability to tolerate an open procedure. Those who survive open repair have their quality of life significantly impacted with most patients being referred to rehab or long-term care facilities. Patients undergoing endovascular procedures experience a far less traumatic procedure.

Morbidity and mortality rates at centres of excellence are less than or equal to centres of excellence performing open repair. Greenberg et al (*J Vasc Surg* 31(1 Pt 1):147-156, 2000) showed an overall 30-day mortality rate of 3.2% for patients treated endovascular for thoracoabdominal aneurysms.

Finally, the majority of patients treated with EVAR for thoracoabdominal aneurysms are released from the hospital within 10 days. Given future advances in technology, device availability and surgical skillsets we can expect the outcomes from EVAR for thoracoabdominal aneurysms to continue to improve and become the treatment of choice for these patients.

What are the potential issues surrounding endovascular repair?

The potential issues surrounding endovascular repair include:

- Just as with open repair, endovascular repair of thoracoabdominal aortic aneurysms is complex and a high skill level is required to ensure good outcomes. Endovascular repair of thoracoabdominal aneurysms should be restricted to high volume centres where these types of cases are completed routinely.
- Currently, devices to treat thoracoabdominal aneurysms are commercially available in a limited number of countries. Those countries without commercial access rely on physician-sponsored studies to gain access to these technologies or treatment via physician-modified endovascular grafts. In order to ensure long-term success of the endovascular repair, devices to treat a broad range of patients need to be developed and made available on a global scale. To date a majority of the published experience in endovascular repair of thoracoabdominal aneurysms is with devices designed to fit each patient’s individual anatomy. In order to treat patients in a more expedient manner, better off-the-shelf devices should be designed or techniques to reduce time to plan, manufacture and deliver a patient-specific endograft should be employed.
- These complex repairs have many potential failure modes (eg. branch vessel instability) and as with all endovascular repairs require long-term surveillance. The aorta is dynamic during the cardiac cycle; when coupled with the movement of the diaphragm, it presents potential challenges for graft durability. Given these challenges, our results to date have shown excellent long-term durability owing to conservative techniques in selection of seal zones and endograft design.
- Bridging stents used to make the modular connections between the endovascular graft and the branch vessels were not originally designed for that purpose. Currently, covered stents intended for use in peripheral disease are typical used to bridge the endovascular graft to the native branch vessels and some concerns have been raised about the long-term durability of these components. Several devices have proven successful in accomplishing the bridging in the short to medium term. Stents designed specifically to bridge fenestrated and branched grafts to native anatomy have the potential to further improve patient outcomes.

How can new technology improve outcomes in complex TEVAR procedures?

Several areas exist where technological evolution can improve patient outcomes. Continued reduction in delivery system profile can have a big impact. Reductions in delivery system size will reduce the need to perform endovascular conduits and reduce rates of access vessel complications especially in women. Advances in delivery techniques also have the ability to simplify these procedures. New technologies, such as preloaded wires, catheters and sheaths can simplify access of fenestrations, branches and target vessel. The results will be reductions in surgical time, fluoroscopy time, total contrast used, and surgical complications.

What is it known in terms of durability of these endovascular procedures?

Complex endovascular procedures are built on the same design philosophies that have evolved in more than 20 years of experience with standard EVAR

Stéphan Haulon

devices. Design features such as active fixation, durable graft materials, and durable stents that provide radial force for sealing that have been proven key in the durability of standard devices are even more critical in complex endovascular repairs often cover a larger portion of the aorta. More contemporary studies (Mastracci *et al*. *J Vasc Surg* 2013;57:926–33) have systematically evaluated branch vessel durability for complex repairs. We believe these studies provide evidence that branched and fenestrated endografts are a durable alternative to open repair in patients with complex aortic disease if the principles of device design are adhered to and vigilant follow-up can be ensured.

What is the role of off-the-shelf branched devices and who should be treated with these devices?

The immediate role of off-the-shelf branched devices for thoracoabdominal aortic aneurysms should be for those patients that need to be treated under emergent surgery. These devices have limitations in the anatomy that can be treated and unanswered questions as to long-term compromises in branch vessel durability. Devices manufactured to fit an individual patient’s anatomy are a better choice in the thoracoabdominal aneurysm setting if the patient is not considered at high risk of aneurysm rupture. As we continue to learn more about off-the-shelf devices, we can begin to better understand the trade-offs in patient-specific and off-the-shelf strategies, and most importantly we can understand what group of patients will benefit most from each technology.

Experience matters when performing complex TEVAR procedures. What operators and centres should be performing this type of procedure?

As with all new surgical procedures, only those operators and centres with the highest skillsets should be performing these procedures in the beginning. These centres see these patients routinely on a referral basis today and have developed the skills and teams required to provide patients the highest standard of care. As confidence builds with these devices, technology improves, and extensive training is established the technology may be disseminated to a larger group of physicians. It is important that both industry and physicians support this strategy from a technology and training standpoint as this will promote long-term success of these complex devices.

A study by Marzelle *et al* (*Annals of Surgery* 2014) concluded that although promising, fenestrated and branched EVAR still carries a significant rate of mortality and complications, mostly related to the complexity of the procedure. In your opinion, what needs to be done to improve outcomes?

Most centres enrolling patients had limited experience with FEVAR for juxtarenal aneurysms and performed their first thoracoabdominal aneurysm endovascular repairs during that study. Their learning curve in patient’s selection and branched EVAR implantation was thus included. While mortality and complications are still experienced with FEVAR and branched EVAR, these rates decrease as user experience has increase. A similar trend was seen with standard EVAR for abdominal aortic aneurysms during the infancy of the treatment but as experience increased, training improved and devices improved, morbidity and mortality were reduced to levels lower than open repair and became the gold standard of abdominal aortic aneurysm treatment. This trend will hold with advanced endovascular repair.

These devices should be used by high volume centres, those that see these cases routinely and have experience with open surgery and advanced technologies. Those wishing to gain access to such technology will need to go through extensive training to ensure they understand how to properly plan these procedures and to ensure they have the proper surgical skills to have positive patient outcomes.

Additionally, our industry partners are working on devices and delivery systems which will significantly reduce the procedure complexity. One example of this is preloaded delivery systems that allow for quick access of the branches and fenestrations on the stent graft. This will significantly reduce surgical time and fluoroscopy and contrast exposure, all of which will improve upon patient outcomes.

Stéphan Haulon is a consultant for Cook Medical and GE Healthcare

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Not all drug-eluting balloons are equal

THOMAS ZELLER

COMMENT & ANALYSIS

Thomas Zeller, Bad Krozingen, Germany, analyses the results of two recent randomised controlled trials comparing drug-eluting balloons to angioplasty alone in femoropopliteal lesions.

Following successful first-in-man trials (THUNDER, FEMPAC) using the Paccocath/Cotavance coating technology (Bayer, iopromide & 3µg/m2 paclitaxel), two recently presented major pivotal trials confirmed the safety and efficacy of paclitaxel-eluting balloons in the endovascular treatment of femoropopliteal arterial disease. The IN.PACT SFA I & II trials using the IN.PACT Admiral device (Medtronic, urea & 3µg/m2 paclitaxel) enrolled overall 331 patients at 57 sites across Europe and the USA in a 2:1 randomisation scheme, and the LEVANT 2 trial including 476 patients who had been treated with the Lutonix 35 balloon (Bard-Lutonix, polysorbate/sorbitol & 2µg/m2 paclitaxel).

The pooled randomised multicentre IN.PACT SFA I & II trials revealed that clinically-driven target lesion revascularisation rates were significantly lower with the drug-eluting balloon as compared to those achieved with angioplasty (2.4% vs. 20.6%, p<0.001). Similarly, the primary patency rate achieved with IN.PACT Admiral was 82.2%, while the primary patency achieved with angioplasty was 52.45% (p<0.001). Primary patency at 360 days calculated by Kaplan-Meier survival estimates was 89.8% for the drug-eluting balloon group and 66.8% for the angioplasty group.

In the LEVANT 2 trial, the primary patency at 12 months defined as freedom from both restenosis and target lesion revascularisation was 65.2% for the drug-eluting balloon which was superior to control angioplasty (52.6%, p=0.015) demonstrating superior efficacy. At 12 months, the freedom from clinically-driven target lesion revascularisation in the Lutonix group was 87.7% compared to 83.2% in the control group (p=0.208).

In both studies no device specific side-effects were reported, and no major amputation occurred. Thus, there was no safety concern regarding wash off of a part of the antiproliferative drug into the distal vasculature.

Are both of the studies comparable? In brief, both studies enrolled only claudicants with femoropopliteal lesions. Lesions in the LEVANT 2 trial were slightly less challenging as compared to the IN.PACT SFA trial regarding mean lesion length (63mm vs. 89mm) and total occlusions (21% vs. 25.8%), and unlike in previous femoropopliteal premarket approval studies, bailout stenting was not considered a failure. Interestingly, the outcome of the control cohorts is almost identical regarding primary patency (52.6% in LEVANT 2 vs. 52.45% in IN.PACT SFA) and freedom from target lesion revascularisation (83.2% vs. 79.4%). Thus, blinding for the treatment, as it was part of the LEVANT 2 protocol but not of the IN.PACT SFA protocol, did obviously not impact the trial outcome; blinding of the duplex physician or technician regarding the treatment modality which the patient received does hardly impact a decision regarding a reintervention in a non-invasive follow-up setting. Opposite to an invasive angiographic follow-up, where it is much more likely that the knowledge of the treatment modality might impact the decision for an ad-hoc target lesion revascularisation, the indication for a reintervention following a non-invasive diagnostic examination is most likely based on the patient's clinical symptoms. Thus, the differences in drug-eluting balloon performance regarding primary patency and freedom from clinically-driven target lesion revascularisation seem therefore to attribute to the different coating technologies. Preclinical animal studies have shown that not every coating technique is equally effective. However, only a direct clinical comparison of both drug-eluting technologies could finally answer this question.

The major message of the both peripheral interventional landmark trials is that a balloon based treatment approach for TASC II A & B femoropopliteal lesions achieves good clinical one-year outcomes regarding freedom from clinical-driven target lesion revascularisation, which is the outcome patient and payers are mainly interested in. Of note, not every drug-eluting balloon is alike; each single device deserves its own clinical efficacy and safety studies.

Thomas Zeller is head, Department of Angiology at Universitäts—Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen, Germany

Drug-eluting balloons closer to approval in the USA, new player debuts in Europe

After the unanimous vote from the FDA Circulatory System Devices Advisory Panel in favour of approval for the Lutonix drug-eluting balloon (Bard), drug-eluting balloons are now closer to becoming available for the treatment of femoropopliteal artery disease in the USA. Medtronic, whose device has been available in Europe since 2009, anticipates an early 2016 US approval for its IN.PACT Admiral. Boston Scientific has recently launched the Ranger drug-eluting balloon in CE-mark countries.

Data from the LEVANT 2 trial comparing the Lutonix drug-eluting balloon with angioplasty alone in the treatment of peripheral arterial disease show that the primary endpoints of both safety and efficacy were met and superior efficacy and non-inferior safety of Lutonix compared to control angioplasty were demonstrated.

Bard submitted the one-year results of LEVANT 2 study to the FDA advisory panel and on 12 June, the panel voted unanimously to recommend the approval of the device in the USA. The results of the LEVANT 2 trial have been submitted for publication in a peer-reviewed journal.

In the LEVANT 2 trial, the primary efficacy endpoint for the Lutonix drug-eluting balloon was primary patency at 12 months defined as freedom from both restenosis and target lesion revascularisation. Primary patency for Lutonix was 65.2%, which was superior to control angioplasty (52.6%, p=0.015) demonstrating superior efficacy. At six months, the primary patency rate was 92.3% for the drug-eluting balloon vs. 82.7% for angioplasty alone (p=0.003).

The primary safety endpoint for Lutonix was freedom from perioperative death and 12-month index limb amputation (above and below the ankle), index limb re-intervention and index-limb related death. The primary safety endpoint rate for Lutonix (83.9%) was non-inferior to control angioplasty (79%, p=0.005). At six months, the rates were similar (94% vs. 94.1%).

At 12 months, the freedom from target lesion revascularisation in the Lutonix group was 87.7% compared to 83.2% in the control group (p=0.208). Differently from other femoropopliteal intervention studies, bailout stenting was not counted as a failure; a post-hoc analysis with procedural stenting counted as a target lesion revascularisation was conducted, and a higher freedom from target lesion revascularisation rate for Lutonix (85.3%) compared to control angioplasty (76.4%, p=0.017) was observed at 12 months.

In a press release, Bard said that LEVANT 2 was designed to reduce bias in the results in order to accurately and scientifically assess and compare the long-term performance of key clinical measures.

"Two key aspects of the study design differentiate this trial from other recent superficial femoral artery studies. First, unlike some other trials, the LEVANT 2 clinical trial did not count bailout stenting as a primary patency or target lesion revascularisation failure. Second, to reduce the potential introduction of bias into the subjective clinical decision for revascularisation, the protocol required the clinical assessment to be performed by a physician who was blinded to the treatment group and the doppler patency measurement, the press release clarifies," the company stated.

IN.PACT Admiral

In June, Medtronic announced that it submitted the final module of its pre-market approval application for the In.pact Admiral device to the FDA. The application included data that demonstrated superior clinical outcomes compared with conventional angioplasty, with the lowest rates of repeat procedures (target lesion revascularisation) and the highest rate of uninterrupted blood flow (primary patency) at 12 months ever reported for the interventional treatment of peripheral artery disease.

In April 2014, Medtronic released at the Charing Cross Symposium the one-year results of the IN.PACT SFA trial. In the study, the IN.PACT Admiral drug-eluting balloon was significantly superior to angioplasty. The primary patency rate achieve with the drug-eluting balloon was 82.2% and for angioplasty it was 52.45% (p<0.001). Freedom from clinically driven target lesion revascularisation was 97.6% with the drug-eluting balloon and 79.4% with angioplasty (p<0.001).

"This exciting milestone keeps us on track for FDA approval of the In.Pact Admiral drug-coated balloon in the USA in early FY16," said Tony Semedo, president of Medtronic's endovascular therapies business.

"The introduction of drug-coated balloons in the USA for the treatment of peripheral artery disease in the superficial femoral artery is highly anticipated as a new standard of care for this difficult to treat condi-

tion, especially due to the consistently strong clinical data we've witnessed with In.Pact Admiral," says John Laird, co-principal investigator of IN.PACT SFA, and interventional cardiologist, UC Davis Medical Center, California, USA. "The IN.PACT Admiral clinical programme has raised the bar for the industry, and may reduce the need for traditional interventions as first-line treatment, such as metal stents, which are not ideally suited for this dynamic artery."

The In.Pact Admiral drug-coated balloon received the CE mark in 2009 but remains an investigational medical device in the USA.

Stellarex

Covidien's Stellarex drug-coated angioplasty balloon continues to be shown as safe and effective for treatment of peripheral arterial disease, according to new 24-month data released from the company's ILLUMENATE first-in-human study. The first-in-human study results were reported at the EuroPCR congress (20–23 May, Paris, France).

The ILLUMENATE first-in-human study is a prospective, multicentre, single arm study designed to assess the safety and effectiveness of the Stellarex drug-coated balloon. In the study, 58 superficial femoral and/or popliteal lesions in 50 patients were pre-dilated with an uncoated angioplasty balloon, followed by treatment with the Stellarex drug-coated balloon. When used to treat lesions in leg arteries, the Stellarex drug-coated balloon is intended to open narrowed or occluded vessels to restore blood flow and simultaneously deliver paclitaxel, the drug used in the balloon coating, to the vessel wall. This helps prevent restenosis after the artery has been treated.

The study found the Stellarex drug-coated balloon to be safe, with durable results to 24 months, including:

- Primary patency (defined as the treated artery remaining open without further treatment required or renewed blockage detected by ultrasound scanning) was 82.3% at 24 months.
- Freedom from clinically-driven target lesion revascularisation at 24 months was 87.9%. This is the same rate observed at 12 months; no new events were reported demonstrating a sustained low rate of repeat treatment out to 24 months.
- No amputations or cardiovascular deaths.

"We are very pleased with the study's promising results, as they support the use of an important emerging treatment for a painful and physically limiting condition that affects millions of people around the world, " says Henrik Schröder, radiologist, Vascular Center-Jewish Hospital, Berlin, Germany, and principal investigator, ILLUMENATE FIH study. "Good patency after two years, which translated into the absence of new clinically-driven target lesion revascularisations after one year and through the second year patient follow-up, demonstrates the durability of the Stellarex drug-coated angioplasty balloon."

Ranger gets the CE mark

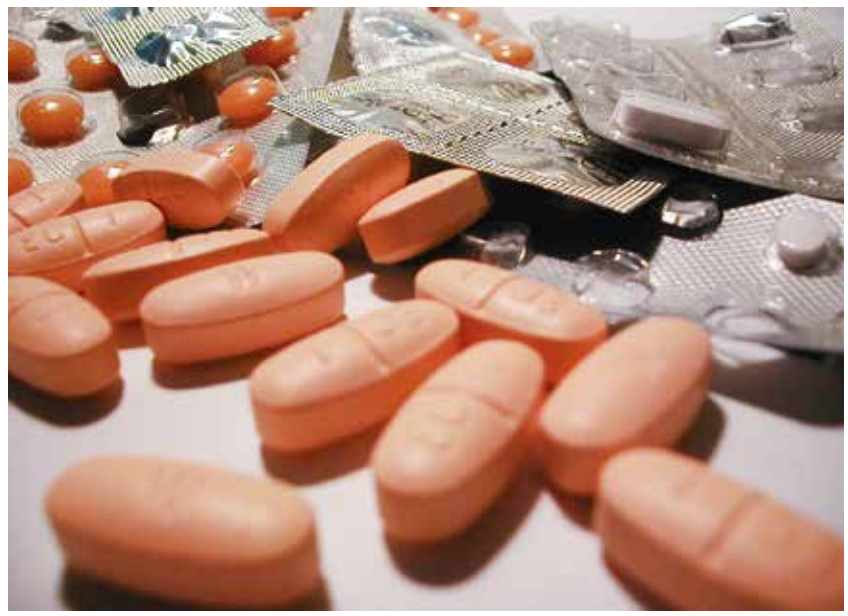
Boston Scientific has received the CE mark for the Ranger Paclitaxel-Coated PTA Balloon Catheter. "The Ranger device offers tremendous promise and will provide another important tool to treat both above-the-knee and below-the-knee lesions," said Dierk Scheinert, director, Center of Vascular Medicine, Angiology and Vascular Surgery at Park Krankenhaus, Leipzig, Germany. "When using contemporary technologies, a significant amount of drug coating can be lost during the handling, insertion and delivery of the device. I am excited by the technology in the Ranger drug-coated balloon, which has the potential to reduce drug loss significantly while optimising both deliverability and the absorption of the drug in the targeted tissue."

Ranger

According to Boston Scientific, the Ranger DCB combines the deliverability of the market-leading Sterling balloon platform and the proven drug Paclitaxel with advanced technologies designed to address the delicate and often unstable nature of the coating associated with contemporary drug-coated balloons. The Ranger DCB features proprietary Trans-Pax coating technology and an innovative loading tool designed to maintain drug-coating integrity and maximise drug-transfer efficiency resulting in consistent and predictable drug delivery.

Antiplatelet therapy and statins improve vascular surgery patient survival by 26% at five years

The use of antiplatelet therapy and statins has increased over time; however, many patients remain medically undertreated around their vascular surgical procedures. An analysis of the Vascular Quality Initiative (VQI) including data for over 50,000 patients shows that optimal medical therapy improves survival by 26% at five years.



Patients undergoing vascular surgical procedures have a high rate of coronary artery and cerebrovascular disease, such that 75% of these patients ultimately die of cardiovascular causes. Antiplatelet and statin medications have shown to reduce cardiovascular events.

Randall De Martino, Mayo Clinic, Rochester, USA, who presented the analysis results on behalf of the VQI at the Society for Vascular Surgery Annual Meeting (5–7 June, Boston, USA), said: "Because of their beneficial effects, multiple societal guidelines recommend antiplatelet and statin use for patients with coronary artery, symptomatic peripheral arterial and cerebrovascular diseases. However, many patients remain medically undertreated and are not administered these medications at an opportune time such as surrounding vascular surgical procedures."

> ***"Guidelines recommend antiplatelet and statin use for patients with coronary artery, symptomatic peripheral arterial and cerebrovascular diseases. However, many patients remain undertreated and are not administered these medications at an opportune time"***

The purpose of the study presented by De Martino was to evaluate antiplatelet and statin use across the VQI and identify the factors associated with improved medical management, such as the duration of participation in the VQI, as well as patient and procedural characteristics.

The investigators analysed all patients undergoing procedures within the VQI from 2005 to 2013 including carotid endarterectomy and stenting, open and endovascular aneurysm repair, peripheral vascular intervention, as well as supra and infrainguinal bypass procedures. The analysis was limited to the first time and elective procedure for each patient. The primary outcome was the use of medical management defined as the use of antiplatelet and statin medications, both preoperatively and prescribed at discharge. The secondary outcome was five-year mortality.

The study excluded patients undergoing urgent and emergent procedures, and patients (<1%) who had missing preoperative data on medications, leaving nearly 53, 000 patients available for perioperative analysis. For the survival analysis, patients who suffered in-hospital post-operative mortality, or who had missing discharge medication data were also excluded, leaving 50,108 patients (94%) of all eligible patients to provide five-year survival analysis.

Of the patient population studied, 37% underwent carotid interventions, 17% aneurysm repair, 16% bypass and 30% peripheral procedures.

De Martino explained that from 2005 to 2009 the use of optimal medical management increased from 55% to 68%—and that this was driven primarily by the Vascular Study Group of New England QI initiative to improve statin use. From 2009 to 2013 a large number of new centres entered the VQI; however, over the same time interval, optimal medical management within VQI dropped from nearly 70% to 59%. "It appeared that centres that joined over this time interval had reduced rates of medical management similar to those seen by centres in 2005 and 2006, deluding the overall rate of optimal medical management in the total of VQI cohort," he said. "To investigate this we looked at medical management as a function of the length of the participation within the VQI. This analysis confirmed that longer participation was associated with improved medical management particularly after the third year."

Randall De Martino

Furthermore, the rise in optimal medical management was not driven by any one procedure collected within VQI. But rather all procedures slowly increased rates of optimal medical management as a function of participation time within VQI.

By multivariable analyses, optimal medical management was less likely in older patients, those with chronic end-stage diseases as well as racial and ethnic minorities. As expected, patients with risk factors for vascular disease were more likely to be on optimal medical management. When analysed by procedure type, patients undergoing all non-carotid procedures were less frequently treated with optimal medical management. However, prolonged participation in VQI of at least three years was associated with improved medical management after controlling for other risk factors.

"Importantly, optimal medical management is associated with improved survival. Patients who were discharged on both antiplatelet and statin medications had five-year survival of 81%, and those discharged on neither medication had a survival of 55%—this represents an absolute survival benefit of 26% at five years," De Martino noted. He added: "As expected the predictors of worse survival included increasing age, male gender, functional capacity, and advanced heart and renal diseases."

De Martino told delegates that the findings were limited by the fact that these were observational data, therefore causation could not be proven. However, he said, "the multivariable model provides strong evidence for our conclusions". In addition, he stated that "although medical adherence was not tracked year on year, we know that 85% of those discharged on these agents remained on them at one-year follow-up".

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Angioscopy system used to guide wiring in chronic total occlusions

Daisuke Kamoi, Nagoya Kyoritsu Hospital, Nagoya, Japan, reported on the first-in-man experience of angioscopy-guided chronic total occlusion techniques in peripheral arterial lesions at the EuroPCR congress (20–23 May, Paris, France). The system used in the study was the I-Light angioscopy system from iHeart Medical.

Kamoi told delegates that chronic total occlusions remain one of the most challenging lesions in interventional medicine, especially in longer and complicated peripheral arterial disease lesions. "Recently, in order to improve the revascularisation success rate, we investigated the efficacy of using an angioscopy-guided technique to penetrate the true lumen of chronic total occlusions," he said.

He explained that the angioscope is positioned proximally to the chronic total occlusion lesion, and the luminal observation of chronic total occlusion entry was achieved for 60 to 80 seconds with single balloon occlusion and saline flushing. After visually identifying the centre of chronic total occlusion entry, the wire is inserted through the balloon and tip lumen to penetrate the lesion. Then the wire drilling is monitored by angioscopic and cineangiography screen simultaneously, to ensure the wire is in true lumen. Furthermore, the stiffer wire is determined after the chronic total occlusion entry is confirmed by angioscopy.

Kamoi then presented the first-in-man cases with the system. In the first, a superficial femoral artery chronic total occlusion lesion, the main artery chronic total occlusion entry was confirmed by angioscopy. After the soft wire penetrated the core, a stiffer wire passed the true lumen easily. In the second case, the retrograde wire was viewed by angioscopy, and the two wires were in the same lumen. Then the retrograde wire was inserted into the antegrade sheath.

"We performed eight cases until February 2014, with 100% success. The new technique using angioscopy to guide wiring in chronic total occlusion lesions was safe and efficient. To further enhance the user friendly procedure, a new delivery catheter of double wires is under development," Kamoi said.

He added, "This forward-looking visual technology enables strategic selections of chronic total occlusion crossing methods from the characteristic observation of the entrance."

Kamoi also noted that the system has limitations: it is difficult to observe the orifice of the superficial femoral artery, and it required pre-dilatation for the bulky device to pass the lesion prior to chronic total occlusion.

Daisuke Kamoi

Directional atherectomy safe in claudication and critical limb ischaemia

Directional atherectomy is safe and effective for the treatment of peripheral arterial disease, according to a multicentre study published online in the *Journal of American College of Cardiology: Cardiovascular Interventions*.

Results from the DEFINITIVE LE study using Covidien's TurboHawk and/or SilverHawk devices demonstrated 95% limb salvage in patients with critical limb ischaemia and 78% overall patency in claudicant patients at 12 months.

The prospective, multicentre study enrolled 800 patients in 47 centres in the USA and Europe. Among patients with claudication, primary patency was 78% at 12 months. This rate did not differ between patients with diabetes (77%) and those without diabetes (78%)—the first such results to be shown in a prospective, powered analysis. Specifically for the superficial femoral artery, the patency rates were 83% in lesions under 10cm in claudicants.

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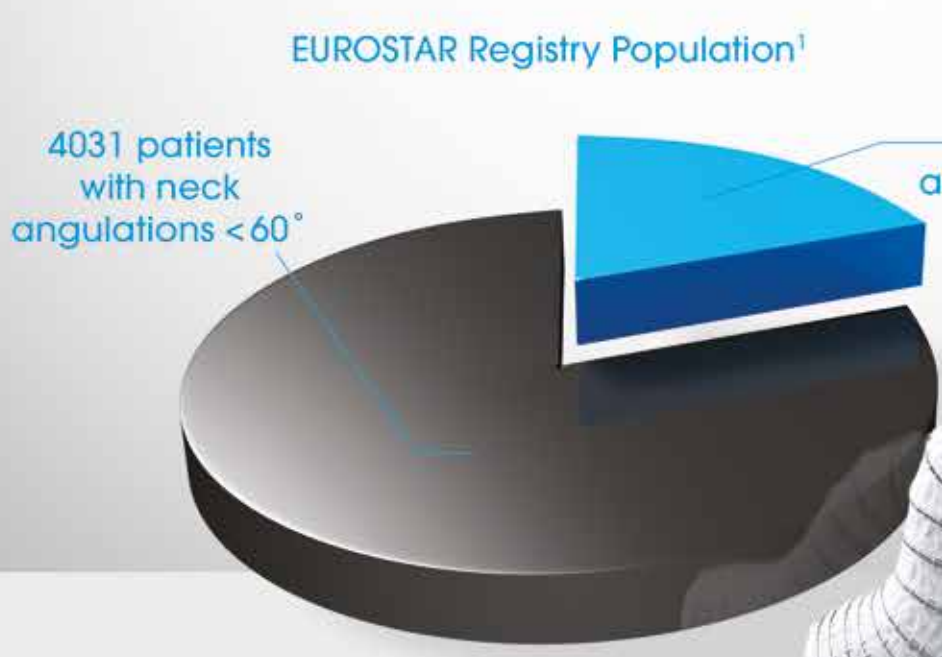

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1. Hobo R, Kievit J, Leurs LJ, Buth J, et al. 2007 Influence of severe infrarenal aortic neck angulation on complications at the proximal neck following endovascular AAA repair: a EUROSTAR study. *J Endovasc Ther*. 14(1), 1-11.
2. Schanzer A, Greenberg RK, Hevelone N, Robinson WP, Eslami MH, Goldberg RJ, Messina L. 2011. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. *Circulation*. 123(24), 2848-55.

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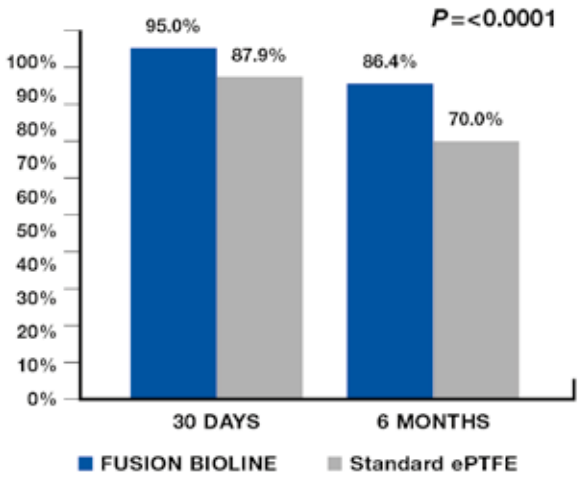

Primary patency at 6 months was significantly higher for FUSION BIOLINE compared to Standard ePTFE with patency rates of **86.4%** vs. 70.0% respectively. The difference was 16.4% **(*P*=<0.0001).**

The FINEST Trial*:

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Silver alginate dressing similar to plain gauze in lower extremity wounds

In a multicentre randomised trial a silver alginate dressing failed to reduce wound complications in patients undergoing open lower limb procedures. The results were presented at the Society for Vascular Surgery Annual Meeting (5–7 June, Boston, USA).

C Keith Ozaki, director of Vascular Surgery Research, Brigham and Women's Hospital/ Harvard Medical School, Boston, USA, told delegates that wound complications negatively impact lower extremity arterial reconstruction outcomes. Acticoat Absorbent, from Smith & Nephew, is a moisture absorbing alginate coated with nanocrystalline silver that delivers a sustained, three-day dose of broadly antimicrobial silver ions. The current study builds on a single-centre retrospective study carried out in Florida between 2002 and 2005 showed that the wound complication rate fell 64% with utilisation of the Acticoat-based dressing (control 14%, treatment 5%).

In this new investigator-initiated, prospective randomised clinical trial, the researchers tested the hypothesis that this silver-eluting topical surgical dressing would reduce wound complication rates in patients undergoing open arterial lower extremity procedures compared to standard gauze.

"The study included patients undergoing open (incision below inguinal ligament) arterial surgical procedures for peripheral vascular disease in which it was anticipated that the incisions would be closed. Open cases combined with endovascular approaches were acceptable," Ozaki said.

Five hundred patients at three institutions (Brigham and Women's Hospital, Beth Israel Deaconess Medical Center and Michael E DeBakey Veterans Affairs Medical Center) were randomised to either standard gauze or silver alginate dressings placed over incisions after lower extremity arterial surgery. This original dressing remained until gross soiling, clinical need to remove, or postoperative day three, whichever first; and subsequent care was at provider discretion.

C Keith Ozaki

The primary endpoint was 30-day wound complication incidence based on NSQIP guidelines. Demographic, clinical, quality of life, and economic endpoints were also collected.

According to Ozaki, patients (72% male, 45% diabetic; 41% critical limb ischaemia) had an overall 30-day wound complication incidence of 30%, with superficial surgical site infection as the most common. In an intent-to-treat analysis, silver alginate (30.4%) had no significant impact on wound complications in comparison with conventional therapy (29.7%, p=0.87). In a multivariable analysis, body mass index (OR 1.05, 95% CI 1.01–1.09, p=0.01) and warfarin (OR 1.72, 95% CI 1.03–2.88, p=0.04) were significantly associated with wound complications.

In conclusion, Ozaki, said, "the incidence of wound complications remains high in contemporary open lower extremity arterial surgery. Under the conditions of this study, a silver alginate dressing showed no effect on wound complications rates".

He noted that the study had some limitations: it was non-blinded; the complications were self-reported, with no independent follow-up observer; there was no standardisation of securing dressing and no tracking of subsequent early incisional care.

"Open lower extremity vascular surgery offers great benefits to selected patients, but these complications continue to negatively impact outcomes," Ozaki concluded. "These results challenge us all to innovate new approaches to prevent these problems. In secondary analyses we did observe some interesting beneficial trends in participants that had open wounds at the time of surgery, and future research will focus on such high risk patients identified via the current trial."

Endovascular-first strategy for aortoiliac lesions irrespectively of TASC category

Two-year data from a prospective, multicentre study suggest that endovascular therapy with stenting may be considered the preferred first-line treatment option for aortoiliac lesions, irrespectively of TASC lesion category.

The results from BRAVISSIMO (Physician initiated multicentre Belgian-Italian trial investigating Abbott Vascular iliac stents in the treatment of TASC A, B, C & D iliac lesions), a non-randomised trial including 325 patients with aortoiliac lesions, were presented at the Society for Vascular Surgery Annual Meeting (5–7 June, Boston, USA).

According to the TASC II recommendations, TASC A and B lesions should be treated endovascularly and TASC C and D lesions should be treated with surgery. The objective of the BRAVISSIMO study was to evaluate the long-term (up to 24 months) outcome of using stenting as a primary approach also for TASC C and D iliac lesions in a controlled setting, Gianmarco de Donato, Vascular and Endovascular Surgery Unit, University of Siena, Siena, Italy, told delegates. The Absolute Pro self-expanding stent and the Omnilink Elite balloon-expandable stent were used in the study, which was carried out in 12 centres in Belgium and 11 centres in Italy.

The endpoint was primary patency at 24 months, defined as a target lesion without a haemodynamically significant stenosis on duplex ultrasound (>50%, systolic velocity ratio >2.0). A separate analysis for TASC A and B vs. TASC C and D population was performed.

Marc Bosiers, Department of Vascular Surgery, Algemeen Ziekenhuis Sint-Blasius, Dendermonde, Belgium, was the primary investigator of the study.

Between July 2009 and September 2010, 190 patients with TASC A or B (140 in Belgium and 50 in Italy), and 135 patients with TASC C or D (85 in Belgium and 50 in Italy) aortoiliac lesions were included. According to the investigators, the demographic data were comparable for TASC A and B cohort and TASC C and D cohort.

Technical success was 100%. Significantly more balloon-expandable stents were deployed in TASC A and B lesions, and considerably more self-expanding stents were placed in TASC C and D (p=0.001).

Gianmarco de Donato

The results showed that primary patency rate after 24 months for the total population was 87.9% (88% for TASC A, 88.5% for TASC B, 91.9% for TASC C and 83.1% for TASC D). There was no statistically significant difference between the groups.

The study also demonstrated that the 24-month primary patency rates were 92.1% for patients treated with the Absolute Pro self-expanding stent, 85.2% for patients treated with the Omnilink Elite balloon-expandable stent and 75.3% for patients treated with a combination of both stents (p=0.06).

Univariate and multivariable regression analyses using Cox proportional hazards model identified kissing stent configuration (p=0.0012) and obesity (p=0.0109) as independent predictors of restenosis (primary patency failure).

This trial, De Donato stated, confirms the findings of earlier retrospective data concerning excellent results of endovascular repair in all iliac lesions. He added, "Mixed use of balloon-expandable and self-expanding stents increases with complexity of the lesion configuration and does not influence primary patency results".

"The 24-month data confirms that endovascular therapy may be considered the preferred first-line treatment option of iliac lesions, irrespectively of TASC lesion category. Neither TASC classification nor lesion length was (independently) predictive of restenosis," he said.

EJVES impact factor increases to 3.07

The 2013 impact factor for the *European Journal of Vascular and Endovascular Surgery* (EJVES) increased to 3.07. This compares with 2.98 for the *Journal of Vascular Surgery*, 1.03 for the *Annals of Vascular Surgery* and 3.59 for the *Journal of Endovascular Therapy*. Never before has the EJVES impact factor exceeded that of the *Journal of Vascular Surgery*.

According to A Ross Naylor, *EJVES* editor-in-chief, and Philippe Kolh, senior editor, the journal has introduced a number of initiatives to improve quality and appearance: "We have changed the way our manuscripts look, with greater use of colour in titles, tables and figures. We now have an iPad *EJVES* app which is free to subscribers. All of our manuscripts are language edited, making style and readability more consistent; we open each issue with either an editorial or a contemporary (controversial) issue or a topical Transatlantic Debate; and we plan to expand our Education section. We also have introduced an 'Editor's Choice' paper which is free to access and all papers that have been in print for more than 12 months are now free to download. As ever, we remain keen to support vascular trainees and the subscription for ESVS trainees (which includes electronic and print access to the *EJVES*) is only €32 per year.

"The editors and editorial board remain committed to further improving the quality of the journal and we hope that many of the readers of *Vascular News* will consider the *EJVES* as first choice for your vascular submissions in the future."

A Comment & Analysis article by Roger Greenhalgh is available on page 19.

Charing Cross announces call for abstracts and posters

The Charing Cross Symposium has announced a call for its abstract sessions, which run parallel to the main programme at the symposium (28 April–1 May 2015, London, UK).

Senior and junior clinicians are invited to submit an abstract or poster online to be considered for the CX Abstract Session. The authors of the abstracts and posters selected by the CX Programme Organising Board will be invited to submit their topic for consideration to be included in the CX Main Programme for 2016. This builds in a route for talent to be spotted and promoted and provides an opportunity to recognise the upcoming key opinion leaders who could potentially be part of the invited CX Faculty.

The deadline for submission is 17 October 2014. Please visit www.cxsymposium.com/abstracts to read the submission guidelines and submit your abstract.

John Mannick receives SVS Lifetime Achievement Award

Photo: SVS

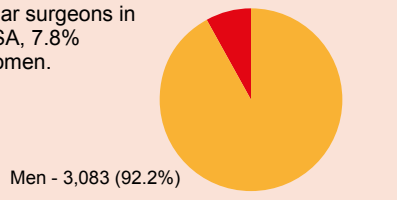
John Mannick, vascular surgeon from Boston, USA, was honoured with the Lifetime Achievement Award at the Society for Vascular Surgery Annual Meeting (5–7 June, Boston, USA).

Julie Freischlag, SVS president 2012–2013, commented: "Dr Mannick has been described as one of the giants in vascular surgery during the formative years of our specialty as we differentiated ourselves from general and cardiac surgery. His accomplishments as a surgeon, scientist, and educator have inspired many and his legacy continues to be a source of inspiration in the specialty today."

"I think I have proven that if you stay alive long enough, you keep getting awards," Mannick said. "I am pleased and honoured to receive the SVS Lifetime Achievement Award."

Women in vascular surgery

Of the 3,345 certified vascular surgeons in the USA, 7.8% are women.



Source: Vivian Gahtan, SVS, June 2014

Surgeons' results

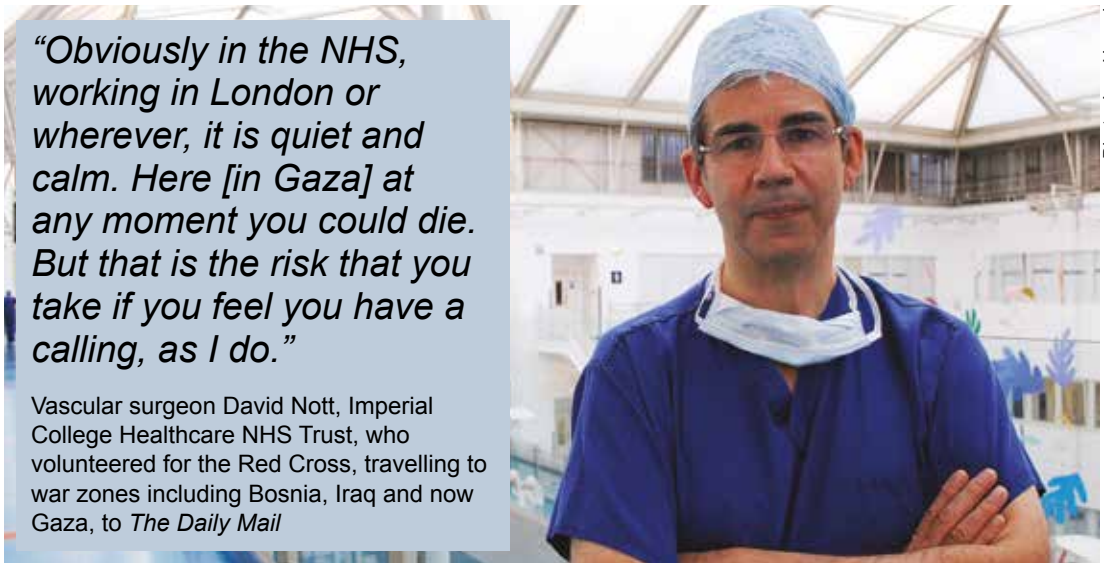
On 30 September, the UK National Vascular Registry will publish surgeon level information on two procedures: abdominal aortic aneurysm repair and carotid endarterectomy for all UK surgeons currently undertaking each procedure in NHS hospitals. For aneurysm repair, it will provide results for the past five years of practice, and for carotid endarterectomy it will provide results for three years of practice.

Screen women smokers for aneurysm

In a recommendation statement published online on 24 June in the Annals of Internal Medicine, the US Preventive Services Task Force (USPSTF) updated its 2005 recommendation on screening for abdominal aortic aneurysm. The document assessed the evidence on the benefits and harms of screening for aneurysm and strategies for managing small (3—5.4cm) screen-detected aneurysms in asymptomatic adults aged 50 years or older. The USPSTF:

- Recommends one-time screening with ultrasonography in men aged 65 to 75 years who have ever smoked (B recommendation)
- Recommends that clinicians selectively offer screening for abdominal aortic aneurysm in men aged 65 to 75 years who have never smoked (C recommendation)
- Concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for aneurysm in women aged 65 to 75 years who have ever smoked (I statement)
- Recommends against routine screening for aneurysm in women who have never smoked (D recommendation)

The paper was published by Michael L LeFevre on behalf of the U.S. Preventive Services Task Force.



"Obviously in the NHS, working in London or wherever, it is quiet and calm. Here [in Gaza] at any moment you could die. But that is the risk that you take if you feel you have a calling, as I do."

Vascular surgeon David Nott, Imperial College Healthcare NHS Trust, who volunteered for the Red Cross, travelling to war zones including Bosnia, Iraq and now Gaza, to *The Daily Mail*

Photo: Leo Hornak

LITERATURE HIGHLIGHTS

Elective endovascular aortic repair conversion for type Ia endoleak is not associated with increased morbidity or mortality compared with primary juxtarenal aneurysm repair

JVS, August 2014, Salvatore T Scali et al, Division of Vascular Surgery and Endovascular Therapy, University of Florida, Gainesville, USA

DOI: 10.1016/j.jvs.2014.02.046

Impact of hybrid rooms with image fusion on radiation exposure during endovascular aortic repair

EJVES, online 21 July 2014, A Hertault et al, Vascular Surgery, Hôpital Cardiologique, CHRU de Lille, Lille, France

DOI: 10.1016/j.ejvs.2014.05.026

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Vascular societies and their journals: Impact on education

ROGER GREENHALGH

COMMENT & ANALYSIS

Journal impact factor results for 2013 have just been announced, and a comparison of five journals is of interest. The current editor-in-chief of the *European Journal of Vascular and Endovascular Surgery* (*EJVES*), Ross Naylor, and his Editorial Board and team of reviewers over the last five years are to be congratulated. During the time of this team, the impact factor (3.07) has overtaken the *Journal of Vascular Surgery* (*JVS*) for the first time (2.98).The team has consolidated the success of Jean-Baptiste Ricco, the previous editor-in-chief (3.01 in 2008). The *JVS* slipped from 3.51, whereas the *EJVES* rose from 1.77 in 2003.

A comparison of the August 2014 issues of the *JVS* and *EJVES* indicates 44 papers/abstracts 32 in vascular surgery (72%) for *JVS* and 19 papers including 14 in vascular surgery (73%) for *EJVES*. The initial essay on the Thompson Reuters Impact Factor draws attention to the need for great care in reading too much into impact factors. The original aim was to have "a measure of the frequency with which the 'average article' in a journal has been cited in a particular year or period". Matters such as title change affect the factor even if the quality stays the same. It is not a "be all and end all" indicator of excellence. But some bias such as journal size is at least reduced. But whatever the shortcomings of this measure, they apply to both of these society journals. Why the elation in European vascular and endovascular surgical circles? Because the ESVS, the European Society FOR Vascular Surgery was created in 1987 in the very image of the great SVS, the Society FOR Vascular Surgery. The ESVS even had the cheek to call its journal *The European Journal OF Vascular Surgery* in February 1987 just like big brother the Journal OF Vascular Surgery. There is no greater flattery than to copy the leader. So, the significance of the news on impact factor results is for the European Society to realise that it is now in the "same ballpark" as its mentor Society and that this reading is but a result of a moment in time, good for those who have brought it about but to be greeted as a challenge both sides of the Atlantic not to relax but to maintain and improve.

Impact factor	EJVES	JVS	AVS*	JET	JVIR**
2013	3.07	2.98	1.029	3.59	2.149
2012	2.82	2.879	0.985	2.699	1.167
2011	2.991	3.21	1.035	2.856	2.075
2010	2.872	3.853	1.332	2.942	2.064
2009	2.919	3.517	1.169	2.902	1.805
2008	3.007	3.77	1.262	2.682	2.217
2007	2.159	3.272	1.5	2.392	2.207
2006	2.156	3.311	1.227	2.135	2.398
2005	2.026	3.173	1.194	1.05	2.675
2004	1.685	2.73	1.067	1.845	1.679
2003	1.774	3.507	0.914	2.636	2.212

*Annals of Vascular Surgery
**Journal of Vascular and Interventional Radiology

It is worth taking a brief look at the results of the *Journal of Endovascular Therapy* (*JET*). This journal is the "baby" of Dr Ted Diethrich who almost single-handedly dragged the cardiovascular establishment in North America and in Europe to enjoy his live case demonstrations from Phoenix, Arizona—we all owe a huge debt to his vision. Ted is a high class open cardiovascular surgeon who had a thriving practice in the Methodist Hospital in Houston alongside Drs Michael DeBakey and Stanley Crawford (he of the "Critical Issues" session on the first mornings of the SVS in its heyday). Against the backdrop of the wonderment of open replacement of the whole aorta including hypothermia and cardioplegia with aortic valve replacement on the way, Ted went to the Arizona desert and pointed to another way, the endovascular way. His journal, the *Journal of Endovascular Therapy* had 25 papers (60%) vascular in August 2014. Dr Diethrich recommended to the Editorial Board of *JET* more than 10 years ago to change its name to be a journal of vascular therapy by vascular specialists not limited to vascular surgeons. The *JET* impact factor in 2003 was 2.64 (*EJVES* 1.77, *JVS* 3.51) and the *JET* impact factor is now 3.59 (*EJVES* 3.07, *JVS* 2.98)! Is there a message there? Dr Michael Dake thinks so and has recommended that the great SVS should become the SVS ie. the Society for Vascular Specialists. I call for the ESVS to do the same. The journals should also follow suit in my view. Why? Because, as editor of a journal or officer of the societies, I would not wish to send signals that only surgeons are welcome. What nonsense. Vascular surgeons have long been vascular physicians at the same time. According to that analysis there is no call for a European Society for Vascular Medicine which is rumoured to begin. We need centralisation and collaboration and inclusiveness not disparity.

The question began as one on impact factor and it is highly possible that the title of a journal will determine the excellence of papers submitted. But surely the key point is that multidisciplinary education should be the norm. Open vascular surgery is not dead by any means and sometimes it is the best option. There is a danger of becoming deskilled. But being together with other vascular disciplines surely gives the patient a better chance of input from various disciplines. So in the end, does it come down to the pride of being a surgeon? Once felt, this pride is hard to shift. But is it time for a little humility on all sides of vascular disciplines in the patient interest? Would we see better attended continental meetings? Would these meetings attract wide ranges of interdisciplinary contribution?

It is time for the Society FOR Vascular Specialists (SVS) and the European Society FOR Vascular Specialists (ESVS) and their journals still *JVS* and *EJVES* or even a return to the original EJVS but now *European Journal OF Vascular Specialties*.

Roger Greenhalgh, Imperial College London, UK, is editor-in-chief of Vascular News

Ultrasound-enhanced delivery of paclitaxel inhibits restenosis after balloon angioplasty

Results from a feasibility study indicate that ultrasound-enhanced paclitaxel delivery inhibits arterial smooth muscle proliferation after angioplasty in peripheral arterial disease. Costantino Del Giudice, University Hospital Tor Vergata, Rome, Italy, spoke about the study at the EuroPCR congress (19–23 May, Paris, France).

Del Giudice, who spoke about "Ultrasound-enhanced delivery of paclitaxel to femoropopliteal artery in patients with Rutherford category 4–6" and conducted the study with Roberto Gandini, noted that ultrasound has been used in several medical therapies.

He explained that CardioProlific has developed a system for ultrasound-enhanced acute delivery of paclitaxel to peripheral arterial lesions, and commented: "Ultrasound energy is used to change lesion compliance and increase vessel permeability and contrast agent is used to deliver paclitaxel to the vessel wall."

According to Del Giudice, the target lesion is treated with balloon angioplasty only. The ultrasound catheter is then introduced in the treatment area and the vessel wall is exposed to ultrasound energy for 60 seconds. A flow protection balloon catheter is positioned distally to the treatment area, inflated, and a mixture of paclitaxel and contrast medium (1.0µg/mm2) is delivered to the treated lesion for at least 60 seconds. Finally, the mixture of paclitaxel and contrast is aspirated from the body.

The study employing the system was conducted at the University Hospital Tor Vergata. The primary endpoint (safety) was freedom from major adverse cardiac events at 30 days (including death, amputations, bypass surgery, myocardial infarction), and the secondary endpoint was procedural success (angiographic restenosis at six months and target lesion revascularisation at six and 12 months).

The study enrolled 21 patients aged 74.2±7.5 years, and 80% were men. At six months, Del Giudice said that the restenosis rate was 5%, and there were no reinterventions, amputations or deaths. He added that there was one reintervention at 12 months and the patient died of bowel ischaemia.

Costantino Del Giudice

"The technology is suitable for superficial femoral and popliteal arteries, with the advantage of not having an implant. It is simple to perform, with easy-to-use hardware and catheter, and is quick and safe. It is also efficient and cost-effective," he said.

He concluded by saying that the human feasibility study indicates that ultrasound-enhanced arterial paclitaxel delivery inhibits smooth muscle proliferation after balloon angioplasty, fits well with standard peripheral interventional techniques and represents a non-implant solution with homogenous drug delivery to the vessel wall. He added that "encouraging results in challenging cases demonstrate a great potential for this technology for critical limb ischaemia patients. A larger clinical study is required to validate this promising new approach".

Renal stenting may benefit patients excluded from randomised trials, says new expert consensus

Randomised controlled trials, including CORAL and ASTRAL, have failed to demonstrate benefit of renal artery stenting over optimal medical therapy. However, a new expert consensus developed by the Society for Cardiovascular Angiography and Interventions (SCAI) and published online in *Catheterization and Cardiovascular Interventions* states that there are patients whose condition might be improved by stenting who were excluded from the trials. Sahil A Parikh, assistant professor of Medicine, Case Western Reserve University School of Medicine, and the paper's lead author, spoke to *Vascular News* about the recommendations.

Why was there a need to develop new recommendations for the treatment of patients with renal artery disease?

The motivation for the society [SCAI] was the emerging data in the field—not just for renal artery disease but also for other areas of peripheral arterial disease. There are few guidelines that focus not only on indications but also on best practices for the performance of the procedures. While in the United States we have appropriate use criteria for coronary intervention, there is a vacuum in the arena of peripheral arterial intervention. We reviewed all of the available data and guidelines and organised them in a single document to make them accessible for clinicians. We tried to capture what we see in clinical practice, with a focus on addressing potential gaps. Our focus was on when renal intervention represents appropriate care. The second point was to delineate the current knowledge base in these areas and try to identify the scenarios that are frequently encountered in clinical practice. And of course we wanted to present our expert consensus on how to perform the procedure safely.

What group of patients would benefit from stenting?

CORAL adds a lot to our knowledge base. And what the trial says is what the guidelines said all along: that patients should be treated with optimal medical therapy. One can argue that CORAL shows that patients who are not refractory to optimal medical therapy will not benefit from revascularisation. That is the takeaway from that study, which was done in a rigorous way. We all accept and believe its results. The problem is that there are patients who are refractory to medical therapy, and who might have been excluded from CORAL—those with progressive nephropathy that results in end-stage renal disease, or those patients with truly resistant hypertension. We can see from the curves that both the medical therapy and revascularisation arms have marked reductions in blood pressure once patients are enrolled in the trial. Whether that is a bias of patients taking part in a trial, or because medical therapy was not optimal before they were enrolled in the trial, it is hard to discern. For example, in SYMPLICITY HTN-3, where the results were surprisingly neutral, both groups showed benefit in reduction of blood pressure. So maybe there is more to it.

The patients who experience the greatest benefit, both anecdotally and in case series, are those with real "flash" pulmonary oedema. These patients frequently were excluded from CORAL. So there are gaps. In addition, the trial did not include global renal ischaemia, meaning bilateral disease, and we feel that global renal ischaemia certainly has the highest level of benefit as the stakes are higher in those patients.

The definitions of significant renal lesions have also changed. While initially in CORAL a significant lesion was 80% stenosis assessed by angiography or 60% or greater with haemodynamic confirmation, that was relaxed during the trial due to slow enrolment. Subsequently it included duplex ultrasound, CT and MRA, and those are not as accurate and have lower sensitivity and specificity compared to direct translesional mean pressure measurement or more stringent criteria, and this is something we say in the document. First, global renal ischaemia, and second, patients with certain conditions that were CORAL exclusion criteria. For example, this would include the mandate to be on three or four medications at maximal doses (as opposed to only two) with systolic blood pressure greater than 160mmHg.

CORAL has set the bar, and the guidelines go in line with the trial. You have to do a good job to evaluate the patient and identify renal artery disease in a rigorous manner. If you do that, and separate

Sahil A Parikh

those patients out, they are the ones likely to benefit, but there is no individual randomised controlled trial data that supports that.

And we cannot forget that this is a highly complex field. If you read only the headline from CORAL, it is that renal stenting is not valuable. But when you dig into the details, there are clear areas where patients would have benefited if they had not been excluded.

How should heamodinamically significant stenosis be determined?

The major point in the document that is not commonly known is renal fractional flow reserve (FFR), as used in the coronary arteries. De Bruyne and colleagues have shown that renal FFR (Pd/Pa) correlates with physiological renin secretion and probably would allow us to discern those lesions that are haemodynamically significant from those that are not. There is a table in the manuscript that is useful to physicians—it shows that if the stenosis is lower than 50%, it is not significant. In fact there were many patients with less than 50% stenosis in ASTRAL, and those patients should never have been treated.

A stenosis of 50–70% (intermediate) can be a grey zone, and we recommend evaluation by one of three methods: measuring the pressure gradient at rest, and if the mean is >10mmHg then you have a significant stenosis; the second would be to induce hyperaemia as we do with FFR except that adenosine is not the right agent, we use dopamine or papaverine, and you have a hyperemic systolic pressure gradient >20mmHg, that also would be a significant lesion; and the last would be those with Pd/Pa of 0.8 or lower. If the stenosis is greater than 70% it is reasonable to assume that it is a haemodynamically significant stenosis. This algorithmic approach will allow us to say "Yes, there is existing atherosclerosis", and "No, it is not haemodynamically significant", or conversely "It is significant and therefore in the right clinical context it may be appropriate for therapy".

Are many patients who do not fall into the category of significant stenosis receiving stents?

While that may have been a concern previously, now we have a strong reluctance to treat some patients who may benefit from revascularisation. I think many of us have patients who we have treated after careful evaluation, in whom we intervened upon and saw improvement in their clinical status. But we have to be rigorous about it. Some would argue that we have gone too far and are being too restrictive with those patients that might benefit from therapy.

In the document, what does each level of evidence category encompass?

This is an expert consensus document, so that is a level evidence C. On the other hand, we review data from clinical trials and other datasets. The problem is that for many of the scenarios there is a paucity of data. There are certain scenarios, particularly those that are in the "may be" appropriate care category, where clinical discretion is applied and patients may or may not benefit but it is reasonable to consider renal intervention when the appropriate steps are taken. And those scenarios are not adequately assessed in clinical trials. For the ones included in the appropriate care category, we would support patient inclusion, and primarily those in the category of case series where there has been corelab control. That leads us to another problem with the original, early trials: the lack of core laboratory. They were basically based on investigator report of angiographic stenosis, for example, and lead to the same conundrum of what a significant lesion is.

Are there any trials underway in the USA looking at renal artery stenting?

To my knowledge there is not an active randomised controlled trial. In truth, I doubt that there will be again after the duration of time that took for CORAL to be completed. The appetite for that kind of study is increasingly going away.

For patients in whom stenting is recommended, what technique should be used?

This paper reviews a good deal about optimal technique for renal stenting. We recommend the use of a no-touch technique whenever possible, or a telescoping catheter, to safely engage the renal artery for multiple reasons but mainly to limit trauma at the time of engagement. We do talk about using selective angiography with appropriate catheters; we talk about the techniques to measure gradients; we review what data there are regarding embolic protection devices and adjunctive medical therapies.

SCAI aims to develop documents that are accessible to physicians, that can help organise their thoughts about a specific disease entity, in this case renal artery disease, which has a great deal of controversy after some of the randomised controlled trial data. We wanted to put it in a way that is digestible and easy to understand, and can also help to identify that subset of patients who might benefit. We did not want the baby to be thrown out with the bathwater.

To read the statement:
The SCAI Expert Consensus Statement for Renal Artery Stenting Appropriate Use and other SCAI documents can be downloaded at www.scai.org/guidelines

Ethical dilemmas surrounding the appropriate use of vascular surgery procedures

At this year's Stanley Crawford Critical Issues Forum which was held at the Society for Vascular Surgery (SVS) Annual Meeting (5–7 June, Boston, USA), Russell H Samson, Sarasota Vascular Specialists, Sarasota, USA, spoke about ethical issues related to frequency of vascular procedures and whether too many procedures are being performed unnecessarily.

"Like all of us in this room, I am daily confronted with ethical dilemmas that can interfere with treatment decisions, and I am proud to be part of the SVS as the society is looking at these ethical issues in an open manner," Samson told delegates. "Three words – ignorance, incompetence and indifference – help to explain why there are unnecessary procedures. The worst physician is the one who is indifferent – indifferent to data, results, complaints and the suffering of others, and who lacks the moral responsibility to being an ethical physician. This type of physician has no moral compass and will do whatever he/she pleases."

He noted that ignorance is a problem amongst some physicians. "There are people in other specialties that are not sufficiently educated in vascular disease and do not recognise that they do not have the judgment nor skills to offer appropriate treatment, nor do they recognise when to refer to a vascular surgeon rather than attempt a procedure they should not be doing." And Samson added that incompetence is also a problem: "Open and endovascular procedures are not generic, not every surgeon or interventionalist will be proficient and bad results lead to more interventions."

Speaking about the impact of reimbursement, Samson commented that until the government and insurance agencies adequately reimburse physicians, there will be professionals who will see volume as the only way to rectify the financial disparity. "I really believe there were fewer inappropriate procedures when there were fewer doctors and they were paid appropriately," he said.

Russell Samson

Insurance issues also drive more procedures, Samson affirmed, and cited atherectomy as an example. "The number of atherectomies being performed has increased so much because now we are being paid to do a procedure that before we were not. Procedures like atherectomy and other innovations are important but they may spur utilisation and cause unnecessary procedures because there will be physicians amongst us who will feel it is important to be the first to bring this procedure to the community. That may be completely ethical if that physician is well trained in this new procedure, but what about if the physician is just jumping in the bandwagon with minimal experience and just trying it out? Then it is probably not ethical at all."

Samson stated that industry can also cause overuse of procedures by promoting benefits before they have stood the test of time. "They seem to encourage adoption with minimal oversight of who is doing it and the credentials of the people who are doing it. Why should they care as long as someone is buying their device?"

Physicians also face an ethical dilemma when deciding on treatments with different long-term outcomes: "Should we perform a highly compensated atherectomy, angioplasty and stent of a totally occluded anterior tibial artery knowing that the patient will be back for the next procedure in the not too distant future or rather perform a less well paid yet time consuming bypass that may last for years?"

Indications may also contribute to overuse. He mentioned not yet well proven procedures such as renal artery stenting or renal denervation, and questioned whether physicians should be able to perform these procedures if the community is not sure if they provide benefits.

Furthermore, Samson said that academic promotion may incentivise a surgeon to do more, especially if it is in the specific area of research that the surgeon is renowned. He commented: "The surgeon who has made a reputation studying surgery for small aneurysms may find the need to operate on ever smaller ones."

He went on to say that perhaps one of the most important causes of ethical lapses is the absence of scrutiny in outpatient environments separate from hospitals. "This is where most bad things are happening. Here anyone can do anything and the only intervention occurs when a major complication sends the patient to a hospital or a negligent act results in a malpractice suit. As long as the government and insurers refuse to certify who can do what in the outpatient setting we will have poorly qualified, immoral doctors let loose on their unsuspecting prey. Now saphenous veins are being ablated on an industrial scale by anyone in so-called 'vein centres' and some cardiologists without vascular training, and even some surgeons, are inserting stents into every known artery in outpatient labs."

Concluding his talk, Samson suggested three ideas to ensure ethical behavior: only physicians who are board certified by a recognised specialty and who have been appropriately trained and have the right credentials should be allowed to perform procedures in hospital and independent facilities; payment must ultimately be based on outcomes where not only the result but the indication needs to be taken into consideration; and medical schools need to provide courses in ethical behavior, which must be recognised as being equally important as anatomy and physiology.

Finally, he told the audience, "I know that all of us try to follow the most ethical path as honest physicians despite the temptations and hurdles that we face in our day to day practices. Accordingly, I think [SVS president] Peter Lawrence and the [SVS] organising committee should be congratulated for organising this symposium. Because with this event, vascular surgeons demonstrate our leadership as the profession most suited to not only treat but also to protect patients with vascular conditions."

Eversion carotid endarterectomy: A technique that matters

PHILIP S K PATY

COMMENT & ANALYSIS

Philip S K Paty, Albany, USA, says that eversion carotid endarterectomy is the preferred technique to treat carotid artery disease. Over the past two decades, his centre has performed over 11,000 of these procedures, with a <1% incidence of perioperative stroke.

Strict attention to technical details is the most important aspect of carotid endarterectomy. The ideal carotid endarterectomy technique should make sense intellectually, be easy to perform, be transferrable to other operators, be modifiable depending on the circumstances, and have superior outcomes and a low rate of recurrence. The neck positioning, exposure and dissection for all types of carotid reconstruction including endarterectomy with or without patch, bifurcation advancement and bypass are similar. The devil, so to say, is in the details with regards to handling of the plaque endpoint and method of arterial closure.

An interesting historical note is that Dr DeBakey's original description of the carotid endarterectomy technique performed in 1959 involved transection of the distal common carotid artery and eversion endarterectomy of the carotid bifurcation. The limitations of this technique were handling of more extensive disease in the internal carotid artery. The current iteration of the eversion carotid endarterectomy involves an oblique transection of the proximal internal carotid artery at the carotid bifurcation, thus isolating eversion of the internal carotid artery from that of common carotid artery and external carotid artery. Transection of the internal carotid artery at the carotid bifurcation simplifies the eversion endarterectomy even in the presence of extensive occlusive disease that spans higher into the internal carotid artery.

As with most surgical techniques, eversion carotid endarterectomy requires careful attention to detail. Aside from preoperative imaging studies, intraoperative visual and tactile clues determine the level of clamp placement. The transition of colour of the distal non-diseased internal carotid artery to a bluish normal tinge is an important visual cue for distal clamp placement. Palpation and compression with a forceps of the common carotid artery determines the proximal level of clamp placement. The technique requires oblique internal carotid artery transection at the bifurcation and circumferential mobilisation to half a centimetre beyond the distal disease. The internal carotid artery plaque is separated with an elevator or fine forceps. Plaque proximally is held by a forceps, gentle downward traction is applied, the adventitia is everted over the plaque like a shirt-sleeve cuff rolling up an arm and the plaque plucked out where it feathers out thinly at the distal end. The endpoint is checked visually and with gently catheter directed irrigation for any loose debris or residual mobile plaque which may embolise or dissect distally. This can be removed by further eversion or stripping debris circumferentially. Alternatively, the plaque can be secured with full thickness tacking sutures. Endarterectomy plane in the common carotid artery is then developed and the plaque cut proximally and removed. External carotid plaque is everted a short distance so that no debris embolises into the internal carotid artery. At this time, redundancy of the internal carotid artery can be excised or the medial wall incised to create a longer patched anastomosis. The internal carotid artery is then sewn to the common carotid artery in an end to side fashion.

Additional measures to deal with extensive internal carotid artery plaque are similar to those used in standard longitudinal carotid endarterectomy and involve division of the ansa hypoglossus, medial and cephalad mobilisation of the hypoglossal nerve and occasionally division of the digastric tendon. Occasionally, reflection of the divided internal carotid artery over the hypoglossal nerve may be required to facilitate eversion. These manoeuvres allow exposure and eversion of the internal carotid artery up to the skull base. If one still cannot obtain a plaque endpoint, the internal carotid artery can be transected and a bypass performed for reconstruction with either a vein or prosthetic graft.

Extensive proximal common carotid artery disease can be managed by encompassing this within a longer caudally directed oblique transection of the carotid bifurcation. Internal carotid artery redundancy and a medial slit often allow a long anastomosis. Alternatively, the usual length oblique transection is made and a longitudinal caudally directed arteriotomy is made. This then is closed with a separate running suture prior internal carotid artery to common carotid artery anastomosis.

If needed, shunt can be placed prior to eversion after internal carotid artery transection. Here the medial internal carotid artery is incised beyond the plaque and the shunt placed in the distal internal carotid artery. The shunt is secured, back bled and air freed, placed in the proximal common carotid artery and flow restored. The shunt then serves as a stabilising point for the distal internal carotid artery facilitating eversion. Alternatively, the internal carotid artery eversion can be performed first, the shunt placed and the internal carotid artery endpoint checked after eversion over the shunt. Either Javid or Pruitt type shunts can be used. The end to side anastomosis is performed around the shunt which is removed prior to complete closure allowing back bleeding and removal of any thrombus.

The currently available carotid stenting options have not achieved equipoise in terms of stroke prevention, risk reduction and recurrent stenosis as compared to open surgery. Carotid endarterectomy, thus, is the best available option currently available. Over the past two decades, we have performed over 11,000 eversion carotid endarterectomy procedures and taught the eversion technique to vascular fellows and residents, the vast majority of whom have adopted this as their go-to technique. The overall incidence of perioperative stroke is <1% for all indications. We perform over 95% of these procedures under cervical block and have routine clamp times of 15 minutes or less.

Implementing a technical change in a vascular surgeon's "routine" management of carotid disease is difficult and involves assessment of manageable risk. This requires knowledge of tangible benefits of the technique, a plan for implementation and dealing with emotions related to change. This issue has parallels in other innovations such as progressive use of the internet for marketing and sales and remote computer linked workplaces to accommodate lifestyles. Although I would acknowledge that one's comfort level and experience is important in choice of reconstruction of the internal carotid artery, eversion endarterectomy, as a result of its facile nature, is, in my opinion, the preferred technique.

Philip S K Paty is professor of Surgery, Albany Medical College, Albany, USA, partner, The Vascular Group, PLLC

Peter Lawrence elected president of the Society for Vascular Surgery

Peter Lawrence was elected 2014–2015 president of the Society for Vascular Surgery (SVS) during the Vascular Annual Meeting (5–7 June, Boston, USA).

Lawrence, Wiley Barker chief of vascular surgery in the David Geffen School of Medicine at the University California Los Angeles (UCLA), is also director of the UCLA Gonda (Goldschmied) Vascular Center and the Bergman Chair in Vascular Research.

Prior to his current positions, Lawrence was on the faculty at the University of Utah in Salt Lake City from 1978–1998, where he served as chief of surgery at the Veterans Administration Hospital, chair of the division of vascular surgery, and president of the medical staff. He moved to California in 1998 to become associate dean of clinical affairs, vice president for specialty services, and professor of surgery at the University of California, Irvine.

Lawrence earned his medical degree with honours from Harvard Medical School and completed his surgical residency and vascular surgery fellowship at Columbia-Presbyterian Medical Center in New York City. He has written over 200 clinical and basic research papers, 70 book chapters, and five textbooks. He is an editor of the *Journal of Vascular Surgery* and has been on the editorial boards of the *Vascular and Endovascular Surgery*, *Perspectives in Vascular Surgery*, and *Contemporary Surgery*.

Julie Ann Freischlag and Peter Lawrence

Freischlag named SVS Foundation chair

The SVS Foundation announced SVS past president Julie Ann Freischlag as the new SVS Foundation Chair. Freischlag follows in the footsteps of Peter Gloviczki, who successfully led the Foundation to increased participation from SVS members. SVS past presidents move into the SVS Foundation Chair position at the end of their term.

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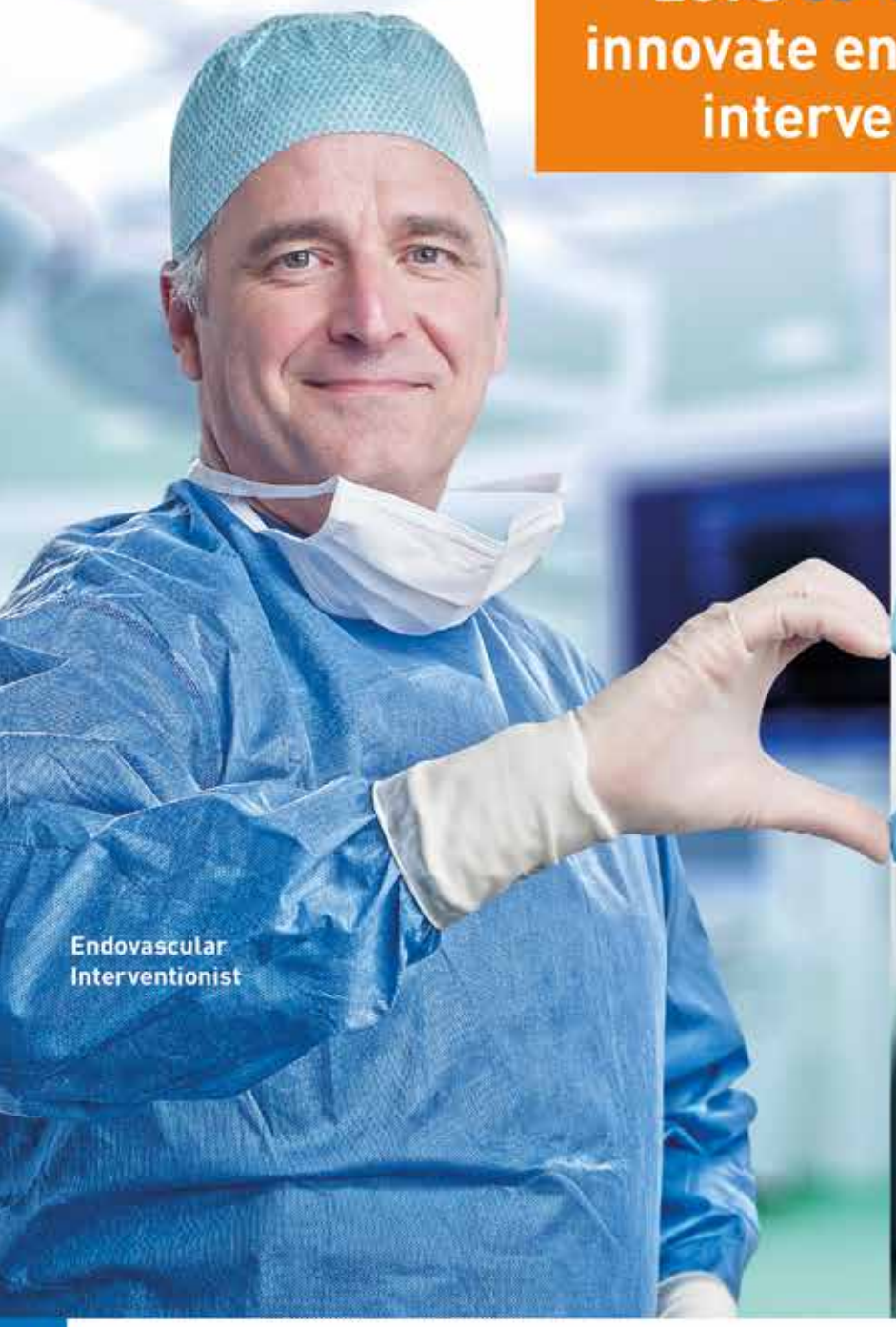

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"We are exploring the scope of robotic catheterisation"

Barry T Katzen, founder and medical director of Miami Cardiac & Vascular Institute, Florida, USA, tells *Vascular News* that his team and other practitioners are gathering data on their early experience with intravascular robotics and trying to establish where in the workflow it offers the most benefit.

Could you provide some perspective on the use of intravascular robotics?

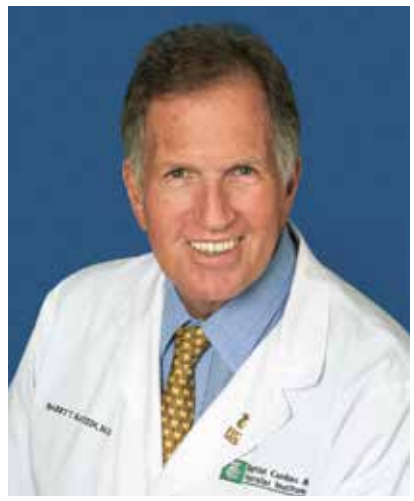
We have been exploring the application of robotic catheterisation to identify clinical benefit to patients as a result of the technology. We are at the early stages of evaluation to understand which cases it might bring advantage to, and as a result we have used it in a very diverse group of clinical applications from renal embolisation to carotid stenting to complex EVAR. Right now, we are exploring the scope of where robotic catheterisation can bring value.

What are the most important benefits of using robotic navigation?

There are several potential benefits, one of which is a less traumatic navigation through the circulatory system. Because of the robotic catheter's ability to be more centrally located and be less dependent on sliding against the side wall of a vessel, which is the way traditional way manual catheterisation works, there may be some clinical benefit there, although this might be difficult to prove. Saying that, in early animal work, there seems to be evidence that robotic catheterisation is actually less traumatic than manual catheterisation. The other important areas of potential benefit are reduction of radiation exposure for both the operator and the patient. One of the areas that we are currently exploring is in left to right crossover catheterisation in the iliac arteries. For example, if we have a patient who needs an embolisation of a right hypogastric artery. Ordinarily, we would approach this with a catheter from the left groin going over to the right side. The operator would be working very close to the pelvis with a lot of scatter radiation, and frequently working with fingers and hands across the field. The use of a robotic catheter actually positions us away from the image intensifier, with significant dose reduction to the operator. If the catheterisation can be done more efficiently, then there is a potential dose reduction for the patient as well as for all the allied co-workers in the room, because people can stand back and away from the patient who is the big source of the X-ray scatter. For instance, we are evaluating use of the technology in EVAR. If we can introduce the robotic catheter into the workflow so that we can reduce the number of catheter and wire exchanges, then there can be a significant dose reduction to the patient as well.

Which procedures have you performed using robotic catheterisation?

We have a diverse group of procedures in which we are evaluating the value of robotic catheterisation including fenestrated and conventional EVAR. In conventional EVAR, when we put the robotic catheter on first instead of a pig-tail catheter to be able to identify the renals for precise localisation. Instead, with a robotic catheter we can just direct it at the lowest renal artery with very small hand adjustments



Barry T Katzen

with 2 or 3cc of contrast during deployment, sparing the need for high volume and high flow injections of contrast. Once the body of the endograft is deployed, we can then use the same robotic catheter, bring it down and catheterise the contralateral gate, all with the same device. So introducing the robotic catheter early in the workflow seems to have more value. In other words, I do not think that using it to just catheterise the contralateral gate has a huge amount of value. The other area that we have seen value for these catheters is in embolisation procedures. We have used it in a variety of embolisation procedures including contralateral hypogastric arteries, and renal artery aneuryms and renal embolisation for renal tumour ablation. Additionally we have utilised the robotic system for carotid interventions.

What are the limitations of robotic systems?

I think the key limitations are the size of the device and cost. The company (Hansen Medical) has recently received FDA approval for the 6F device (catheter) which is shapeable. We have had some initial experience with the 6F catheter which offers a reduced size and the ability to do robotic assisted microcatheter procedures. The other aspect is cost, as investing in intravascular robotics represents a significant capital investment. It is not a device that you can do the entire procedure with (with the exception of carotid stenting and embolisation) using the robotic catheter and delivery system and those limitations would have to be addressed.

What is the evidence to show that robotic catheterisation has any benefit?

The value conferred by a procedure is defined as a combination of clinical benefit and financial cost. At this stage , we do not have a lot of evidence and are trying to accumulate data. There are two studies that are ongoing; one is the Rover Registry that is trying to capture all of the data related to all of the applications in which this device is being used. The question of whether it is a workhorse device or a unique application device remains to be proven. The one thing I can say anecdotally, on initial experience, is that there definitely have been patients in whom the robotic catheter has made possible things that would have been extremely difficult, or impossible with manual catheterisation techniques. However, being able to identify which patients would benefit most requires more data. We are working with other users to identify where the clinical benefit is and how it is measured. This may be technology that will help people who have lesser interventional skills or experience to carry out better catheterisations, but that remains to be proven. Interventional radiologists, the most skilled 'catheter jockeys' in the world, need to evaluate and assess this technology in order to see if there is any meaningful value it can bring.

Novel sealing technology conforms to the aortic neck and minimises pressure on luminal wall

Fixating and sealing abdominal aortic aneurysms with a stent graft that uses an O-ring polymer sealing system shows positive outcomes with no incidence of type I endoleaks at two years, according to data presented at the Charing Cross Symposium (5–8 April, London, UK). Syed Hussain, Christie Clinic, Champaign, USA, who spoke about novel sealing technology for EVAR using the TriVascular Ovation stent graft system, stated that the device has the benefit of confirming to the aortic neck and exerting little force on the aortic wall.

Ovation has characteristics that make it different from all other devices currently available, at least in the USA, Hussain said, and addresses some of the limitations of endovascular grafting that can lead to unsuccessful sealing: heavy calcification, severe thrombus, and reverse taper conical necks.

The Ovation Global Pivotal Study showed 100% freedom from types I and III endoleaks at one and two years with Ovation. He added, "All patients were also free from graft migration, and the incidence of enlargement was minimal. A subgroup analysis of this trial also demonstrated that 40% of the patients had access vessel <6mm diameter and also neck lengths <10mm, or both, so this study included a more challenging group of patients than we would often use in a stardard endograft trial."

Another study, the Ovation Post Market Registry including 501 patients treated in a real-world setting, showed freedom from types I and III endoleaks of 99.2% at one year and of 100% at two years.

"So what is the durability of the O-ring seal and the graft? With self-expanding stent grafts, conventional wires and fabric grafts may not be able to fully conform to in an irregular luminar surface, with calcification or large amounts of thrombus, invariably exposing the risk for type I endoleak," Hussain noted. "With Ovation Prime, we have the ring filled with polymer. The polymer is injected in a low viscosity liquid state, allowing the sealing ring to mould and conform to irregular luminal surfaces, creating a customised seal." He continued, "A second point is that when you have a self-expanding graft against the aortic wall there is constant outward radial force on the wall. You also have blood pressure constantly causing an outward force. With Ovation, the O-ring exerts very little pressure on the aortic wall, with non-expansive circumferential apposition from sealing ring creates no chronic outward radial force and no aortic neck dilatation." With Ovation, he said, there is minimum or no aortic neck dilatation over a period of two years.

Hussain then reported the experience with Ovation Prime in Illinois, where the first case was performed in November 2012. To April 2014, 46 grafts were implanted. The technical success rate was 100%, and there were no late type I endoleaks or type III, IV or V endoleaks at 14 months. There were eight cases of type II endoleaks, with no aneurysmal growth to date. Sixty seven per cent of devices were delivered via a percutaneous approach. There were no cases of limb occlusions or secondary procedures. The average length of stay was 1.7 days.

"We had an interest in Ovation because we deal with patients with limited access—small or calcified iliac arteries—who otherwise would have been treated with open repair or fenestrated grafts, and the low profile (14F OD, 12F ID) has also facilitated the treatment of these patients. The sealing ring works very well producing little pressure on the aortic wall," Hussain said. "Looking ahead, customised polymer seal offers an opportunity for further enhancements to aortic disease management."

PEVAR with Perclose ProGlide is non-inferior to femoral exposure and yields shorter time to haemostasis

Totally percutaneous endovascular aneurysm repair (PEVAR) with an adjunctive preclose technique (Perclose ProGlide) is safe and effective, with minimal access-related complications, and it is non-inferior to standard open femoral exposure, according to results of a randomised trial published in the *Journal of Vascular Surgery*. Compared with femoral exposure approach, the percutaneous access yielded significantly shorter times to haemostasis and procedure completion and favourable trends in blood loss, groin pain, and quality of life.

The first multicentre randomised controlled trial on PEVAR was designed to assess the safety and effectiveness of the percutaneous technique with use of a 21F endovascular stent graft system and either an 8F or 10F suture-mediated closure system. The PEVAR trial was a non-inferiority study comparing percutaneous access with standard open femoral exposure.

Between 2010 and 2012, 20 US centres participated in the prospective, FDA-approved trial to evaluate percutaneous femoral artery access and closure by a "preclose" technique in conjunction with endovascular abdominal aortic aneurysm repair. A total of 151 patients were allocated by a 2:1 design to percutaneous access/closure (n=101) or open femoral exposure (n=50). PEVAR procedures were performed with either the 8F Perclose ProGlide (n=50) or the 10F Prostar XL (n=51) closure devices, both from Abbott Vascular. All endovascular abdominal aortic aneurysm repair procedures were performed with the Endologix 21F profile (outer diameter) sheath-based system.

In the paper, published by Peter R Nelson, Division of Vascular Surgery, University of South Florida, Tampa, USA, and colleagues, they explain that patients were screened by CT with 3D reconstruction and independent physician review for anatomic suitability and adequate femoral artery anatomy for percutaneous access.

The primary endpoint (treatment success) was defined as procedural technical success and absence of major adverse events and vascular complications at 30 days. An independent access closure substudy evaluated major access-related complications. Clinical utility and procedural outcomes, ankle-brachial index, blood laboratory analyses, and quality of life were also evaluated with continuing follow-up to six months.

Baseline characteristics were similar between groups. Procedural technical success was 94% with Perclose ProGlide, 88% with Prostar XL, and 98% with femoral exposure. One-month primary treatment success was 88% with Perclose ProGlide, 78% with Prostar XL, and 78% with femoral exposure, demonstrating non-inferiority vs. femoral exposure for Perclose ProGlide (p=0.004) but not for Prostar XL (p=0.102). Failure rates in the access closure substudy analyses demonstrated non-inferiority of Perclose ProGlide (6%; p=0.005), but not of Prostar XL (12%; p=0.100), vs. femoral exposure (10%). Compared with femoral exposure, Perclose ProGlide and Prostar XL yielded significantly shorter times to haemostasis and procedure completion and favourable trends in blood loss, groin pain, and overall quality of life. Initial non-inferiority test results persist to six months, and no aneurysm rupture, conversion to open repair, device migration, or stent graft occlusion occurred.

Peter R Nelson

The investigators conclude that, amongst trained operators, PEVAR with an adjunctive preclose technique using the ProGlide closure device is safe and effective, with minimal access-related complications, and it is non-inferior to standard open femoral exposure. "Training, experience, and careful application of the preclose technique are of paramount importance in ensuring successful, sustainable outcomes," they write.

According to Nelson, these results have led to the FDA approval of the preclose technique for large bore access closure up to 21F using the ProGlide device and for totally percutaneous EVAR using the Endologix system.

He noted that the PEVAR study had important implications: "First, PEVAR now has an on-label indication, alleviating concerns of many early non-adopters and allowing them to safely offer this strategy to their patients. Second, these data show that PEVAR is as good if not better for patients than standard femoral exposure, so we will be able to quickly address any cost disincentives to use this approach. And, finally these findings open the door to pursue totally percutaneous indications for treatment in other areas that require large profile devices (ie. TEVAR, FEVAR, TAVI)."

Investigation on the potential to expand the indications for PEVAR to a broader set of patients (ie. obese, scarred groins, calcified femoral vessels) is underway. "This will also determine if the percutaneous approach makes outpatient EVAR under local anaesthesia for some a reality," Nelson said.

Similar results with elective post-EVAR open conversion and primary open juxtarenal aneurysm repair for type Ia endoleak

Elective open surgical conversion for type Ia endoleak after endovascular aneurysm repair (EVAR) is not associated with increased morbidity or mortality compared with open juxtarenal aneurysm repair in appropriately selected patients, according to a study published in the *Journal of Vascular Surgery*. Open surgical conversion patients required longer procedure times and received more plasma transfusions.

In the paper, the authors, led by Salvatore T Scali, Division of Vascular Surgery and Endovascular Therapy, University of Florida, Gainesville, USA, write that type Ia endoleak after EVAR can be a challenging complication to manage, and due to concerns regarding morbidity and mortality of open surgical conversion, reports of complex endoluminal salvage techniques are increasing.

"Despite development of these endovascular remedial strategies, many patients ultimately require open surgical conversion. The purpose of this analysis was to assess the outcomes of elective open surgical conversion for type Ia endoleak and compare them with elective primary open juxtarenal aneurysm repair to determine if these concerns are warranted," they say.

From 2000 to 2012, 54 patients underwent EVAR and open surgical conversion at median time of 27 months (interquartile range, 9–55 months). Indications included endograft thrombosis in 2 (4%), intraoperative EVAR failure in 3 (6%), rupture in 5 (9%), graft infection in 6 (11%), and type Ia endoleak in 25 (all: 38 [70%]).

"Because many open surgical conversions are performed for emergency indications without endovascular options, we chose elective type Ia endoleak patients as our study group. These 25 patients were compared with an elective open juxtarenal aneurysm repair cohort matched by anatomy and comorbidities," Scali *et al* write.

The primary endpoint was 30-day and one-year mortality. Secondary endpoints included early complications, cross-clamp time, procedure time, blood loss, and length of stay.

Demographic and comorbidity data in the open surgical conversion and open juxtarenal aneurysm repair groups did not differ, with the exception that open juxtarenal aneurysm repair patients presented with smaller aneurysm diameter and a higher rate of chronic obstructive pulmonary disease (p=0.03).

Open surgical conversion patients more frequently underwent a nontube graft repair (open surgical conversion, n=20 [80%] vs. open juxtarenal aneurysm repair, n=6 [24%]; p=0.0002), required longer procedure times (p=0.03), and received more plasma transfusions (p=0.03). The 30-day mortality was 4% in both groups, and a similar rate of major complications occurred (open surgical conversion, n=9 [36%] vs open juxtarenal aneurysm repair, n=8 [32%]; p=1). One-year survival was 83% in open surgical conversion and 91% in open juxtarenal aneurysm repair (p=0.65).

In their conclusion, the investigators say that despite many advances in EVAR technology, the need for open surgical conversion persists and will likely become more common as older-generation devices fail or providers attempt EVAR in more anatomically complex patients.

"Elective open surgical conversion for type Ia endoleak can be technically challenging but is not associated with increased morbidity or mortality compared with open juxtarenal aneurysm repair in appropriately selected patients. These results should be considered before pursuing complex endovascular remediation of EVAR failures," they conclude.

Speaking to *Vascular News*, Scali said that this manuscript brings attention to the clinical decision making that surrounds management of type Ia endoleak after EVAR. He commented: "As the dwell time for older generation grafts increase and providers push the envelope of conventional EVAR, we may see a steady increase in the rate of EVAR conversion. Currently, there are many different off-label endovascular techniques that are used to manage type Ia endoleak and often, patients undergo multiple remedial salvage procedures that may or may not be successful. This increases resource utilisation, cost, extends time that the patient has an unrepaired aneurysm and may complicate subsequent open conversion. It is clear that open conversion is technically more complex than native juxtarenal aneurysm repair; however, this preliminary analysis would support more timely conversion in appropriately selected patients since comparable results can be achieved."

Scali explained that his group is currently analysing the Vascular Quality Initiative (VQI) database using Medicare claims data to understand the long-term outcomes of open aneurysm repair and EVAR.

"These efforts will provide insight about the rates of aortic-related reintervention and mortality after EVAR, as well as provide greater statistical power to better understand the risk of conversion. What is most needed is to understand the modes of failure and selection bias that leads to open conversion with specific focus on graft-specific, aortic morphologic and patient level factors. Insight about these questions will hopefully come from iterative analyses of the VQI database and industry-sponsored registries," he said.

Fewer adverse events with Aorfix in high angulated aneurysm neck patients

Data from the US PYTHAGORAS clinical trial show that major adverse events are lower in patients treated with Aorfix Endovascular Stent Graft (Lombard Medical) than with open repair, and similar in patients with less severe anatomies treated with other EVAR devices. Results from the trial were presented by Mark Fillinger, director, Vascular Surgery Training Programs, professor of Surgery, Geisel School of Medicine, Dartmouth, USA, at the Society for Vascular Surgery Annual Meeting (5–7 June, Boston, USA).

Fillinger, who is principal investigator for the randomised controlled PYTHAGORAS trial, stated, "Aorfix's highly conformable design allows for the treatment of a wide range of abdominal aortic aneurysm anatomies. The PYTHAGORAS trial was unique and challenging in its focus on anatomy that has never been studied before in an FDA trial, yet Aorfix delivered results very similar to competitor devices used in much less challenging cases."

Aorfix was designed to treat abdominal aortic aneurysms with highly angulated aortic necks. It is a highly flexible, soft, conformable device, made of polyester fabric and nitinol rings, with four pair of hooks proximally and an 8mm-long primary seal zone. It is commonly placed in a transrenal position.

Fillinger told delegates that type I endoleaks increase with neck angle in most EVAR devices, and that neck angle has an effect on seal zone; and noted that in highly angulated aortic necks, the central lumen line is not a good indicator of the actual seal zone.

The US PYTHAGORAS clinical trial is the first EVAR pivotal trial focusing on highly-angulated aortic necks 60–90°. In the roll-in group, 65 EVAR patients with aneurysm neck angle <60° were treated, and in the primary study group, 150 EVAR patients with neck angles 60–90° and higher were included. The US trial enrolled 205 patients on an intention-to-treat basis. The control arms were the SVS Registry meta-analysis of control patients from US EVAR clinical trials (n=323) and the trial concurrently enrolled open surgical controls (n=76) for neck angulation and other variables not in the SVS Registry.

In terms of demographics, comorbidities and anatomy in the PYTHAGORAS trial, EVAR and open control patients had similar aneurysm sac diameter (5.8cm in each group) but the two groups differed with regards to four factors previously shown to adversely affect outcomes: age (EVAR 75.4±8 vs. 69.2±7 years, p=0.001), female gender (EVAR high angle 35% (51/145) vs. 20%, p=0.017), chronic heart failure (EVAR 12.6% vs. 6.5% p<0.05, SVS controls), neck angle (EVAR all 72°±22°, EVAR high angle 83°±15° vs. open repair 48°±22°, p<0.001) ; EVAR 69% >60°, open 27% >60° (p<0.05); open cohort had shorter necks on average.

Mark Fillinger

"This is the first trial with more female patients in the test group, and the first trial with more severe neck angles in the test group," Fillinger said.

Aortic endografts were successfully implanted in 197/205 cases according to the intention-to-treat analysis (all eight cases were access-related, and device was not attempted in four cases). The mortality rate was 2% for the entire cohort (4/205), 1% for the 60–90° angle group (1/103), and 2.6% for the open controls (9/323, p=ns). Thirty-day outcomes favoured the test group for procedure duration, estimated blood loss, transfusion, and hospital length of stay (all p<0.05).

Freedom from major adverse events with Aorfix was superior to open controls at one year. Amongst patients treated with Aorfix, those with aneurysm neck angles 60–110° experienced sac expansion (1.8% had 5mm expansion at one year), type I/III endoleak at one year (2%) and migration (1.7% 10mm at one year).

In conclusion, Fillinger said, despite significant predictors of worse short and long-term outcomes, major adverse events and other pertinent outcomes were better for Aorfix than for open repair, and similar to EVAR trials with much less severe anatomy. "This device provides a less invasive option for patients with highly angulated neck anatomy who would otherwise have poor endovascular options," he added.

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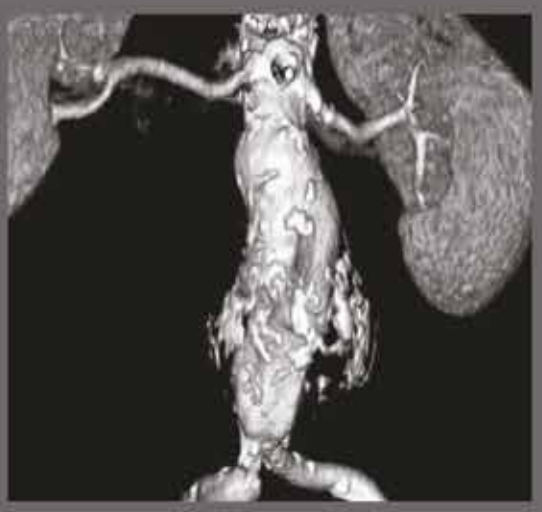
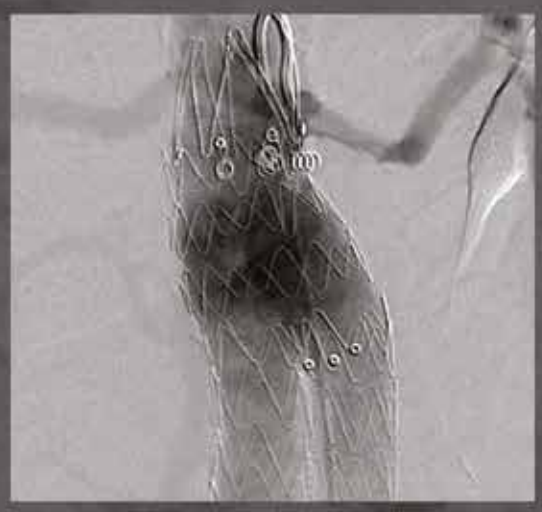
/// Primary EVAR



- Complex neck anatomy is a reason for late seal complication concerns
- Patient unfit for open surgical repair due to comorbidities

- Angio demonstrates proper implantation of endograft and no endoleaks



- 4 EndoAnchors implanted to lock the endograft to the aorta
- EndoAnchors augment proximal seal strength and address late complication concerns

Peter Schneider, MD
Hawaii Permanente Medical Group
Honolulu, Hawaii

Patient Details

- Male, 73yo
- **Aneurysm:** 5.5cm AAA diameter, 15mm proximal neck length (conical neck geometry), 21mm proximal neck diameter
- **Co-morbidities:** Past smoker, hyperlipidemia, hypertension, diabetes mellitus, valvular disease, COPD, S/P stroke, GI disease, GU disease, carotid disease

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Penile artery angioplasty safe and improves erectile function, first-in-man study shows

A study from Taiwan, published in *EuroIntervention* in May and presented at the EuroPCR congress (20–23 May, Paris, France), shows that penile artery angioplasty is safe and can achieve clinically significant improvements in erectile function in 60% of patients with erectile dysfunction and isolated penile artery stenoses at six months.

The authors Tzung-Dau Wang, Cardiovascular Centre and Division of Cardiology, Department of Internal Medicine, National Taiwan University Hospital and National Taiwan University College of Medicine, Taipei City, Taiwan, and colleagues, set out to assess the safety and feasibility of balloon angioplasty for isolated penile artery stenoses in patients with erectile dysfunction in this first-in-man study.

"Obstructive pelvic arterial lesions are highly prevalent in patients with erectile dysfunction and commonly located in penile artery segments," Wang and colleagues write.

The researchers enrolled 25 patients with erectile dysfunction and isolated penile artery stenoses (unilateral stenosis ≥70% or bilateral stenoses ≥50%) as identified by pelvic computed tomographic angiography. From these, 20 patients (mean age 61 years [range, 48-79 years]) underwent balloon angioplasty. Three of these patients had bilateral penile artery stenoses, Wang told delegates at EuroPCR.

Wang and colleagues achieved procedural success in all 23 penile arteries, with an average balloon size of 1.6mm (range, 1-2.25mm). The average International Index for Erectile Function-5 (IIEF-5) score improved from 10.0±5.2 at baseline to 15.2±6.7 ($p<0.001$) at one month and 15.2±6.3 ($p<0.001$) at six months. Clinical success (change in the IIEF-5 score ≥4 or normalisation of erectile function [IIEF-5 ≥22]) was achieved in 15 (75%), 13 (65%), and 12 (60%) patients at one, three, and six months, respectively. There were no adverse events through follow-up.

An accompanying editorial in *EuroIntervention* by Jason H Rogers, University of California, Davis Medical Centre, Sacramento, USA, notes: "Erectile dysfunction is a complex, multifactorial psycho-physical condition. For interventionalists, it is tempting to look at an angiographic stenosis in an erectile-related artery in a patient with erectile dysfunction and attribute a cause-effect relationship."

Tzung-Dau Wang

Rogers also writes that the results of the study from Taiwan had shown "modest" response to intervention as measured by IIEF-5 that could be explained by the placebo effect. "Eighty five per cent of patients at six months still had an IIEF score of <22, which continues to meet the definition for some degree of erectile dysfunction. Longer term clinical follow-up will be required. Without any objective assessment of penile arterial inflow or imaging follow-up, it is not possible to describe what physiologic effect was achieved by performing angioplasty. Given the excitement to find an interventional solution for such a common clinical condition as erectile dysfunction, carefully controlled studies are required," he writes.

ClearWay catheter is a safe and effective fast-track method for peripheral artery occlusion

The ClearWay therapeutic infusion catheter from Atrium Medical, Maquet, is a low-pressure polytetrafluoroethylene microporous balloon catheter. It is an atraumatic delivery system used in the intima for distorting the thrombus and delivering thrombolytic agent at a high local concentration.

Patrick Bagan, Department of Vascular Surgery and Interventional Radiology, Victor Dupouy Hospital, Argenteuil, France, speaks about his experience with the ClearWay catheter in the peripheral vasculature.

The ClearWay catheter is available in two different forms and is indicated for localised perfusion of various diagnostic and therapeutic agents into the coronary and peripheral vasculature. Of the two versions, the catheter designed for peripheral indications is the 0.035"-compatible over-the-wire device. The second is the ClearWay RX, a 0.014" guidewire-compatible platform, which is intended for use in the coronary and peripheral vasculature.

The ClearWay 0.035" device is indicated for use in the periphery and is available in significantly larger diameters than a coronary balloon and is specifically designed for vascular therapeutic drug delivery purposes. This device is US Food and Drug Administration (FDA) approved for any catheter drug delivery.

Other features of the ClearWay are its low-profile and its rapid-exchange for therapeutic infusion ability. The ClearWay therapeutic infusion catheter enables local drug delivery to reach an approximately 500-fold greater drug concentration vs. systemic delivery.

Bagan says that the ClearWay is, at his centre, used for acute thrombotic or embolic Rutherford stage II in patients with acute lower limb ischaemia and adds that it is "currently our first choice for all *in situ* fibrinolysis". He states that infusion of an intrathrombus fibrinolytic agent is now the standard of care in the management of acute peripheral artery thrombosis at his centre.

In terms of choosing the correct size of catheter, Bagan notes that he adapts the diameter of the catheter to the calibre of the artery and the length of the thrombosis; this can range from 3mm to 7mm in diameter and 20mm to 50mm in length.

He adds that traditionally, and previous to using the ClearWay technique, he infused fibrinolytic agent (Urokinase) using a syringe pump through a catheter (Multi-site Port catheter from Cook). During the traditional *in situ* fibrinolysis, Bagan says the catheter is placed inside the thrombus for four to 48 hours. He comments that the patient is immobilised in the intermediate care unit and the procedure is not very comfortable, adding that it is an expensive technique as it requires hospitalisation and the patient needs constant attention from physiologist, physiotherapists and specialised nurses.

On the other hand, he says that because the ClearWay is the fast track method and a bolus of adjunct fibrinolytic is administered quickly, there is an immediate result; therefore the technique with the ClearWay catheter is less expensive. As the ClearWay is the only microporous balloon catheter available on the market at the moment, Bagan states, that fibrinolysis with the device is an effective method that can be used in conjunction with other revascularisation techniques such as endoluminal thrombo-aspiration.

Case report

Bagan explains that at his centre from January 2010, he has treated a range of occlusions ranging from iliac to the below-the-knee arteries in more than 30 patients. From this experience, he notes that an 88% recanalisation rate was observed and there was a significant reduction in hospital stay duration.

"We performed two comparative studies, comparing the ClearWay technique with traditional *in situ* fibrinolysis. We observed that the balloon catheter reduces the fibrinolytic dose required due to the large diffusion surface area and to the deformation of the thrombus by the balloon inflated at low pressure."

In the studies, the efficacy of localised delivery of thrombolysis compared to traditional *in situ* infusion of thrombolytics for acute peripheral ischaemia was assessed.

Between January 2010 and December 2011, 17 patients (mean [±SD] age, 64.6±11.1 years) with acute (symptoms for ≤14 days) peripheral arterial occlusions were investigated. Six patients (group one) were treated by catheter-directed thrombolysis (Urokinase, Actosolv) and 11 consecutive patients (group two) were treated with the ClearWay catheter for localised delivery of Urokinase (group 2).

According to Bagan, intra-arterial infusion dose, morbidity rates associated with thrombolytic treatment and intensive care unit hospitalisation after primary interventions were compared. Recanalisation was achieved in 88.2% of all cases. There was no difference in primary therapeutic success between the two groups.

He notes that the dose of thrombolytic agent infused was significantly inferior in group two (38,000 unit/cm of occluded artery vs. 98,000 unit/cm, $p=0.001$) and intensive care unit duration stay was shorter in group two (1.4 day vs. 3.4 days). The morbidity rate was 12.5%. The limb salvage rate after primarily successful recanalisation was 88%.

Further highlighting the ClearWay catheter's success in the periphery, Bagan describes the case of a 65-year-old patient presenting with acute ischaemia three days after a bilobectomy for lung cancer.

The vessel treated was a popliteal occlusion; a 7-French sheath was used. Fibrinolysis with the ClearWay 4–10mm with an infusion of 1,500,000 units of Urokinase was applied to the occlusion. Bagan reports that there was recanalisation of two arteries and no blood in the chest tube was observed.

"Thrombolysis with the ClearWay catheter is an effective and safe fast-track method for treating acute peripheral arterial occlusion with a low dose of thrombolytic agent," he summarises.

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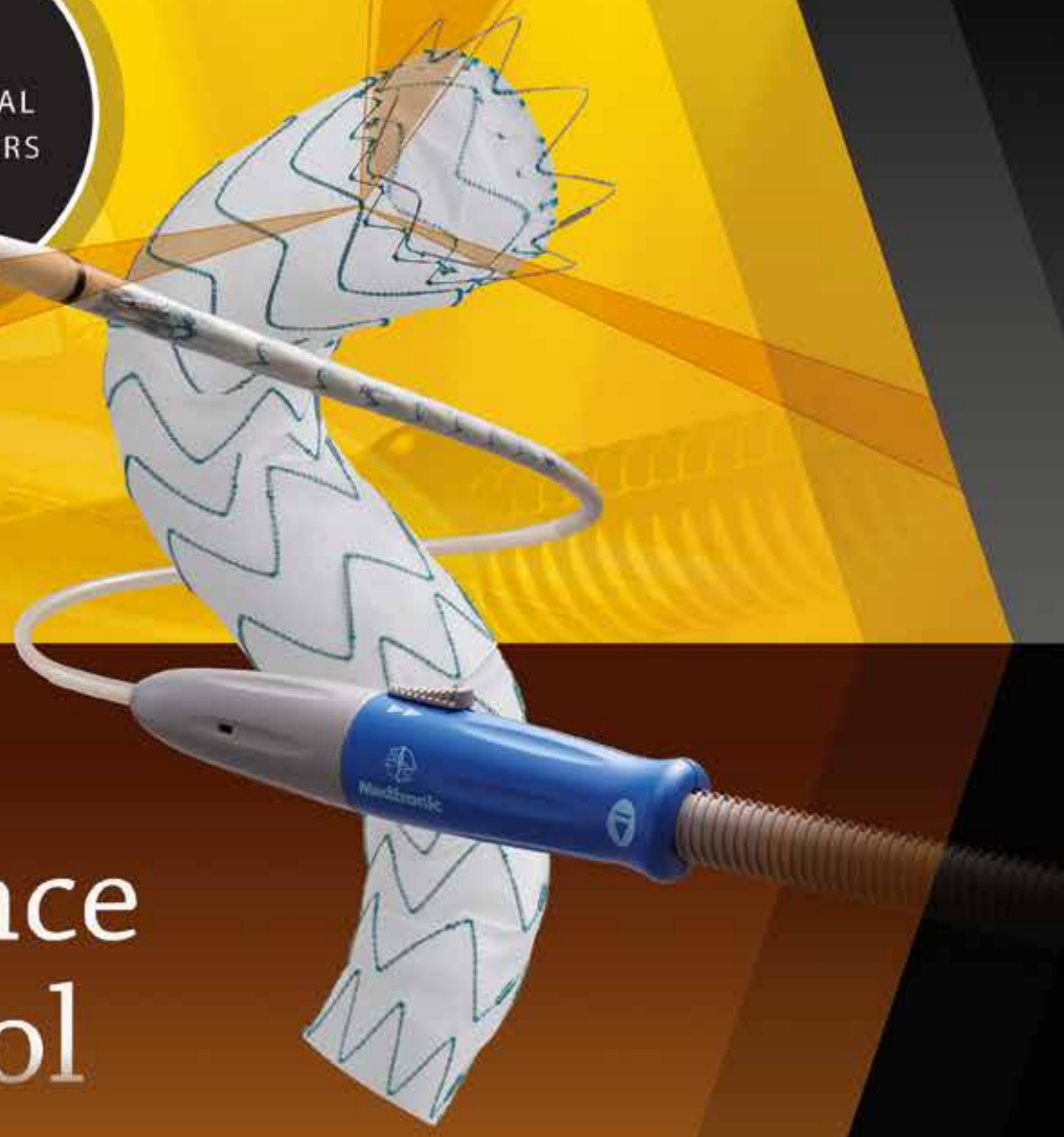

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Innovating for life.

Profile Martin Björck

Martin Björck, professor of Vascular Surgery, Institution of Surgical Sciences, Department of Vascular Surgery, Uppsala University Hospital, Sweden, holds the only professor-chair of vascular surgery position in Sweden. A strong advocate of abdominal aortic aneurysm screening programmes, Björck has been at the forefront of the Swedish experience in identifying men over 65 years of age at risk of aneurysm rupture. He tells *Vascular News* about his early career, proudest moment and hobbies, including moose hunting, hiking and cooking.

When did you decide you wanted a career in medicine and in particular, why did you choose vascular surgery?

I had an international upbringing, living in India, Iran and Iraq as a child. My early interest in medicine was guided by an interest to practise medicine in developing countries. On my way to serve in the newly independent southern African nations Angola and Mozambique I realised I needed surgical training. During war-time surgery, and later when I returned to Sweden, I observed that the only situation in which well-trained surgeons lost control was during major haemorrhage. I trained in vascular surgery to be able to stay in control, but enjoyed it so much that it became my speciality.

Who has inspired you in your career and what advice of theirs do you remember today?

My first inspiration was my mother, who was a nurse. She was hard-working and claimed she never experienced a single dull working-day. My first surgical tutor was Arne Kjellgren, an excellent surgeon, technically speaking, and with an extraordinary ability to meet the suffering patient. He taught me empathy, to listen to the patient, and to examine and operate with meticulous detail. My tutors in vascular surgery were Bengt Hedberg in Umeå and Prof David Bergqvist in Uppsala. David was my tutor in science as well. He taught me dedication to detail, in both surgery and science.

During your career, what have been your proudest moments?

I never did anything alone, it has been always a team effort, but building that team is probably my main achievement. The following moments felt particularly good: 1) When my first two PhD students Anders Wanhainen and Stefan Acosta defended their theses, a public event in Sweden, and when later they both became successful academic vascular surgeons; 2) Starting the Swedish abdominal aortic aneurysm screening programme in Uppsala together with Anders in 2006, and observing that in only 5–6 years, all of Sweden followed; 3) Replacing David Bergqvist as the only full professor of vascular surgery (chair) in Sweden in 2008; and 4) The creation of a distance learning course in vascular surgery in 2002 became a great success, and I was given the task to organise training on a national level in 2008.

How has vascular surgery evolved since you began your career?

In Sweden we used to be a subspecialty of general surgery. In 2006 we became a branch specialty, and in 2015 we will become a monospecialty. The endovascular revolution was initiated by innovative radiologists in Sweden, such as Sven-Ivar Seldinger, but soon this minimally invasive technique was embraced by vascular surgeons. This is an important development, from imaging-focused interventional radiology towards patient-oriented endovascular surgery. It also results in great demands in training, since you need to master clinical know-how as well as both open and endovascular techniques.

What have been your most memorable clinical cases?

I was the only vascular surgeon in Skellefteå, a hospital in the scarcely inhabited northern region, and the population had high prevalences of aneurysms and other vascular diseases. Those were nine tough years with many demanding cases, day and night. A man with vascular Ehlers-Danlos' syndrome, who I treated for a ruptured abdominal aortic aneurysm, was maybe the toughest challenge. The fact that he survived with a favourable outcome makes this case even more memorable. After having moved to Uppsala in 2001 I have had many difficult carotid body tumours, reaching to the base of the scull. I receive referrals from all over Scandinavia for this condition. Offering these young patients a multidisciplinary team to minimise post-operative morbidity has been very rewarding.

Screening for abdominal aortic aneurysms is one of your interests. In your view, why is screening important?

When I worked in the north we had a great case-load of ruptured aneurysms. Thanks to a great team effort with anaesthesiologists and intensivists we managed to reduce the mortality after ruptured aneurysms to only 16%. We did also have a high autopsy rate; however, explained by a research interest in cancer epidemiology and cardiology. It made me realise that we were only seeing the tip of the iceberg. Most patients with ruptured aneurysms never reached the hospital. This was the rationale for performing the first population-based abdominal aortic aneurysm screening in Sweden in 1999, and following the path of those who evaluated aneurysm screening in the UK, Denmark and West Australia.

What do you think a comprehensive screening programme should involve?

Inviting all 65-year-old men is very practical and straightforward, although strictly speaking this design of abdominal aortic aneurysm screening was never evaluated in a randomised trial. We have data that suggest that it may not be safe to leave those with an aortic diameter above 24mm without follow-up. The issue of whether smoking women should be included is controversial. Smoking cessation and secondary prevention are important components.

How can other countries replicate the Swedish experience with screening?

I am sure many will follow the UK and Sweden in creating national screening programmes. After all, this is the only way to effectively reduce the mortality from aneurysm rupture. In our experience we were astonished how relatively easy it was to organise the programme, how quickly you could screen a person (it only takes us four minutes), and how well it was received by the population.

What are the key unanswered questions in the management of abdominal aortic aneurysms?

The changing epidemiology transforms aneurysm screening into a moving target. When the population smokes less and lives longer they may need screening and repair later in life. Another issue of great importance is to try to distinguish healthy from diseased people among those with an aortic diameter 25–35mm. It is also important to follow the development of the disease among smoking women.

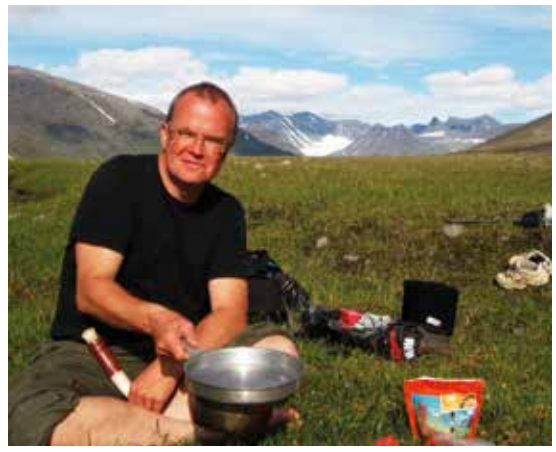
The issue of how to measure the aorta is crucial, and we need a consensus. To develop the optimal medical treatment to prevent aneurysm growth and cardiovascular events is also important, to offer the maximum benefit to the patients.

You are a member of the World Society of the Abdominal Compartment Syndrome (WSACS). The syndrome has gone from being something seen as imaginary to one that is recognised as being a serious condition. What have been the other developments in how we understand the condition?

The first step was to recognise the problem, and this is achieved in most places. The second step was how to manage patients with the syndrome. Here we have also had success in the development of new algorithms and adjunctive procedures, such as the VAC with mesh mediated fascial traction, to enable early closure. The third step, which maybe should have been the first, is how to prevent abdominal compartment syndrome. Here we were assisted by the experiences in the wars in Iraq and Afghanistan, where it was shown so elegantly that whole blood resuscitation makes a great difference. The short version is: "If the patient bleeds crystalloids, give crystalloids, but if he/she bleeds blood, give blood!"

The WSACS guidelines were published last year. What were their key recommendations?

The importance of classification of the open abdomen was recognised. There are no data that support prophylactic open abdomen, but a wealth of data suggest that protocolised monitoring of intra-abdominal pressure in patients at risk of developing abdominal compartment syndrome makes a difference. Strategies utilising negative pressure wound therapy should be used, versus not, and preventing lateralisation of the abdominal wall is important. Both enhance early closure, which prevents complications.



What are your current research interests?

We are currently performing a randomised trial to evaluate the potential of preventing growth of small abdominal aortic aneurysm with the new platelet inhibitor ticagrelor, which seems to have no non-responders. Anders Wanhainen is the principal investigator of this trial. We have many research projects regarding aneurysm screening, and if we could offer an effective drug therapy to prevent growth of small aneurysms that would add benefit to the programme. The development of a more effective smoking cessation programme is also underway. We have a great interest in popliteal, thoracic and thoracoabdominal aneurysms, as well as in vascular trauma and intestinal ischaemia.

What is the most interesting paper you have come across recently?

The IMPROVE trial is a great paper, both the paper in *BMJ* and the cohort study published in the *BJS*. People who criticise this trial are not aware of the difficulties in performing research in emergency patients. If it had not been for the unfortunate new Swedish law that requires informed consent without exception, we would have participated in the trial. I am working on trying to change that law, actually with good chances of success.

What advice would you give to a vascular surgeon just starting their career?

The early advice would be to focus on learning to know the patients and the diseases, rather than the technology of treatment, and to keep the patient focus throughout your career.

To combine innovation with scientific evaluation, and to collaborate with industry, but maintain independence are the keys to academic success. There are so many examples of new technology that have never been properly evaluated. Embrace the new endovascular technology, but with a critical thinking. Make sure that you have a good training in both open and endovascular surgery, and in science!

And last but not least, take care of your family. That is what counts most in the end.

Outside of medicine, what are your interests?

I am very fond of nature, and concerned about how we treat our planet. Moose hunting, mushroom picking, hiking in the mountains, as well as biking, are all great to rinse your body and mind. My son hunts with me, which adds pleasure. I enjoy cooking too, and not only the moose. I have a small piece of forest that I "take care of" with the chainsaw, and an old farmstead that needs some attention. I enjoy books, film and theatre—afterall Ingmar Bergman was born and raised here in Uppsala.

Fact File

Current position

Professor of Vascular Surgery, Institution of Surgical Sciences, Department of Vascular Surgery, Uppsala University Hospital, Sweden

Education

1978	Medical doctor, examination
1990	Specialist in Surgery, examination
1998	Dissertation for PhD: On intestinal ischaemia after aortoiliac surgery, Epidemiological, clinical and experimental studies, Uppsala University

Appointments

1992	Consultant in vascular surgery
2000–	Consultant in vascular surgery, Uppsala University Hospital
2002	Associate professor, Vascular Surgery, University of Uppsala
1999–2002	Editor of the *Journal Svensk Kirurgi* (Swedish Surgery)
2003–2009	Co-editor of the *Journal Svensk Kirurgi* (Swedish Surgery)
2008–	Professor chair of Vascular Surgery, Uppsala
2012–	Associate editor, *European Journal of Vascular and Endovascular Surgery*

Societies

1997–2001 and 2008-2012	Board member of the Swedish Society for Vascular Surgery
1999–2002	Board member of the Swedish Surgical Society
1999–2007	Board member of SWEDVASC (Swedish Vascular Registry)
2002–2007	Chairman of SWEDVASC (Swedish Vascular Registry)
1997–	Board member of Vascunet
2003–2006	Chairman of Vascunet
2001–2005	Member of the Educational Committee of Scandinavian Association of Vascular Surgery
2003–2005	Chairman of the Education Committee, SAVS
2005–	Member of the International Surgical Group
2008–2012	National Director of Training in Vascular Surgery
2009–	Consultant to the National Board of Health and Welfare
2011–2014	Councillor of the European Society for Vascular Surgery
2014–	Member, Ethical committee of the Swedish Research Council

Awards

1998	Swedish Vascular Award
2003	The Acrel Medal (Most distinguished award of the Swedish Surgical Society)
2011	Surgical educator of the year (Swedish Surgical Society)

Academic achievements

- Publication of 160 original articles and 80 review articles and book chapters
- Supervisor of seven PhD students who completed their thesis and another 14 are underway
- Member of editorial boards: *British Journal of Surgery, European Journal of Vascular and Endovascular Surgery, World Journal of Surgery, Scandinavian Journal of Surgery, Angiologia e Cirurgia Vascular*, and *Pan Arab Angiology Journal*

Preliminary experience with a carbon-coated stent in iliac and femoral atherosclerotic lesions

LEONARDO ERCOLINI

COMMENT & ANALYSIS

Leonardo Ercolini, Florence, Italy, says that a new generation carbon-coated stent that improves the metal surface compatibility with blood and arterial wall shows positive outcomes in a small experience with 18 patients with peripheral arterial disease.

The history of the carbon-coated stents started in the late 90s in the treatment of coronary artery disease. The carbon-coated stent is a metal stent coated with a pure carbon film that has been proven to reduce thrombogenity more than uncoated ones. It has been demonstrated (*Appl Biomater* 2009; 90B:338–349) that in contact with blood the carbon surface strongly inhibits the activation of the coagulative cascade and the release of prothrombotic/pro-inflammatory factors promoting a complete endothelialisation already after seven days from implantation as observed in animal model. Moreover, long-term biocompatibility has been tested in the coronary arteries and it has been showed that the carbon-coated stent is well tolerated in vivo, inhibiting neointimal hyperplasia, especially in high-risk patients.

A second-generation stent, designed to improve the long-term outcomes in iliac and femoral arteries has been developed in the latest years. The commercial name is Easy Flype (from 6 to 8mm in diameter, 6F compatible OD) and HiFlype stent (Alvimedica) (9 to 12mm diameters, 6F compatible OD). Two features of this stent make it unique: the mirror-like finishing of the stent surface and the new generation of pure integral carbon coating named Bio Inducer Surface (iCarbofilm) which improves the metal surface compatibility with blood and arterial wall. This is particularly important for long lesions, where both wall and blood flow are exposed to a greater surface of metal. Furthermore, the unique Bio Inducer Surface acts as a seal against the release of heavy metal ions, like nickel, from the nitinol alloy, benefiting patients with nickel allergy.

In our centre, we tested the Easy Flype and HiFlype stents in iliac and superficial femoral artery lesions. Eighteen patients—16 men and two women—were enrolled, and the data were prospectively collected. The mean age was 71.3 years. The clinical presentation was severe claudication in 16% of the cases, ischaemic rest pain in 61%, and tissue loss in the remaining 23%. We implanted 23 stents to treat 22 limbs and 26 lesions. The target vessel was the common iliac artery in 52%of the cases, the external iliac artery in 39% of the cases and the superficial femoral artery in 9% of the cases. We had no procedural complications and all the cases had technical and clinical procedural success. About two-thirds of the patients received monoantiplatelet therapy, while the remaining one-third was under dual antiplatelet therapy (mostly clopidogrel and aspirin). Mean follow-up was seven months (range 1–14). The follow-up evaluation was performed with ankle brachial index (20% of increase vs. the pre-operative values) and colour Doppler ultrasound evaluation.

All stents were found patent with no in-stent restenosis. The results also showed that all patients benefited from clinical improvement. Minor amputation rate was 11% (all these patients presented major tissue loss). No major amputation was recorded in the follow-up period.

The Easy Flype and HiFlype stents coated with the Bio Inducer Surface technology showed excellent mid-term outcomes in our experience. However, randomised controlled trials are needed to confirm these results on a wider population with longer follow-ups.

Leonardo Ercolini is with the Vascular Surgery, Azienda Sanitaria Firenze, Florence, Italy. He authored this article with Emiliano Chisci, Nicola Troisi, Clara Pigozzi and Stefano Michelagnoli

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Geometric remodelling of vein bypass grafts and the impact on graft failure

SCOTT A BERCELI

COMMENT & ANALYSIS

Through a multitude of retrospective, single-institution studies, vascular surgeons have documented the clinical outcomes for lower extremity vein bypass grafts. The five-year primary patency rate of 70% has been relatively unchanged since the inception of the procedure. In recent years, the movement towards prospective, multicentre studies has yielded more discouraging results, with one-year primary patency rates approximating 60–70%. While these sobering results have resulted in a more critical evaluation of this therapy, an extension of this work has been the broader understanding of the demographic, anatomic, and conduit-specific factors that are associated with vein graft failure. Extremes of age, critical limb ischaemia, and lack of good quality saphenous vein have been among the variables associated with compromised outcomes following graft placement. Although these recognised relationships provide useful guidance in the clinical management of patients, they yield limited insight into the mechanisms through which these factors contribute to early graft failure.

Reductions in lumen diameter, secondary to a combination of intimal thickening and negative wall remodelling, are the genesis of vein graft failure. Over the last two decades, a wealth of laboratory research has defined the complex array of molecular pathways that control these remodelling events. Unfortunately, translation of this fundamental biology into a clinically effective therapy to improve vein graft survival has been disappointing, and in large part hampered by the limited understanding of the morphologic changes through which an implanted vein is transformed into a successful or pathologically remodelled conduit. Such insights are critical in targeting therapies at the best times and optimum locations to prevent graft failure.

To fill this knowledge gap, we developed a study to examine the dynamics in vein graft adaptation and identify the anatomical, pharmacological, and demographic factors associated with successful or pathologic graft remodelling. To achieve this goal, a cohort of 60 patients undergoing lower extremity vein bypass graft were examined with high resolution CT angiography at one week and one, six and 12 months following graft implantation. Graft geometries were extracted and co-registered to determine the interval changes in lumen cross-sectional area at 1mm intervals along the length of the graft.

Among the initial observations were the distinct temporal phases that defined the remodelling changes. Between one week and one month, grafts were highly dynamic, with a 25% increase or decrease in lumen area frequently observed. By one month, much of the dynamics of the remodelling had subsided, so that area changes in the one to six-month and six to 12-month time intervals were modest. Most notable in this early dynamic phase was the substantial patient-to-patient heterogeneity. Approximately one-third of the grafts increased in size, one-third decreased, and one-third remained the same. Interestingly, once a graft demonstrated a positive or negative remodelling trajectory in these initial weeks following implantation, this course was rarely altered. This has profound implications in designing new therapeutic strategies. Approaches with activity profiles extending to one month, and capable of influence the initial remodelling trajectory, may be sufficient to impart a durable and improved outcome for the vein graft.

Examining the demographic, pharmacologic, and anatomic factors that are associated with the remodelling characteristics was also revealing. Vein grafts in African American patients demonstrated substantial negative remodelling, with an average 20% reduction in lumen area at one month. A significant reduction in graft patency, compared to Caucasian patients, was identified in parallel with this finding. Among the most interesting and directly translatable observations was the influence of the three-type phosphodiesterase inhibitor cilostazol on graft remodelling. Patients receiving cilostazol in the post-operative period demonstrated an approximate 20% increase in lumen area, both in the one week to one month and one to six month time interval. This observation is in agreement with recent studies that have demonstrated improved patency following peripheral endovascular procedures, but has yet to be prospectively evaluated in a large cohort of patients undergoing vein bypass grafting. Also significant are those factors that have limited influence on graft remodelling. Use of systemic anticoagulation, the indication for bypass (tissue loss vs. rest pain), and the source of conduit (arm vs. saphenous vein) had no notable effect on lumen remodelling.

While it is attractive to view demographic, pharmacological, and anatomical variables as the drivers of vein graft remodelling, these factors are actually just surrogates for differences in vein wall biology, systemic inflammation, and regional biomechanics, which are the most proximal mediators for these remodelling events. The current study was designed to encompass many of these domains. Computational analysis of haemodynamic forces, high throughput examination of circulating monocyte genomics, and predictive modelling using a panel of serum biomarkers are all parallel components of the current data set. In isolation, evaluation of a single domain is unlikely to yield definitive insight into the problem of vein graft failure. An integrated analysis at the intersection of the local biology, systemic milieu, and the regional biomechanics offers the best opportunity for advancing a field that has been stalled at the interface of basic biology and clinical care.

Scott A Berceli is professor of Surgery, University of Florida, and chief, Vascular Surgery, Malcolm Randall VAMC, Gainesville, USA

Large real-world experience shows positive results with Zilver PTX in challenging patient population

A post-market surveillance (PMS) study of the Zilver PTX drug-eluting stent (Cook Medical) conducted in Japan has shown positive results with the device in the treatment of femoropopliteal lesions. According to the investigators, the results "confirm the benefit of the Zilver PTX technology". The 12-month results, which were presented at the EuroPCR congress (20–23 May 2014, Paris, France), show no safety concerns and no increased thrombosis with the device.

Hiroyoshi Yokoi, Department of Cardiovascular Medicine, Fukuoka Sanno Hospital, Fukuoka, Japan, who presented the results on behalf of the investigators, explained that the

Hiroyoshi Yokoi

Zilver PTX clinical programme included pre-market studies (a randomised controlled trial and a single-arm study) and post-market studies such as the Japan PMS study of 907 patients.

Yokoi said that, in comparison to the pre-market studies, the Japan PMS study treated more complex patients and lesions as it was all "all-comers study" with no exclusion criteria used to eliminate patients from enrolment. "The Japan PMS patients were older and had a higher prevalence of diabetes and renal disease," he said. "In addition, the lesions were more complex—they were longer, with more in-stent restenosis and fewer patent runoff vessels—and patients had significantly greater incidence of critical limb ischaemia, twice the incidence reported in the pre-market studies."

At EuroPCR, he presented 12-month follow-up results that were available for 802 patients. In 58% of them, he said, patency was assessed by ultrasound if this was the standard of care.

He told delegates that freedom from target lesion revascularisation was 97.3% at six months and 91.4% at 12 months, similar to the rates seen in both pre-market studies, and that the rate of thrombosis/occlusion was 3.2% at 12 months.

"The 12-month thrombosis/occlusion rate from the Japan PMS was low and similar to the rates seen in the ZILVER PTX randomised controlled trial (1.9%) and the single-arm study (2.7%). It is also similar to the rates seen with the Zilver bare metal stent in the randomised controlled trial (3.6%) and to bare metal stent periprocedural rates in the literature (2–5%)," he stated.

The primary patency rate as assessed by duplex ultrasound (n=469) was 84.4% at 12 months, and this rate was similar to the rates seen in both pre-market studies.

Yokoi said that the Japan PMS study results were positive and confirmed the benefit of this paclitaxel-eluting technology.

"There is a large amount of clinical data available for Zilver PTX, ranging from carefully controlled level I evidence to large, global, real-world experience. As expected, the patient population and lesion characteristics become more challenging in real-world, all-comer studies. The consistency seen across studies provides added assurance of the performance of the Zilver PTX drug-eluting stent," he concluded.

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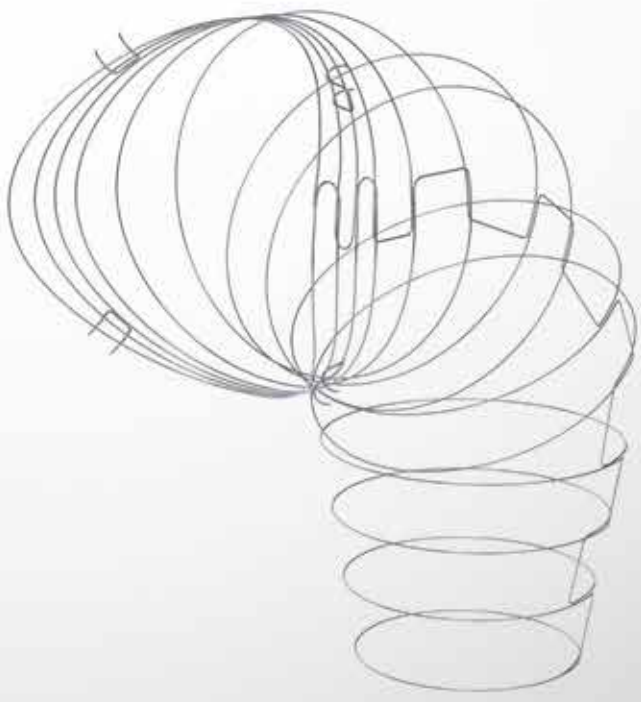

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Cyanocrylate embolisation similar to radiofrequency ablation, randomised FDA study finds

A study presented at the European Venous Forum (26–28 June, Paris, France), by Nick Morrison from the Morrison Vein Institute, Scottsdale, USA, showed that cyanoacrylate embolisation as compared to radiofrequency ablation demonstrates similar closure at three months (non-inferiority p-value <0.0001).

Principal investigator Morrison reported the results of a randomised, controlled, non-inferiority, FDA study comparing the safety and efficacy of cyanoacrylate adhesive embolisation to radiofrequency ablation for closure of incompetent great saphenous veins.

"From March 2013 to September 2013, 222 patients with symptomatic great saphenous veins reflux at 10 US clinical sites were randomly assigned to treatment with either cyanoacrylate adhesive embolization using the VenaSeal Sapheon Closure System or radiofrequency ablation with the ClosureFast System (Covidien). "Follow-up visits were arranged on the third day after the procedure, and at one and three months. Adjunctive procedures were not allowed until after the three-month visit," Morrison said.

The primary efficacy endpoint was complete closure of the symptomatic great saphenous veins at three months as measured by Doppler ultrasound and assessed by an independent core laboratory. The investigator at each site recorded CEAP classification at screening and three-month follow-up and Venous Clinical Severity Score (VCSS) at baseline, day three, and one and three months. Pre-specified procedure-related adverse events and patient-reported adverse events were recorded.

Nick Morrison

"The great saphenous vein closure results as judged by each site investigator were further reviewed by an independent vascular core laboratory with 100% agreement between the investigator sites and the core laboratory," Morrison clarified. There were 108 veins that were embolised. At one month 105 were evaluated and 100% showed complete closure (complete vein closure was defined as closure along the entire treated vein segment with no patency >5cm). At three months, 104 patients were evaluated and 103 (99%) were completely closed. In the group that received radiofrequency ablation, 114 veins were treated. At one month, 109 veins were evaluated and 94 showed complete closure (86.2%). At three months, 108 patients were evaluated and 103 (95.4%) showed completely closed. In both instances the non-inferiority p value (hypothesis 10%) was <0.0001. The VCSS was not significantly different for both groups at all the time points during follow-up. The incidence of procedure-related adverse events and other adverse events throughout the study was similar between groups.

Study identifies key factors affecting catheter-directed thrombolysis for iliofemoral deep vein thrombosis

A study from Denmark has found that the most important factors to predict long-term competent veins after catheter-directed thrombolysis are symptom duration of less than two weeks and use of the pulse spray technique.

The study was presented at the European Venous Forum (26–28 June, Paris, France) by Pia Foegh, Vascular Clinic, Gentofte Hospital and Rigshospitalet, Copenhagen, Denmark, on behalf of the investigators.

Foegh stated that many factors seem to influence the outcome of catheter-directed thrombolysis of deep thrombosis of the iliofemoral vein and explained that this study set out to identify the factors associated with long-term competent veins after catheter-directed thrombolysis.

The investigators analysed data from 1999 to 2013, obtained from nearly 200 patients (over 200) limbs with iliofemoral involvement who underwent thrombolysis. They noted that the median follow-up was five years. The researchers obtained information on gender, age, side that treatment was carried out, inferior vena cava atresia, inferior vena cava thrombolysis, history of stenting, duration and type of lysis (infusion vs. pulse spray), duration of symptoms, and chronic lesions from the patient records. The study outcome was defined as competent vein (as a primary patent vein without signs of reflux on ultrasound). They tested the association initially in a univariate survival model (Kaplan-Meier with log-rank test) and subsequently on a multivariate Cox proportional hazard model.

Pia Foegh

The researchers found that univariate analyses revealed that gender, duration of lysis, stenting, duration of symptoms, type of lysis (infusion vs. pulse spray) and chronic lesions were significantly associated with outcome whereas age, side, inferior vena cava atresia and inferior vena cava thrombosis were not. The Kaplan-Meier model showed that the estimated per cent of competent veins was 79% after seven years. On the other hand, the multivariate Cox proportional hazard model revealed that symptom duration >2 weeks, infusion and chronic lesions were the only factors significantly associated with poorer outcome. This model also showed that stenting was more frequently reported in patients with a longer history of symptoms and this was not identified as a prognostic predictor.

Niels Baekgaard, Vascular Clinic, Gentofte Hospital and Rigshospitalet, Copenhagen, Denmark, the senior author of the paper, told *Vascular News*: "This study emphasises, for the first time, that the duration of symptoms prior to treatment has a great impact on the results after catheter-directed thrombolysis.

This means that patients with more than two weeks of symptom duration will achieve inferior results with this treatment that are almost similar to anticoagulation and compression alone for this category of patients. The results of this study also show that physicians are able to rely on the accuracy of patient's memories with regard to the duration of symptoms. Perhaps, in the future, some of the newer imaging modalities in combination with patient history, will be able to estimate the thrombus age even more accurately and strictly in order to determine the best course of treatment."

The researchers concluded that the most important factors for predicting long-term competent veins after catheter-directed thrombolysis are symptom duration less than two weeks and use of the pulse spray technique. "This corresponds very well with the international definition of acute deep venous thrombosis (which is deep venous thrombosis less than two weeks)," Foegh told delegates. She also noted that patients with chronic lesions distally to the iliac compression area seem to have poorer outcomes, perhaps because of previous subclinical episodes of former deep venous thrombosis.

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Aspirin may reduce the risks of reoccurring venous thromboembolism

Aspirin after anticoagulant treatment reduces the overall risk of recurrence by more than a third in a broad cross-section of patients with a first unprovoked venous thromboembolism, without significantly increasing the risk of bleeding, according to new research in *Circulation*.

In a combined analysis of two similar independent studies, 1,224 patients who received 100mg of aspirin a day to treat blood clots were monitored for at least two years. In the INSPIRE (International collaboration of aspirin trials for recurrent venous thromboembolism) analysis, researchers found that aspirin reduced the risk of recurring blood clots by up to 42%.

"The treatment is warfarin or a newer anticoagulant usually given for at least six to 12 months to prevent a further blood clot," says John Simes, lead author of study and director of the National Health and Medical Research Council Trials Centre and professor at the University of Sydney in Australia. "However, these people continue to be at risk."

Of the 1,224 patients included in the analysis, 193 had recurrent venous thromboembolism over 30.4 months median follow-up. Aspirin reduced recurrent venous thromboembolism (7.5%/year versus 5.1%/year; hazard ratio [HR], 0.68; 95% confidence interval [CI], 0.51–0.90; p=0.008), including both deep-vein thrombosis (HR, 0.66; 95% CI, 0.47–0.92; p=0.01) and pulmonary embolism (HR, 0.66; 95% CI, 0.41–1.06; p=0.08). Aspirin reduced major vascular events (8.7%/year versus 5.7%/year; HR, 0.66; 95% CI, 0.50–0.86; p=0.002). The major bleeding rate was low (0.4%/year for placebo and 0.5%/year for aspirin). After adjustment for treatment adherence, recurrent venous thromboembolism was reduced by 42% (HR, 0.58; 95% CI, 0.40–0.85; p=0.005). Prespecified subgroup analyses indicate similar relative, but larger absolute, risk reductions in men and older patients.

Co-author Cecilia Becattini adds, "Aspirin does not require laboratory monitoring, and is associated with about a 10-fold lower incidence of bleeding compared with oral anticoagulants. We are convinced that it will be an alternative for extended prevention of venous thromboembolism after 6–12 months of anticoagulant treatment."

Although the study yielded clear results, researchers advise patients to talk to their doctor about taking aspirin after stopping treatment with anticoagulants.

"It is not recommended that aspirin be given instead of anticoagulant therapy, but rather be given to patients who are stopping anticoagulant therapy or for whom such treatments are considered unsuitable," Simes says.

"Although less effective, aspirin is inexpensive, easily obtainable, safe and familiar to patients and clinicians worldwide. If cost is the main consideration, aspirin is a particularly useful therapy. The costs of treating future thromboembolic events are greater than the cost of the preventive treatment."

The authors conclude: "This prospective, combined analysis of the WARFASA and ASPIRE trials provides clear evidence that aspirin reduces the risk of recurrent venous thromboembolism events by approximately 40% and is a very safe and effective therapy. Although it does not reduce the rate of venous thromboembolism by as much as vitamin K antagonists or newer oral anticoagulants (direct thrombin inhibitors or factor Xa inhibitors), among patients for whom such therapies are not considered appropriate or are discontinued, aspirin should be strongly considered."

Other co-authors are Giancarlo Agnelli, John W Eikelboom, Adrienne C Kirby, Rebecca Mister, Paolo Prandoni, and Timothy A Brighton.

Two-ring radial fibre effective in large great saphenous veins


Andreas Fiebig

Endovenous laser ablation using a new two-ring radial fibre in combination with a 1470nm diode laser (ELVeS, biolitec) is an effective method to treat insufficient great saphenous vein with diameter greater than 8mm, using less energy and resulting in an optimal homogenous radiation.

An experience using the new configuration was presented by Andreas Fiebig, Kompetenznetz Chronische Venenkrankheiten, Kiel, Germany, at the European Venous Forum (26–28 June, Paris, France).

In the study, patients suffering from great saphenous vein insufficiency were assigned to endovenous laser therapy using the new two-ring radial fibre in combination with a 1480nm diode laser. All interventions were performed on ambulatory patients in a specialised vein centre in Germany. The study with a planned examination of 300 patients started in March 2013, and up to June 2014, the investigators had enrolled 125 patients. Performance characteristics of each endovenous laser therapy procedure were evaluated, including length of the treated vein, diameter of the vein and linear endovenous energy density (LEED). Duplex examination was performed in line with the UIP consensus document.

Patients were divided into two subgroups: subgroup A included veins with a diameter ≥8mm and subgroup B those with a diameter <8mm. Patients had an average age of 47.5 (20–72) years. The mean diameter was 9.1mm in subgroup A and 6mm in subgroup B.

The results showed that both groups had an occlusion rate of 100%. The length of the treated vein was 42.5cm. Laser treatment was continuously carried out with a power of 13.1 watts (10–15) at 3cm around the saphenofemoral junction resulting in a LEED of 91.3J/cm and an energy fluence equivalent of 52.8J/cm2 (SD=14.1). There were no significant differences between male and female patients. After treatment the average diameter was 4.7mm (51.6%) and 2.6mm (43.3%) for subgroup A and B respectively (3cm from the saphenous vein junction) 1.2 days after treatment. Modified CEAP severity score decreased from 2.1oC to 0.48oC.

"We demonstrated an effective method to treat large insufficient great saphenous vein (diameter >8mm) by using the new developed two-ring radial fibre laser. This new design employs less energy and results in an optimal homogenous radiation. In addition, patient satisfaction was high, and CEAP severity, VCSS and CIVIQ indicators were better after 1.2 days and three months."

The other authors of the paper are Knuth Rass, Norbert Frings and Aljoscha Greiner.

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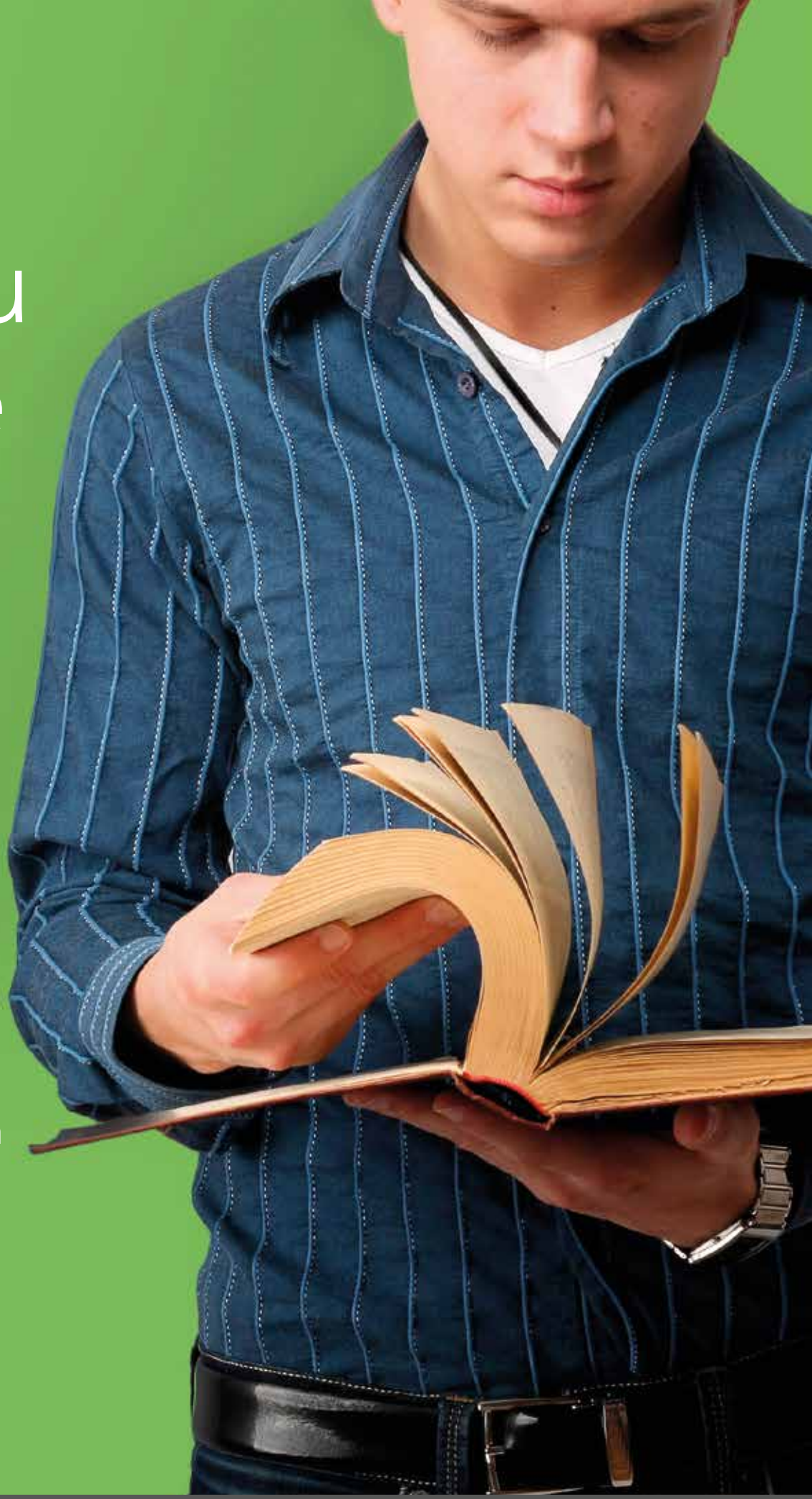

1. Circulation figure relates to period from 01/01/13 to 31/12/13

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vascularnews

Multicentre study evaluates method to improve retrieval rate of inferior vena cava filters

Studies have shown that approximately 80–85% of retrievable inferior vena cava filters are never retrieved. The successful removal of retrievable filters requires diligent patient follow-up and interdepartmental cooperation and even then, successful removal is not always accomplished.

With the objective of increasing retrieval rates in the USA, the Heart and Vascular Outcomes Research Institute (HVORI) is collaborating with a number of medical centres to launch the iRetrieve study. John E Rectenwald, associate professor of Surgery, University of Michigan is the principal investigator for iRetrieve study, and the clinical trial is currently underway.

"Physicians in the USA place an estimated 250,000 retrievable filters in patients annually. Using the algorithm we are testing in the iRetrieve study, we anticipate a retrieval rate of more than 90%, as the system will ensure a robust follow up for patients and also a reminder for physicians," says Uchenna Onyeachom, director of Endovascular Research at HVORI and study director for iRetrieve. "The model also can eliminate the huge overhead cost incurred in the implementation of a dedicated IVC Filter Clinic."

Uchenna Onyeachom

The iRetrieve study employs the IVC Filter Module which combines a novel retrieval algorithm with a pathway incorporated in the Venous Patient Outcome Registry that catalogues clinical outcomes for various treatments of deep and superficial venous diseases. HVORI is the sponsor of the study.

Onyeachom spoke to *Vascular News* about the study.

What is the iRetrieve study and why is it important?

The iRetrieve study is a prospective multicentre trial based on a novel algorithm to improve the retrieval rate of retrievable inferior vena cava filters placed across the United States. Since the introduction of the retrievable inferior vena cava filters, there has been a shift for indication for filter placement from deep vein thrombosis to pulmonary embolism prophylaxis in high risk patients. The study is important as the retrievable rate of these filters is very low (in most cases less than 30%) and concerns on safety and efficacy of retrievable filters have been raised.

Why should filters be retrieved and what are the possible complications of non-retrieval?

These filters are intended for short-term placement and once a patient's risk for pulmonary embolism subsides, the filters should be removed. Known complications for non-retrieval associated with inferior vena cava filters include but are not limited to lower limb deep vein thrombosis, filter fracture, filter migration, filter embolisation and inferior vena cava perforation. This was why the FDA released an alert in August 2010 advising physicians to remove retrievable filters whenever possible and updated that letter again in May 2014.

What kind of information will be available in the iRetrieve study?

We are collecting data on patient demographics, clinical details, indication for procedure, filter types, retrieval details and follow-up information. Note that we are collecting data on all filters both retrievable and non-retrievable as we are also assessing the safety and efficacy of both filter types. We are recruiting 1,800 patients across 30–45 sites.

What steps will be taken in iRetrieve to improve retrieval rate in the USA?

We hope the algorithm will automate the process of filter retrieval through a structured follow-up based on multiple parameters which include but is not limited to placement indication, risk score of retrieval, indwell time and other clinical details. An alert is sent to the physician and then to the patient, based on a weighed score. The system is designed to take the workload off the physician and assess each patient based on their individual condition.

What is the duration of the study and when the first data will be made available?

The study will run for 24 months but preliminary data will be available at 12 months and each site can benchmark their own retrieval rate and complication rate based on different types of filters in real time. The next phase will be to implement the programme in all hospitals where filters are placed as a cost effective alternative to a dedicated inferior vena cava filter clinic.

European Commission approves apixaban for treatment of deep vein thrombosis and pulmonary embolism

Bristol-Myers Squibb and Pfizer have announced that the European Commission has approved Eliquis (apixaban) for the treatment of deep vein thrombosis and pulmonary embolism, and the prevention of recurrent deep vein thrombosis and pulmonary embolism in adults. The European Commission approval applies to all European Union (EU) member states as well as Iceland and Norway. This approval broadens the clinical use for apixaban which is also approved for use in the EU for the prevention of venous thromboembolism (VTE) in adults who have undergone elective total hip or knee replacement surgery, and the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors.

"Venous thromboembolism is a major public health concern, and a burden to the UK and the NHS," commented Alexander T Cohen, Guy's and St Thomas' Hospitals, London, UK "In fact, the total cost of the management of venous thromboembolism is estimated to be between £340 and £640 million per year, placing a significant burden on the health system. In the AMPLIFY trial apixaban was shown to be effective in the treatment of venous thromboembolism, with the additional benefit of having a significantly lower risk of bleeds compared to current standard therapies, which is positive news for patients and healthcare professionals. This improved risk benefit profile will provide clinicians with confidence when considering prescribing this treatment and provide greater reassurance for patients. The fact it is an oral treatment that does not require INR monitoring has additional advantages in terms of convenience for patients with the additional potential to reduce hospitalisations."

The marketing authorisation follows the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency, and is supported by two pivotal phase 3 clinical trials, AMPLIFY and AMPLIFY-EXT.

The AMPLIFY (Apixaban for the initial management of pulmonary embolism and deep vein thrombosis as first-line therapy) study, was a randomised, double-blind, multicentre, non-inferiority trial which evaluated apixaban therapy compared to standard of care. It included 5,395 patients (2,691 were randomised to apixaban and 2,704 were randomised to standard of care, which was initial enoxaparin treatment overlapped by warfarin therapy). The AMPLIFY-EXT (Apixaban after the initial management of pulmonary embolism and deep vein thrombosis with first-line therapy-extended treatment) study was a randomised, double blind, multicentre trial. It included 2,486 patients (842 were randomised to apixaban 2.5mg, 815 were randomised to apixaban 5mg and 829 were randomised to placebo). In this study, patients randomised had previously completed six to 12 months of anticoagulation treatment for deep vein thrombosis or pulmonary embolism and went on to receive apixaban therapy or placebo for a further 12 months.

First varicose vein patient treated with FDA-approved Varithena

BTG International has announced that the first varicose vein patient has been treated with Varithena (polidocanol injectable foam, 1%), the only FDA-approved foam for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous veins system both above and below the knee.

Varithena improves symptoms related to or caused by varicose veins, and the appearance of varicose veins, and is proven to reduce the five symptoms patients consider most important – heaviness, achiness, swelling, throbbing, itching (HASTI symptoms).

Marlin Schul of the Lafayette Regional Vein & Laser Center in Indiana, USA, who conducted the first Varithena procedure, says, "Varithena is a convenient, minimally invasive treatment and patients can return to normal activities shortly after treatment."

Varithena is a uniform, low-nitrogen, polidocanol microfoam, dispensed from a proprietary canister device. The physician injects a small amount of Varithena into the malfunctioning vein through a catheter or a needle. It displaces the blood from the vein to reach and treat the vein wall; the diseased vein collapses and blood flow is diverted to healthy veins nearby.

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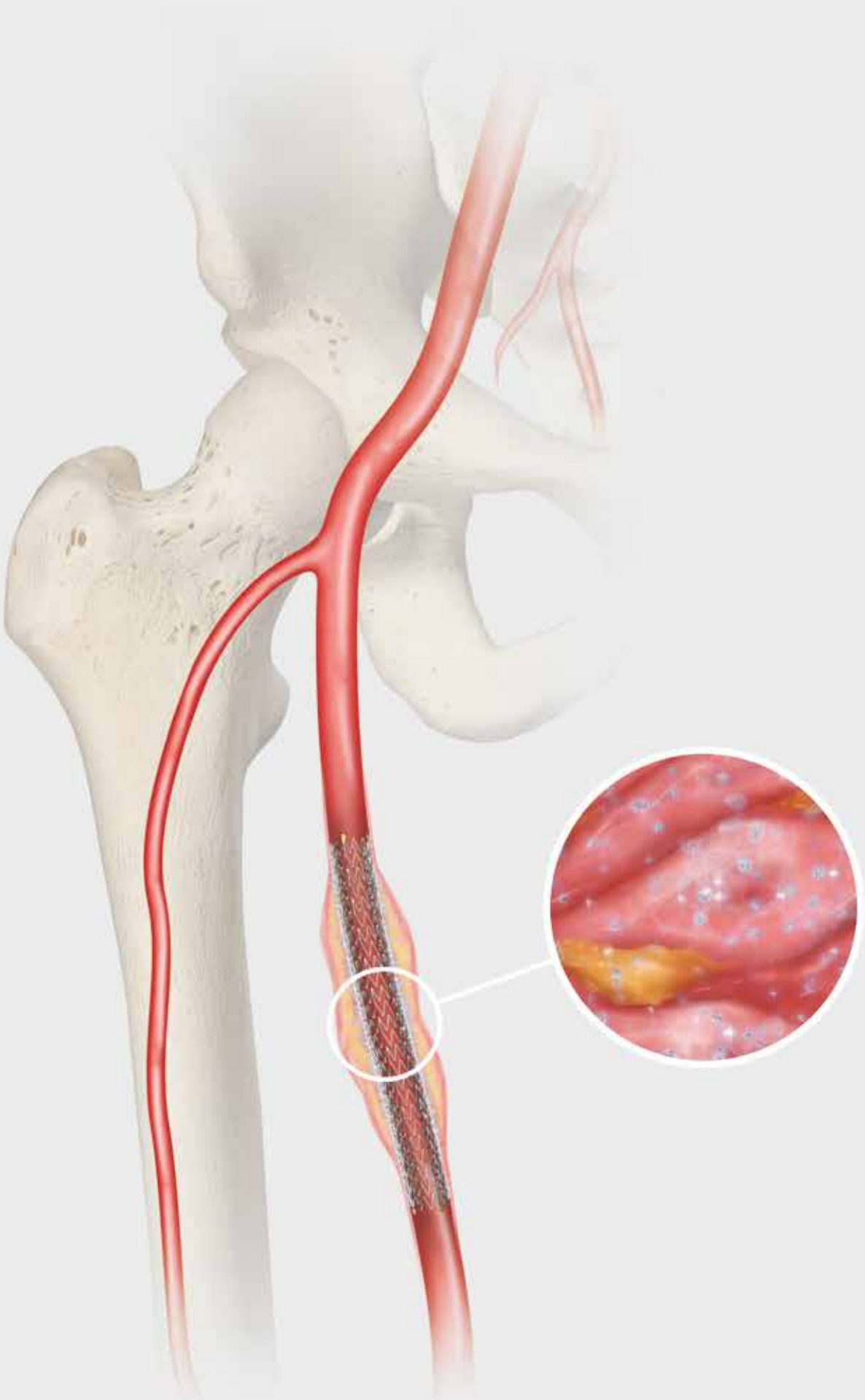

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3. Compared to bare-metal stents.
   Ansel G. Zilver PTX randomized trial of paclitaxel-eluting stents for femoropopliteal disease: 24-month update. Presented at: the Society for Cardiovascular Angiography and Interventions (SCAI) 2011; May 4-7, 2011; Baltimore, Maryland.

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Vascular News' Quick 4

New deep vein thrombosis guidelines: What you need to know

Suresh Vedantham, professor of Radiology, Interventional Radiology Section, Washington University School of Medicine in St Louis, USA, spoke to *Vascular News* on the latest from the paper "Quality improvement guidelines for the treatment of lower-extremity deep vein thrombosis with use of endovascular thrombus removal" hot on the heels of its online publication in the *Journal of Vascular and Interventional Radiology* (*JVIR*).

What prompted the need for new guidelines?

The quality improvement guidelines for catheter-directed thrombolysis for deep vein thrombosis have been updated to reflect current practice, and have a substantially improved evidence foundation due to inclusion of information from new studies including two randomised trials. During the last decade, there have been major changes in the key pillars of clinical deep vein thrombosis practice. New oral anticoagulant classes have been introduced; the completed SOX trial (Compression stockings to prevent the post-thrombotic syndrome) has cast major doubt on the idea that compression stockings can prevent the post-thrombotic syndrome; and the practice of catheter-directed thrombolysis has evolved considerably to incorporate improved patient selection, technical refinements (including the frequent use of thrombectomy devices, stents, and retrievable caval filters), and longitudinal care by endovascular practitioners.

Why is this paper important currently?

A new study published in *Journal of the American Medical Association* (*JAMA)* (see page 21) observed a substantially higher risk of adverse safety outcomes in patients who received catheter-directed thrombolysis plus anticoagulation vs. anticoagulation alone in real-world US practice between 2005 and 2010. While this study's non-randomised methodology and reliance on administrative coding data likely introduced substantial bias into the comparison, physicians who offer catheter-directed thrombolysis should work hard to meet the high standard of safety that is being demanded by the medical community. We must not take for granted the risks involved in routinely offering thrombolytic therapy to patients with deep vein thrombosis who, after all, are being treated not in a life-saving capacity (as with myocardial infarction or stroke) but to optimise limb function and quality of life.

Suresh Vedantham

What are the key updates in the revised guidelines?

Key changes include: a) safety thresholds that are a little more stringent, reflecting the improved safety observed in catheter-directed thrombolysis studies between 2006–2013 compared to before; b) a focus on ensuring longitudinal care to optimally assess the outcomes of therapy and to reduce unnecessary late risks such as those from long-term inferior vena cava filter implantation; and c) sections that succintly summarise measures to prevent bleeding and pulmonary embolism during and after catheter-directed thrombolysis.

How will this paper serve as a tool for local quality improvement programmes?

This article offers physicians a template around which to design internal deep vein thrombosis quality improvement programmes. The authors' ambition is for practicing physicians to build strong longitudinal care systems around deep vein thrombosis care, to ensure that patients can be provided catheter-directed thrombolysis as safely and as effectively as possible.

This article represents the best consensus quality improvement tool we could develop within the bounds of existing catheter-directed thrombolysis studies, which are still quite limited in scope and methodology. We hope and expect that the next version of these guidelines will be created with the benefit of additional randomised trial data, including that from the National Institute for Health-sponsored, multicentre, randomised, assessor-blinded, ATTRACT (Acute venous thrombosis: thrombus removal with adjunctive catheter-directed thrombolysis) trial which has nearly completed patient accrual.

What the trials have taught us about aggressive therapy of deep venous thrombosis

STEPHEN T KEE
AND ADAM PLOTNIK

COMMENT & ANALYSIS

Ongoing research and recently published studies are changing the treatment landscape for post-thrombotic syndrome. Although current evidence in favour of catheter-directed thrombolysis for deep venous thrombosis may not be robust enough to allow for a shift in clinical practice, that may soon change with strict adherence to thrombolysis exclusion criteria, meticulous interventional techniques, and close treatment monitoring to minimise the risk of bleeding complications with catheter-directed thrombolysis, write Stephen T Kee and Adam Plotnik.

Deep venous thrombosis occurs in 300,000–600,000 patients per year in the USA, and is associated with significant rates of short (pulmonary embolus) and long-term morbidity (post-thrombotic syndrome). Post-thrombotic syndrome has been reported to develop in over 50% of patients within two years following deep venous thrombosis despite standard therapy. The syndrome results from venous obstruction and inflammatory destruction of the valves. Manifestations include chronic limb pain, swelling, heaviness, early fatigue, skin pigmentation and/or venous ulceration. Consequently, there is significant impairment on the patient's quality of life and the care required places a major economic burden on both the patient and healthcare providers.

Conventional therapy

Standard treatment of acute deep venous thrombosis is anticoagulation, which prevents pulmonary embolus and the propagation of thrombus, but does not affect the outcome or severity of post-thrombotic syndrome. Historically the only treatment for post-thrombotic syndrome with level one evidence is compression stockings. Thrombolysis, initially published in 1994 by Semba and colleagues in *Radiology*, has also been used to treat extensive deep venous thrombosis, however, the data supporting its use to prevent post-thrombotic syndrome is limited. Ongoing research and recently published studies are changing the treatment landscape for this devastating disease. This article provides an update of this data.

Data on thrombolysis and acute deep venous thrombosis

A 2014 Cochrane review evaluating randomised controlled trials, with a total of 1103 patients from 17 studies, examined thrombolysis and anticoagulation vs. anticoagulation alone in the setting of acute deep venous thrombosis. They demonstrated significantly less post-thrombotic syndrome in those receiving thrombolysis compared with anticoagulation alone. However, it identified significantly increased bleeding complications (10% vs. 8%). Notably, most of these bleeding complications occurred in early studies (pre-1990), whereas recent adaptations in the standard practice of thrombolysis (lower dose rates and reduced concomitant heparin administration) should mitigate many of these issues.

Only two randomised controlled trials have specifically compared catheter-directed thrombolysis with anticoagulation. Elsharawy and Elzayat (*European Journal of Vascular and Endovascular Surgery*, 2002) published data from 35 patients, half treated with catheter-directed thrombolysis and anticoagulation, half with anticoagulation alone. They found significantly less reflux and higher patency in the catheter-directed thrombolysis group although numbers were small and short follow-up

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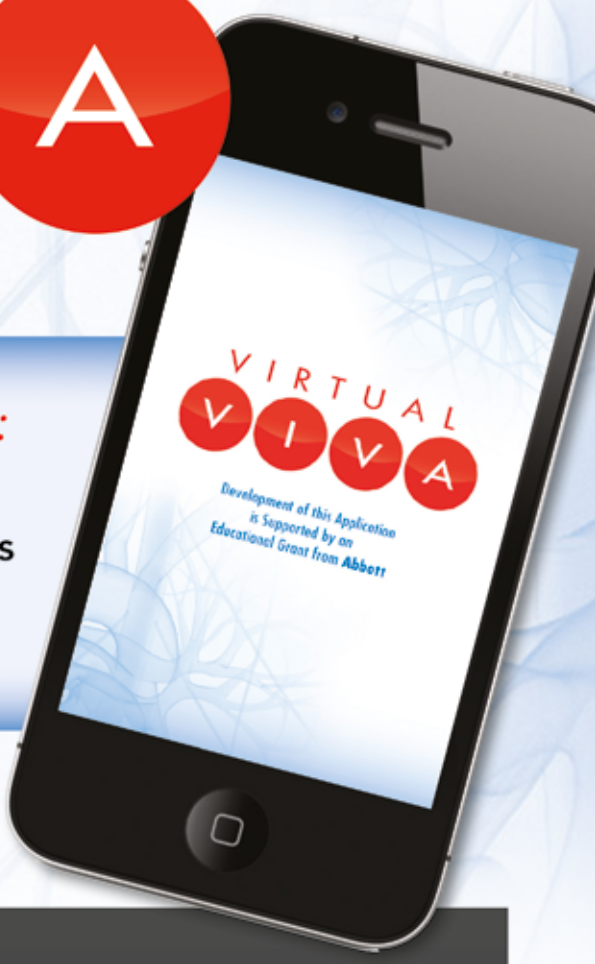

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precluded evaluation of post-thrombotic syndrome. The other more significant randomised controlled trials was CaVent, a Norwegian study that included 209 patients. Half were treated with catheter-directed thrombolysis and anticoagulation, half with standard anticoagulation. Post-thrombotic syndrome was significantly lower in the catheter-directed thrombolysis group. Other observational studies have demonstrated improvement in long-term quality of life following catheter-directed thrombolysis, including Comerota in 2000 (54 patients) and Grewal in 2010 (42 patients). Despite this data, there continues to be widespread reluctance to change the paradigm of treatment for deep venous thrombosis, based mainly on the concerns regarding bleeding risks.

Unresolved questions as to the benefits and risks of catheter-directed thrombolysis may be answered by an ongoing National institute of Health sponsored, multicentre trial, ATTRACT (Acute venous thrombosis: thrombus removal with adjunctive catheter-directed thrombolysis). Patients with an iliofemoral and femoropopliteal deep venous thrombosis are being stratified into catheter-based techniques of thrombolysis vs. anticoagulation alone. The primary endpoint is the development of post-thrombotic syndrome at 24 months, and there will also be a cost-benefit assessment. Their study hypothesis targets a reduction in post-thrombotic syndrome of 33% in the lysis group, with hopefully, a low incidence of bleeding complications. Should these large multicentre randomised controlled trials result in clinical improvement with acceptable risk and an overall cost-benefit, it may shift the playing field in favour of aggressive thrombolytic therapy for deep venous thrombosis.

Why are we not doing more thrombolysis?

The challenge to incorporating catheter-directed thrombolysis into standard practice lies in the fact that post-thrombotic syndrome develops long after the patient's acute hospital admission for deep venous thrombosis. Many physicians dealing with the acute stage have a low-level of appreciation of the long-term sequelae. Data from trials clearly show a significant reduction in post-thrombotic syndrome with catheter-directed thrombolysis and ATTRACT will hopefully demonstrate further improvement with the added inclusion of pharmacomechanical techniques, and cost-benefit data. Furthermore, with strict adherence to thrombolysis exclusion criteria, meticulous interventional techniques, and close treatment monitoring, the risk of bleeding complications can be minimised. Although current evidence in favour of catheter-directed thrombolysis for deep venous thrombosis may not be robust enough to allow for a shift in clinical practice, that may soon change.

Stephen T Kee is associate professor of Radiology and section chief, Interventional Radiology, David Geffen School of Medicine at UCLA, Los Angeles, USA. Adam Plotnik is a radiologist at the same institution. The authors have reported no disclosures pertaining to the article

More bleeding with catheter-directed thrombolysis than with standard anticoagulation in deep venous thrombosis

A study published in the *Journal of the American Medical Association (JAMA)* has found no difference in mortality rates between deep vein thrombosis patients treated with catheter-directed thrombolysis or anticoagulation alone. In the study, evidence of higher adverse events was noted in the catheter-directed thrombolysis group. The study was conducted by Riyaz Bashir, Temple University School of Medicine, Philadelphia, USA, and colleagues.

"Several small studies have suggested catheter-directed thrombolysis can reduce the incidence of post-thrombotic syndrome, which can impair quality of life for patients because of resulting pain, swelling and ulcerations. But catheter-directed thrombolysis is controversial with conflicting directives on its use because of inconclusive comparative safety outcomes," the authors write.

The investigators examined in-hospital mortality, as well as secondary outcomes of bleeding complications, length of stay and hospital charges, in a group of 90,618 patients hospitalised for deep vein thrombosis from 2005 to 2010 as part of the US Nationwide Inpatient Sample database. They compared patients treated with catheter-directed thrombolysis plus anticoagulation with patients treated with anticoagulation alone.

Of the 90,618 patients hospitalised for deep vein thrombosis, 3,649 (4.1%) underwent catheter-directed thrombolysis. The catheter-directed thrombolysis utilisation rate increased from 2.3% in 2005 to 5.9% in 2010. In-hospital mortality was not significantly different between the catheter-directed thrombolysis and anticoagulation groups (1.2% vs. 0.9%). However, rates for blood transfusion, pulmonary embolism, intracranial haemorrhage and vena cava filter placement were higher among patients treated with catheter-directed thrombolysis. Patients in the catheter-directed thrombolysis group also had longer average lengths of stay (7.2 vs. five days) and higher hospital charges (US$85,094 vs. US$28,164) compared with the anticoagulation group.

"Since our results are based on observational data, our findings could be subject to residual confounding, which further highlights the need for randomised trial evidence to evaluate the magnitude of the effect of catheter-directed thrombolysis on outcomes such as mortality, post-thrombotic syndrome and recurrence of deep vein thrombosis," the authors wrote.

Venous Product News

FDA approves IDE for Veniti Vici Venous Stent

Veniti has received approval from the FDA for an investigational device exemption (IDE) to begin the VIRTUS trial of the Veniti Vici Venous Stent System. The Vici Venous Stent System was designed from inception to be compatible with the unique anatomy and pathophysiology of the venous system.

Co-principal investigators for the VIRTUS trial are William Marston, chief, Division of Vascular Surgery, professor, Department of Surgery, UNC Department of Surgery, Chapel Hill, USA, and Mahmood Razavi, director for Clinical Trials & Research at the Heart and Vascular Center, St Joseph Hospital, Orange, USA.

The trial has commenced in Europe, with first patients enrolled and treated by Marta Ramirez Ortega at Hospital Madrid Monteprincipe in Madrid, Spain. "It is important for my patients to be able to be treated with a stent specifically designed for the venous anatomy and for them to have their data collected so that future patients can benefit from knowing how well venous stenting works," said Ramirez.

Vici venous stent

FDA clears EkoSonic

Ekos Corporation has announced that the FDA has cleared the EkoSonic endovascular system for the ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism. The Ekos devices are designed to gently accelerate the penetration of thrombolytic agents into thrombus, providing high levels of lysis.

Samuel Z Goldhaber, professor of medicine, Harvard Medical School and director, Thrombosis Research Group, Brigham and Woman's Hospital, Boston, USA, says, "The Ekos clinical data established that patients stricken with a life-threatening pulmonary embolism can be successfully and safely treated with the EkoSonic system. This is the first FDA cleared treatment option for pulmonary embolism since the approval of the drug, tPA, in 1990."

In January 2014, the outcomes of ULTIMA were published in *Circulation*. The trial demonstrated that for pulmonary embolism patients at intermediate risk of adverse events, Ekos treatment was clinically superior to anticoagulation with heparin alone in reversing right ventricular dilation at 24 hours, without an increase in bleeding complications.

Following ULTIMA, the SEATTLE II, a prospective, single-arm multicentre trial of 150 patients, demonstrated that ultrasound-facilitated catheter-directed low-dose fibrinolysis for acute pulmonary embolism minimises the risk of intracranial haemorrhage, improves right ventricular function, and decreases pulmonary hypertension.

EkoSonic

Covidien launches next generation Trellis system

Covidien has announced the launch of its next generation Trellis peripheral infusion system. This latest Trellis system has been optimised to enhance drug delivery and the removal of the dissolved clot.

The Trellis system provides a way for physicians to dissolve acute thrombus and intervene on deep vein thrombosis before it advances to post-thrombotic syndrome. The system is comprised of an over-the-wire catheter with two occlusive balloons to close off the treatment area and block drug release to other areas of the body; an infusion zone to deliver the lytic drug; and an oscillation drive unit that disperses the drug to dissolve the clot.

The updated Trellis system features enhanced drug delivery and increased amplitude of the dispersion wire to better distribute the drug throughout the clot. Additionally, it features a larger aspiration window than the previous version, which allows for better removal of the drug and the dissolved clot.

Trellis is currently available in the USA, Europe and Canada.

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High patency rates with early cannulation graft with bioactive surface

Results of vascular access using a new ePTFE graft show "satisfactory" primary patency rates at one year, and are similar to those achieved with an autogenous access. In the experience, conducted in one centre in Italy, the graft also demonstrated a low thrombosis rate.

Vascular surgeon Matteo Tozzi, Department of Surgery and Morphological Sciences, University of Insubria School of Medicine, Circolo University Teaching Hospital, Varese, Italy, presented the results with the Gore Acuseal (Gore) for prosthetic vascular access at the Society for Vascular Surgery Annual Meeting (5–7 June, Boston, USA).

Matteo Tozzi

Tozzi explained that the structure of the new graft has been specifically created to reduce the complications seen with previous ePTFE grafts for vascular access, but most importantly to allow a rapid cannulation. He said that with this device, cannulation can be carried out in the first 48 hours from the graft implantation.

The Acuseal graft is composed of three layers: the external layer consists of ePTFE; the middle layer is an elastomeric membrane that allows the sealing during anastomosis and cannulation; and the internal layer consists of ePTFE with Carmeda BioActive Surface (CBAS Surface) on the luminar surface. This surface is thrombore-sistant due to the heparin covalent bond to ePTFE (Figure 1).

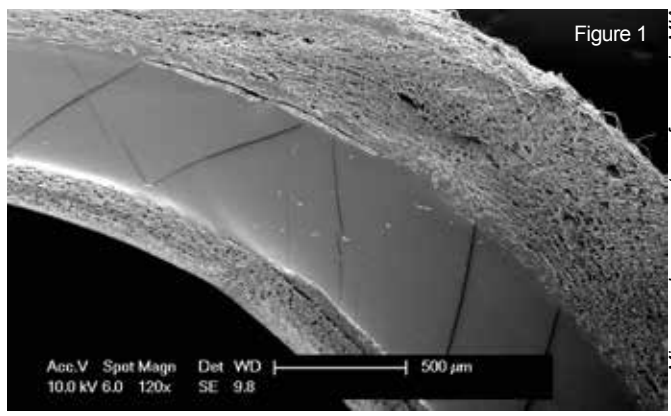

Figure 1

Microscpy Images courtesy of consorzio MIA

"Autogenous vascular access is the gold standard in patients with end-stage renal disease, due to long-term patency and lower frequency of complications such as stenosis and thrombosis. The disadvantages are the long maturation time of autogenous vascular access, of around 2–3 weeks before usage, and the fact that 10–24% thrombose directly after operation or fail to mature," he said. "Prosthetic vascular access is an alternative in case of autogenous vascular access failure or when the native vessels are poor."

Tozzi noted that from 2011 to 2014 his group performed early cannulation with the Acuseal prosthetic graft in 60 patients (mean age 63.6 years; 34–85 years, 39 men and 21 women). The most frequent causes for prosthetic access was autogenous vascular access failure (42.6%) and malfunction of central venous catheter (22%). All patients had an average of at least 2.2 previous autogenous accesses and the mean interval time from the start of haemodialysis and prosthetic access was 28.4 months.

Figure 2

"We prefer the loop configuration of vascular access in the upper arm. The most common procedure is the radio-basilic/axillary vein vascular access. We have also performed straight configuration in the upper arm and loops in the lower limb (Figure 2)," Tozzi said.

He further commented: "The Kaplan Meier analysis showed unexpectedly favourable results. Graft freedom from thrombosis at one year was 83% with a secondary patency of 93.5%. However, the mean follow-up is still short at 10.7 months. The mortality rate was 6.7% but the deaths were not related to our intervention."

After surgery, patients were treated with dual antiplatelet therapy: clopidogrel (75mg) and aspirin (100mg) and also with fish oil capsules (4000mg) for three months after surgery and with clopidogrel only thereafter.

Tozzi concluded that his group's preliminary experience with Acuseal for prosthetic vascular access was satisfactory—the graft proved to be safe and effective in patients with end-stage renal disease undergoing haemodialysis.

"Primary patency rates were satisfactory going up to 70% at 12 months, similar to those of an autogenous vascular access. The low thrombosis rate of this graft could be related to the heparin bonding on the endoluminal surface, a characteristic that might help restoration of the graft as documented by the overall high secondary patency rate of 90%," he said.

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Product News

Aorfix receives regulatory approval in Japan for treatment of abdominal aortic aneurysms

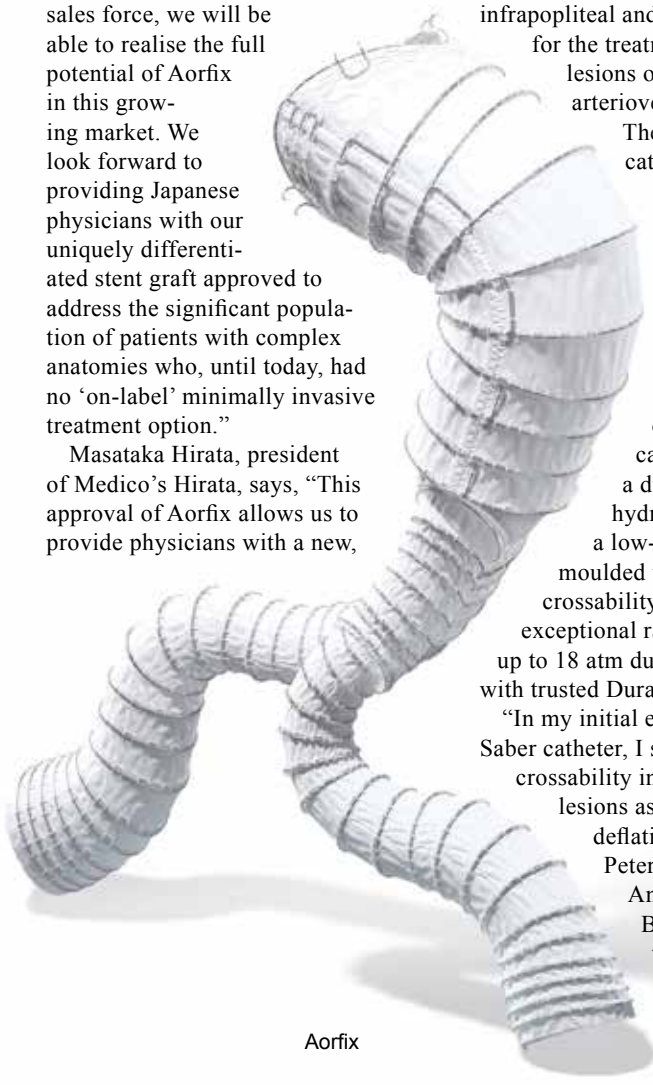
Lombard Medical has announced that its lead product, Aorfix, an endovascular stent graft to treat abdominal aortic aneurysms, has received approval from the Japanese Ministry of Health, Labour and Welfare. Commercial sales will follow reimbursement approval, which the company anticipates receiving in September. Aorfix will be exclusively distributed by Medico's Hirata, one of Japan's leading suppliers of vascular products with proven expertise in building significant market share for abdominal aortic aneurysms stent grafts. Japan is the world's second largest, standalone EVAR market.

Aorfix is the first and only endovascular stent graft approved in Japan to treat abdominal aortic aneurysms in patients with aortic neck angulations up to 90 degrees, commonly considered to be challenging cases. Aorfix is currently approved to treat patients with neck angles up to 90 degrees in the USA and Europe.

Lombard Medical's chief executive officer, Simon Hubbert comments, "Japan is a substantial EVAR market – both strategically and financially - and the approval of Aorfix is a significant milestone for the company. We are confident that, through Medico's Hirata's experienced and established sales force, we will be able to realise the full potential of Aorfix in this growing market. We look forward to providing Japanese physicians with our uniquely differentiated stent graft approved to address the significant population of patients with complex anatomies who, until today, had no 'on-label' minimally invasive treatment option."

Masataka Hirata, president of Medico's Hirata, says, "This approval of Aorfix allows us to provide physicians with a new, minimally invasive treatment option for Japanese patients with challenging abdominal aortic aneurysms. These physicians would otherwise have had to choose between taking responsibility for attempting treatment with a stent graft not specifically approved for more complex abdominal aortic aneurysm anatomies, or resorting to open surgery, which is more invasive and, typically, carries higher associated risks."

www.lombardmedical.com



Aorfix

Cordis launches Saber PTA dilatation catheter

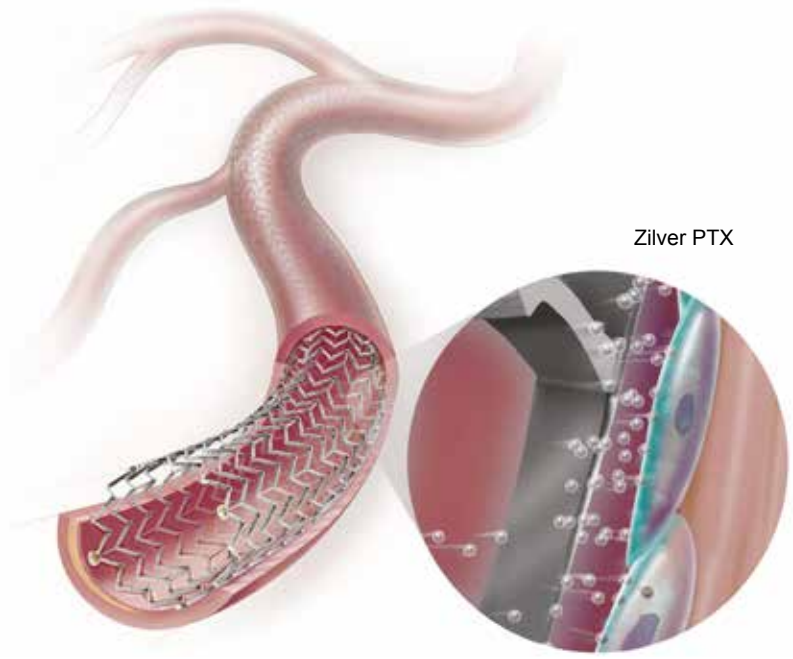
Cordis has announced the launch of its Saber percutaneous transluminal angioplasty dilatation catheter for the treatment of patients with peripheral arterial disease. The Saber catheter is cleared for use and now available in Europe, the United States and Japan. According to Cordis, this new product offers outstanding crossability and a comprehensive offering of balloon sizes on the widely-used 0.018" over-the-wire platform. Physicians can now treat a wider range of peripheral arterial disease patients with a single balloon brand.

Developed to complement the Cordis angioplasty portfolio as a next-generation, high-performance workhorse 0.018" balloon catheter, Saber catheter is intended to dilate stenoses in iliac, femoral, iliofemoral, popliteal, infrapopliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for post-dilation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Saber catheter is available in balloon diameters of 2–10mm and lengths of 20–300mm. Saber catheter combines a durable dual layer hydrophilic coating with a low-profile body and new moulded tip design to enhance crossability. The catheter has exceptional rated burst pressures of up to 18 atm due to its construction with trusted Duralyn Material.

"In my initial experience with the Saber catheter, I see outstanding crossability in very tight lesions as well as excellent deflation times," says Peter Goverde, ZNA Antwerpen in Brussels, Belgium. "Given these performance characteristics combined with the size offering that Saber catheter provides, I see the value in adopting this as the preferred 0.018" workhorse balloon in my practice."

www.cordis.com



Zilver PTX

Zilver PTX drug-eluting stent available in Canada

Cook Medical has launched its Zilver PTX drug-eluting peripheral stent in Canada at the Canadian Interventional Radiology Association (CIRA) meeting in Montreal. It is the first drug-coated stent in Canada indicated to treat peripheral arterial disease in the superficial femoral artery.

"Launching Zilver PTX in Canada brings the benefits of drug-eluting stents to Canadian peripheral arterial disease patients," says Mark Breedlove, vice president of Cook Medical's Peripheral Intervention clinical division. "We are very pleased to be the company that introduces this technology in Canada."

The device is a self-expanding metal stent coated with the drug paclitaxel. The drug is absorbed by the surrounding tissues to prevent the growth of scar tissue that can reclog the artery. It is indicated for use in treating new or recurring lesions as long as 140mm per leg. In Canada, Zilver PTX is sold in 40, 60, 80 and 100mm lengths and in 6 and 7mm diameters.

Four-year data from the international Zilver PTX randomised trial show 75% of patients treated with Zilver PTX maintained blood flow in the superficial femoral artery at four years. That compares to 57.9% patency for patients who received a bare metal Zilver stent.

Since its initial launch in 2009 in Europe, Zilver PTX has been used to treat more than 25,000 peripheral arterial disease patients. The device is now available in more than 50 countries across Europe, the Middle East, North and South America, and the Asia-Pacific region.

zilverptx.cookmedical.com

FDA clearance of CorMatrix ECM for vascular repair

CorMatrix Cardiovascular has announced that it has received FDA clearance to market the CorMatrix ECM (extracellular matrix) for vascular repair.

The CorMatrix ECM for vascular repair is intended for use as a patch material for repair and reconstruction of peripheral vasculature including the carotid, renal, iliac, femoral, and tibial blood vessels. The CorMatrix ECM for vascular repair may be used for patch closure of vessels, as a pledget, or for suture line buttressing when repairing peripheral vessels. It is constructed from a multi-laminate sheet of decellularised, non-crosslinked, lyophilised extracellular matrix derived from porcine small intestinal submucosa.

According to Richard F Neville, professor of surgery, chief, Division of Vascular Surgery at George Washington University, Washington, DC, USA, "CorMatrix ECM for vascular repair is an innovative scaffold permitting the patient's own stem cells to regenerate viable autogenous tissue improving the results of revascularisation procedures that often fail due to myointimal hyperplasia and accelerated atherosclerosis."

"The CorMatrix ECM for vascular repair is an expansion of the current indications for our CorMatrix ECM for carotid repair and was pursued due to requests by our physicians for a product that could be used to repair blood vessels throughout the vascular system. CorMatrix devices have now been used in over 100,000 patients worldwide to treat a growing number of cardiovascular indications. We are pleased that we can address these additional requests by physicians, providing a novel device to meet current clinical needs," comments Andrew Green, CorMatrix Cardiovascular's executive vice president of Operations. "Expansion of our current FDA-cleared devices to satisfy unmet indications further strengthens our leadership position in the field of ECM technologies and regenerative medicine, utilising the patient's own stem cells and their natural healing ability."

www.cormatrix.com

Product News

Spectranetics announces FDA clearance of peripheral laser atherectomy devices for in-stent restenosis

The Spectranetics Corporation has announced receiving US FDA 510(k) clearance of their peripheral atherectomy products, Turbo-Tandem and Turbo Elite, for the treatment of in-stent restenosis.

FDA clearance comes on the heels of the EXCITE ISR (Excimer laser randomised controlled study for treatment of femoropopliteal in-stent restenosis) study's clinical findings. The study, which is the first multicentre, randomised, prospective trial conducted for the treatment of in-stent restenosis, demonstrated highly superior safety and efficacy of laser atherectomy with adjunctive percutaneous transluminal angioplasty compared with angioplasty alone. The trial shows a 94% procedural success rate using laser atherectomy with angioplasty versus 83% with angioplasty alone.

"With mean lesion length at 20cm, approximately one-third of the patients being re-treated for in-stent restenosis and also approximately one-third with total occlusions, EXCITE represents a very sick, real-world patient set," said Eric Dippel, Genesis Heart Institute, Davenport, USA. "The highly superior outcomes for both safety and efficacy and the delta in procedural success rates between the two arms of the trial are compelling. Given that a significant number of patients today are treated with percutaneous transluminal angioplasty alone with very poor outcomes, EXCITE ISR demonstrates a proven treatment algorithm that physicians and their patients need."

A press release from the company notes that the average lesion length was approximately 20cm in EXCITE ISR as compared to various stent investigational device exemption studies with average lesion lengths of 4–6cm. Additionally, a high number of complex or advanced disease-state patients were enrolled in the trial, indicative of success in treating all types of lesions, including the most complex cases. Complete results from the EXCITE trial have been submitted to a peer-reviewed medical journal, the release states.
www.spectranetics.com

Jotec post marketing study of the E-liac Stent Graft System initiated

Jotec has announced that it has initiated the PLIANT study (A post-market registry in patients with iliac aneurysm undergoing endovascular stenting with a new generation of low profile E-liac Stent Graft System).

The objectives of the multicentre study are to evaluate clinical and technical success as well as safety and feasibility of the new E-liac Stent Graft System used in endovascular treatment of unilateral or bilateral aorto-iliac or isolated common iliac aneurysm. The main target of the study is the exclusion of aneurysm with primary patency of the internal iliac artery and external iliac artery on the iliac implantation side.

A total number of 40 male and female patients will be included and treated with the E-liac Stent Graft in the course of the study. The period of data collection for each patient will be 36 months from the intervention. The study was started in May 2014 with the primary ethical vote and is planned to be completed in 2018.

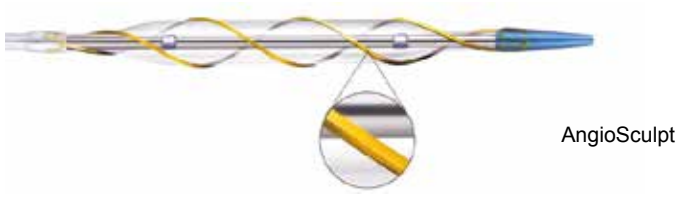
Principal investigator of this study is Jan Brunkwall from the University Hospital Cologne, Germany. More than 11 European clinical centres specialised in the endovascular treatment of iliac aortic aneurysms will participate in this cohort study.

The Jotec E-liac Stent Graft is a new generation side branch device that incorporates numerous innovative technical solutions to treat a broad range of anatomies. The stent graft features a unique asymmetric spring configuration to achieve high 3D flexibility while maintaining appropriate longitudinal stiffness. A free standing side branch with distal compression stent and excellent X-ray visibility are some of the features of the device. According to Jotec, various stent graft configurations are available. The low profile 18F delivery system is adapted for crossover manoeuvres and is equipped with a new designed end cap with several functionalities.
www.jotec-eliac.com

FDA clears 150cm length Arrow GPSCath balloon dilatation catheters

Teleflex Incorporated has announced that its subsidiary Hotspur Technologies received FDA 510(k) clearance to market the Arrow GPSCath balloon dilatation catheters designed for use with 0.014" guidewires and in 150cm length.

These novel products enable a variety of peripheral vascular procedures to be performed below the knee with one dual function catheter, potentially reducing procedure time, radiation dosage, and expense for both patients and medical professionals.



AngioSculpt

The Arrow GPSCath balloon dilatation catheter is the first dual functional balloon dilatation catheter that combines angioplasty with the proprietary VisioValve injection system. This innovative combination enables physicians to perform peripheral below-the-knee angioplasty and inject physician selected fluids, such as contrast media, while maintaining guide wire position.

"With this latest product approval we continue our commitment to enabling medical professionals to perform peripheral access procedures that simplify and improve the doctor and patient experience while reducing health care costs," says Benson Smith, chairman, president and chief executive officer of Teleflex. Smith adds, "We are excited to bring this innovative product for use in below-the-knee peripheral interventions to the market."
www.teleflex.com

New 200mm length AngioSculpt scoring balloon catheters launched

The Spectranetics Corporation has announced that its wholly-owned subsidiary, AngioScore, launched its new 200mm length AngioSculpt angioplasty scoring balloon catheters for the treatment of peripheral artery disease above-the-knee.

The new AngioSculpt catheters received FDA 510(k) clearance to be marketed for the dilatation of lesions in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and to treat obstructive lesions of native or synthetic arteriovenous dialysis fistulae. They are not approved for use in the coronary or neurovasculature.

The catheters incorporate 200mm balloons in diameters of 4, 5 and 6mm with a novel scoring element specifically designed for these longer balloons. The devices are expected to be particularly useful in treating the typical complex and long lesions found above the knee.

"These new longer scoring balloons extend the capability of the AngioSculpt in treating the most challenging femoropopliteal lesions safely and efficiently and will be a very important addition to the armamentarium of physicians treating complex endovascular disease," says Nelson L Bernardo, medical director of the Peripheral Vascular Laboratory, MedStar Heart Institute, MedStar Washington Hospital Center, Washington, DC, USA.

The AngioSculpt balloon catheter was developed by AngioScore, which was acquired by The Spectranetics Corporation on 30 June 2014. Scott Drake, president and chief executive officer of Spectranetics states, "We are proud to introduce a viable new product to treat peripheral arterial disease so quickly following the joining of our two companies. At Spectranetics, we focus on solutions for the sickest and trickiest patient population. Now, united with AngioScore, we continue our commitment to provide solutions to cross, prep and treat the most complex morphologies associated with coronary and peripheral diseases."
www.angioscore.com

Oscor launches the Adelante Magnum introducer in the USA

Following a European launch, Oscor has received clearance to market the Adelante Magnum in the USA. The Adelante Magnum is a high performance haemostatic valve introducer for large size vascular access, specifically designed and optimised for the introduction and placement of endovascular catheters, aortic valves, and stent graft systems.

The Adelante Magnum features a proprietary multilayer hydrophilic coated sheath, having a special designed distal tip portion to accept and tolerate the insertion and manipulation of large and complex devices. The Adelante Magnum SureSeal technology facilitates optimum haemostasis, allowing the insertion of multiple catheters and wires simultaneously with minimal blood loss. The Adelante Magnum comes readily available in multiple French sizes and sheath lengths.
www.oscor.com

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Clinical News

Enrolment complete in ROADSTER trial for carotid artery disease

Silk Road Medical has announced the completion of enrolment in its pivotal ROADSTER study. The trial was the first of its kind to study the treatment of carotid artery stenosis by placing a stent via direct access to the common carotid artery in the neck in an entirely new minimally invasive procedure. The device under study is the company's Enroute transcarotid neuroprotection system which incorporates proven surgical principles to protect the brain from a stroke during carotid angioplasty and stenting, and features a mechanism to divert dangerous debris away from the brain by temporarily reversing blood flow. Data from the trial will be used to support 510(k) clearance of the Enroute transcarotid neuroprotection system as well as pre-market approval of the Enroute transcarotid stent system.

"The Enroute transcarotid neuroprotection system was designed to reduce the excess stroke risk of a carotid stent procedure, while at the same time minimising the surgical risks of an open carotid artery surgery known as carotid endarterectomy," says Sumaira Macdonald an expert in the field of carotid artery disease and Silk Road Medical's chief medical officer. "Until now, carotid stents were typically placed via the femoral artery approach, which is about three feet from the culprit carotid stenosis, and requires navigation of catheters and other instruments through often hostile territory, increasing the risk of stroke during or immediately after the procedure," she says. "We know that carotid stents are effective in preventing strokes in the long term, but we need a safer way to deliver them. The Silk Road procedure moves the access point to within inches of the stenosis to avoid at-risk steps and provides a surgically-inspired method of protecting the brain throughout the simplified procedure."

"The ROADSTER trial included an elite, multidisciplinary group of physicians across the USA and Europe with vast experience in treating carotid disease," says Christopher Kwolek, director of the Vascular and Endovascular training programme at Massachusetts General Hospital, chief of Vascular Surgery at Newton Wellesley Hospital, and national co-principal investigator for the ROADSTER trial. "Similar to important endovascular innovations in aortic aneurysms and peripheral arterial disease, this new minimally invasive procedure will be an important step forward in the treatment of carotid artery disease for the vascular specialist."

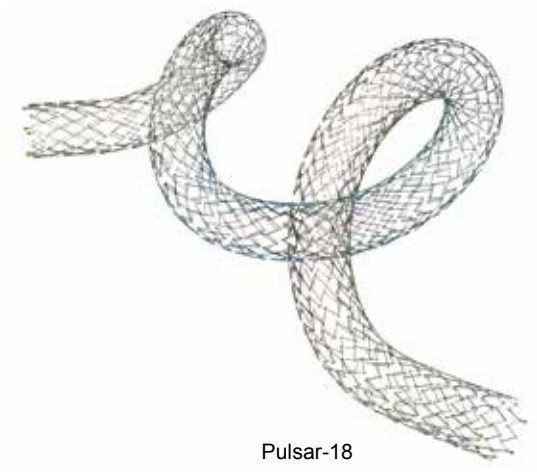
Both the Enroute transcarotid neuroprotection system and stent system have been granted CE mark approval. The Enroute transcarotid neuroprotection system is limited by United States law to investigational use.

Biotronik announces study evaluating efficacy of combined Pulsar-18 stent and Passeo-18 Lux balloon

Biotronik has announced that the first patient has been enrolled in the investigator-initiated BIOLUX 4EVER trial. Given the positive results from each of the previous drug-eluting balloon and self-expanding stent trials, investigators were interested in exploring the combined use of the Pulsar-18 self-expanding stent and Passeo-18 Lux drug-eluting balloon to see if the outcome could be improved further. BIOLUX 4EVER will follow the study design of the previously completed, investigator-initiated 4EVER trial, which examined the efficacy of the Pulsar-18 self-expanding stent in the treatment of superficial femoral artery lesions, but this time adding the Passeo-18 Lux drug-eluting balloon to the treatment. The study will enrol 120 patients treated with both products, with the primary endpoint of primary patency at 12 months.

"Studying these two devices in combination is a novel idea," says principal investigator Marc Bosiers, St Blasius Hospital, Dendermonde, Belgium. "Previous studies of each device have yielded encouraging results, but we wanted to go one step further. Now, patients will be treated with both the Pulsar-18 stent and the Passeo-18 Lux, hopefully pushing the results off the charts."

BIOLUX P-I was the first in-human study investigating the performance of the Passeo-18 Lux drug-eluting balloon compared to an uncoated Passeo-18 balloon catheter in the treatment of superficial femoral artery lesions. At 12 months, freedom from target lesion revascularisation was achieved in 84.6% of drug-eluting balloon patients and 58.3% of percutaneous transluminal angioplasty patients. The 4EVER study investigated both the acute and long-term performance of 4F-compatible devices in treating superficial femoral artery lesions. The study examined the efficacy of Pulsar stents and the feasibility of treating patients with Biotronik 4F devices. Twenty-four-month data from 4EVER for the full cohort of 120 patients showed an impressive 72.3% primary patency rate and a freedom from target lesion revascularisation rate of 82.7% with no significant difference between calcified and non-calcified lesions.



Pulsar-18

Pantheris

Avinger enrols first patient in VISION trial

Avinger has announced that John Pigott of Jobst Vascular Institute, Toledo, USA has enrolled the first patient in VISION. VISION is a global investigational device exemption (IDE) clinical trial, approved by the FDA, to evaluate Avinger's Pantheris catheter for the treatment of peripheral artery disease.

The Pantheris system combines directional atherectomy capabilities with real-time intravascular visualisation to remove plaque from blocked arteries. The minimally invasive catheter is designed to remove plaque, while avoiding the disruption of normal arterial wall structures. Despite other attempts in the industry, this has never been accomplished until now.

"For the first time ever, I am able to visualise the inside of the artery and selectively remove plaque without disrupting the healthy portion of the vessel. This has the potential to revolutionise the treatment of vascular disease," says Pigott.

"We are convinced that Avinger's Pantheris catheter will be a major step forward for our patients and for the entire medical community as the increased precision allowed by direct visualisation is immediate and significant," say VISION co-principal investigators William Crowder and J Gray Bennett of St Dominic Hospital, Jackson, USA.

Full two-year Mimics data confirm long-term patency protection with BioMimics 3D stent

Full two-year data from the Mimics study, presented for the first time at the 15th Annual New Cardiovascular Horizons (NCVH) Conference (28–30 May, New Orleans, USA), have confirmed that BioMimics 3D provides a significant improvement in long-term patency compared to a straight nitinol control stent in patients undergoing femoropopliteal artery intervention. BioMimics 3D, a nitinol stent with unique three-dimensional helical geometry, has been developed by Veryan, based on pioneering research by Colin Caro at Imperial College London, UK, into the link between blood flow mechanics and vascular disease.

The Mimics study is a prospective, randomised, multicentre controlled trial conducted at eight German investigational centres and supported by an independent core lab. A total of 76 patients were enrolled and randomised 2:1 (50 BioMimics 3D v 26 Control) in patients undergoing femoropopliteal artery intervention. Mimics' investigators compared the safety, efficacy and vascular haemodynamics of the BioMimics 3D stent to straight nitinol stents (24/26 control subjects were treated with C R Bard's LifeStent).

The BioMimics 3D stent incorporates Veryan's patented 3D helical technology, an advanced stent design that promotes natural swirling blood flow to elevate wall shear stress which has been shown to reduce neointimal hyperplasia and improve the biomechanical performance of the femoropopliteal artery during knee flexion, mitigating the risk of stent fracture and vessel kinking.

The full two-year data from Mimics were presented by principal investigator Thomas Zeller, Universitäts-Herzzentrum, Freiburg-Bad Krozingen, Germany. There are two key findings; firstly, the Kaplan Meier survival analysis of freedom from loss of primary patency at two years was 72% for BioMimics 3D subjects vs. 55% for the control group (p=0.0497); secondly, there was no increase in the clinically driven target lesion revascularisation rate in the BioMimics arm between 12 and 24 months (9% at both timepoints) compared to an increase of 16% (8% at 12 months and 24% at 24 months) in the control arm. The data indicate a correlation between primary patency and stent curvature. BioMimics 3D stented segments showed significantly greater curvature (p=0.02) compared with the control, providing improved blood flow and elevated wall shear, which may explain the longer term patency protective effect seen with BioMimics 3D. No stent fractures were detected by the independent core lab.

"The final 24-month data for the BioMimics 3D stent confirm that the flow effects produced by its helical design are contributing to an improved outcome compared to that achieved with the straight control stents. The results of the Mimics study show a significantly greater freedom from loss of primary patency with BioMimics in the 24-month Kaplan Meier survival analysis," comments Zeller. "Importantly, there was no change in the rate of clinically-driven target lesion revascularisation in the 12 and 24 month follow-ups for BioMimics 3D and this longer-term benefit appears to correlate with a trend to lower peak systolic velocities. Overall, these data suggest that a biomimetic stent with 3D helical curvature may provide a new performance benchmark in femoropopliteal stenting."

Veryan has received CE mark approval for the BioMimics 3D stent and plans to commercialise the stent later this year.

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Industry News

Medtronic to acquire Covidien for US$42.9 billion in cash and stock

Medtronic and Covidien announced on 15 June 2014 that they have entered into a definitive agreement under which Medtronic has agreed to acquire Covidien in a cash-and-stock transaction valued at US$93.22 per Covidien share, or a total of approximately US$42.9 billion, based on Medtronic's closing stock price of US$60.70 per share on 13 June 2014.

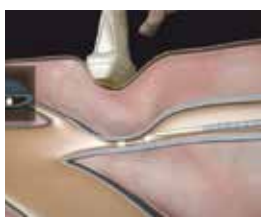
The combined company will have a comprehensive product portfolio, a diversified growth profile and broad geographic reach, with 87,000 employees in more than 150 countries.

Covidien acquires Sapheon

Covidien has announced that it has acquired Sapheon, a privately-held developer of venous disease treatments. Financial terms of the transaction were not disclosed.

Sapheon develops and manufactures the VenaSeal system, which uses a specially formulated medical adhesive to close the great saphenous vein in patients with varicose veins and chronic venous insufficiency. The procedure is performed with a minimally invasive catheter technique under ultrasound guidance in an office or outpatient setting. In many cases, patients are able to resume normal activity immediately after the procedure. Additionally, the procedure requires no tumescent anaesthesia (a technique that requires multiple injections to deliver local anaesthesia) and often results in less bruising than traditional thermal energy treatment.

"Sapheon will significantly enhance Covidien's global peripheral vascular business by providing additional treatment options for physicians and their patients who suffer from chronic venous insufficiency," said Brian Verrier, president, Peripheral Vascular, Covidien.



VenaSeal

The VenaSeal system is currently approved in Canada, Europe and Hong Kong, and more than 2,000 patients have been treated with the system. Additionally, Sapheon successfully completed enrolment and follow-up of its VeCLOSE randomised pivotal clinical trial in the USA and submitted documentation to the US Food and Drug Administration in support of a premarket approval. The VenaSeal system is currently limited to investigational use in the USA.

Boston Scientific closes acquisition of Interventional Business of Bayer

Boston Scientific has closed on its previously announced agreement to purchase the Interventional business of Bayer. According to Boston Scientific, the acquisition enhances its ability to offer physicians and healthcare systems a more complete portfolio of solutions to treat challenging vascular conditions.

A press release from Boston Scientific stated: "The addition of the Bayer Interventional commercial organisation and innovative technologies supports the Boston Scientific strategy to provide a comprehensive portfolio of leading solutions to treat peripheral vascular disease. The transaction includes the leading AngioJet thrombectomy system and the Fetch 2 aspiration catheter, which are used in endovascular procedures to remove blood clots from blocked arteries and veins, and the JetStream atherectomy system, used in an innovative and fast-growing therapy to remove plaque and thrombi from diseased arteries."

The company expects the transaction to be immaterial to adjusted earnings per share in 2014, accretive by approximately US$.01 in 2015 and increasingly accretive thereafter. On a GAAP earnings per share basis, the company expects the transaction to be slightly dilutive in 2014, immaterial in 2015, and less accretive than on an adjusted earnings per share basis thereafter as a result of acquisition-related net charges and amortisation, which will be determined following the closing.

Spectranetics completes acquisition of AngioScore

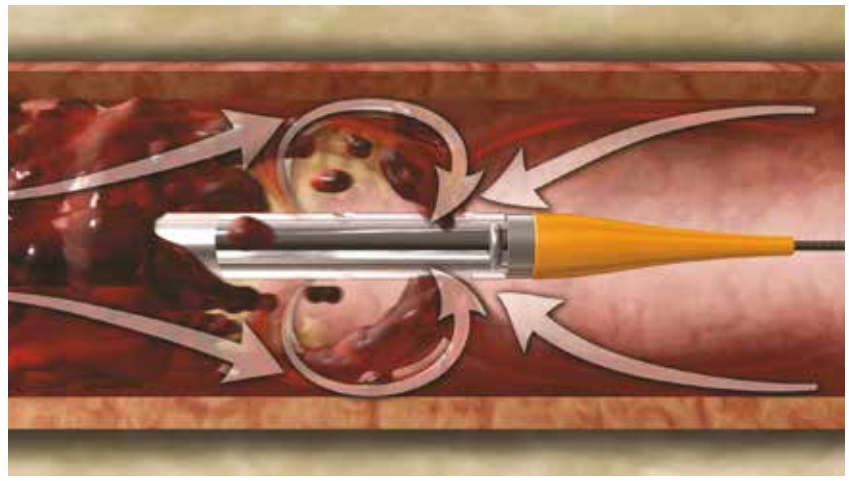
Spectranetics has acquired AngioScore, a developer, manufacturer and marketer of cardiovascular, specialty balloons, for US$230 million in cash, along with additional contingent commercial and regulatory milestone payments.

AngioScore, based in Fremont, USA, develops and markets the AngioSculpt scoring balloon technology platform, which is a comprehensive portfolio to treat blockages in the coronary and peripheral vasculature. AngioScore's product and distribution platforms diversify Spectranetics' portfolio while expanding physicians' options to treat critical limb ischaemia, in-stent restenosis, calcified lesions and chronic total occlusions.

Volcano announces agreement to acquire AtheroMed

Volcano has announced that it has signed an agreement to acquire AtheroMed, a privately-held company that has developed the Phoenix Atherectomy System used in the treatment of peripheral artery disease.

The Phoenix, which received 510(k) clearance in January 2014 and has CE mark approval, enables physicians to treat peripheral artery disease with a low profile peripheral atherectomy catheter that continuously removes diseased material as it is debulked. The device has reimbursement in the USA and select countries in Europe.



AngioJet

Under terms of the agreement, Volcano will pay US$115 million in cash at closing. In addition, Volcano will make a US$15 million milestone payment if a Phoenix device currently before the FDA receives clearance by 15 November 2014. This application covers design for manufacturing improvements to the currently approved device. In addition, the agreement calls for potential future revenue-based milestone payments by Volcano to AtheroMed.

The Phoenix is a peripheral atherectomy system that has been designed to provide physicians with a safe, versatile, easy-to-use primary therapy for treating peripheral artery disease to restore blood flow to the ankle and foot. The over-the-wire system uses a rotating, front-cutting element located at the distal tip of the catheter to shave material directly into the catheter. The debulked material is then continuously captured and removed by an internal Archimedes Screw running the length of the catheter. The device is available in multiple sizes to treat diseased vessels both above and below the knee.

CryoLife appoints Pat Mackin as president and chief executive officer

CryoLife has announced that its Board of Directors has appointed James Patrick (Pat) Mackin as president and chief executive officer, effective 2 September 2014. Mackin is expected to be appointed to the company's Board of Directors after his employment begins.

Steven G Anderson will continue to serve CryoLife as its president and chief executive officer until Mackin's employment begins and then continue as its executive chairman.

Steven G Anderson states, "We are excited to have Pat Mackin join us as our chief executive officer and president. We believe he is an ideal leader for CryoLife given his strong background in cardiac and vascular medical devices and broad international sales and marketing experience. In addition, Pat's accomplishments, professionalism and commitment to excellence complement the culture, mission and values of CryoLife perfectly. I am confident that Pat will bring significant value as we continue to execute on our growth strategy and, personally, I am greatly looking forward to working with him."

Mackin joins CryoLife from Medtronic, where he most recently served as president of Cardiac Rhythm Disease Management, the company's largest operating division. Mackin is a highly respected professional with more than 20 years of medical device industry experience. At Medtronic, he previously held the positions of vice president, Vascular, Western Europe and vice president and general manager, Endovascular Business Unit.

Prior to joining Medtronic in 2002, Mackin worked for six years at Genzyme, serving as its senior vice president and general manager for the Cardiovascular Surgery Business Unit and, earlier, as director of Sales, Surgical Products division. Before joining Genzyme, he spent four years at Deknatel/Snowden-Pencer, in various roles and three years as a First Lieutenant in the United States Army.

Pat Mackin

Mackin received a Master's in Business Administration from Northwestern University's Kellogg Graduate School of Management and is a graduate of the United States Military Academy at West Point.

Intact Vascular hires Bruce Shook as president and chief executive officer

Intact Vascular has announced that Bruce J Shook is joining the company as president and chief executive officer and as a member of its Board of Directors. Shook spent the past 11 years at Neuronetics, a medical device company he co-founded and led as its president and chief executive officer.

Shook says, "I am very impressed with what the Intact Vascular team has accomplished. They have developed an extraordinarily innovative approach to the treatment of peripheral vascular disease that holds significant promise to advance endovascular therapy beyond the current practice of stenting. Intact has exceptional assets and I am truly excited to be working with this team to improve patient care, offer customers novel solutions, and build value for our stakeholders."

Calendar of events

23–25 September
The European Society for Vascular Surgery (ESVS) XXVIII Annual Meeting
Stockholm, Sweden
Waterfront Congress Centre
E administration@esvs.org
W www.esvs.org

25–26 September
VASBI—The Vascular Access Society of Britain & Ireland
Stratford Upon Avon, UK
Holiday Inn
E vasbi.org@gmail.com
W www.vasbi.org.uk

2–5 October
World Federation of Vascular Societies Congress 2014
Stellenbosch, South Africa
Stellenbosch Protea Hotel (Technopark)
W www.wfvscongress2014.co.za

9–12 October
Endovascology International Congress
Shanghai, China
Sheraton Shanghai Waigaoqiao Hotel
E endovascology@xueguan.net
W www.endovascology.org

9–12 October
5th Balkan Venous Forum
Sofia, Bulgaria
Kempinsky Hotel
E Bvf2014@abv.bg
W bvf.bnsavs.org

9–12 October
The VEINS
Chicago, USA
Swissotel Chicago
E arees@crf.org
W theveins.org

23–24 October
CIDA—Controversies in Dialysis Access
Salt Lake City, USA
The Grand America Hotel
E questions@ccmcme.com
W www.dialysiscontroversies.org

30 October–1 November
5th EVF HOW 2014—Hands-on Workshop on Venous Disease
Limassol, Cyprus
Grand Resort
E admin@europeanvenousforum.org
W www.europeanvenousforum.org

4–7 November
VIVA—Vascular Interventional Advances
Las Vegas, USA
Wynn Las Vegas
W www.VIVAPVD.com

18–22 November
VEITHsymposium
New York, USA
Hilton New York
E admin@veithsymposium.org
W www.veithsymposium.org

26–28 November
AGM Vascular Society of Great Britain and Ireland
Glasgow, UK
SECC Glasgow
E office@vascularsociety.org.uk
W www.vascularsociety.org.uk

22–24 January 2015
CACVS—Controversies & Updates in Vascular Surgery
Paris, France
Marriott Rive Gauche & Conference Centre
E vbergeron@cacvs.org
W www.cacvs.org

27–30 January 2015
LINC—Leipzig Interventional Course
Leipzig, Germany
Trade Fair Leipzig
W www.leipzig-interventional-course.com

31 January–4 February 2015
ISET—International Symposium on Endovascular Therapy
Hollywood, Florida, USA
Westin Diplomat
E Questions@ccmcme.com
W www.iset.org

9–11 February 2015
iCON—International Congress on Endovascular Interventions
Phoenix, USA
W www.iconmeeting.com

8–10 March 2015
EVC—19th European Vascular Course
Maastricht, The Netherlands
W www.vascular-course.com

9–11 March 2015
LINC Asia-Pacific
Lantau Island, Hong Kong
AsiaWorld-Expo
Hong Kong International Airport
E info@cong-o.de
W www.lincasiapacific.com

9–11 April 2015
New Cardiovascular Horizons—NCVH America Latina
Bogota, Colombia
W www.ncvh.org/americalatina

15–18 April 2015
VAS 2015 – 9th Congress of the Vascular Access Society
Barcelona, Spain
Palau Congresos Barcelona
W www.vas2015.org

16–18 April 2015
Venous Symposium
New York, USA
Hilton New York
E questions@ccmcme.com
W www.venous-symposium.com

28 April–1 May 2015
Charing Cross International Symposium
London, UK
Olympia Grand
E info@bibamedical.com
W www.cxsymposium.com

15–16 May 2015
19th International Expert Symposium on Critical Issues in Aortic Endografting
Liverpool, UK
E info@cong-o.de
W www.critical-issues-congress.com

8–9 June 2015
MEET—Multidisciplinary European Endovascular Therapy
Nice, France
Radisson Blu Hotel
E info@meetcongress.com
W www.meetcongress.com

24–27 June 2015
SITE—International Symposium on Endovascular Therapeutics and Congress of the CELA Society (Endovascular Surgeons for Latin America)
Barcelona, Spain
Palau de Congressos de Catalunya
E secretariat@sitesymposium.org
W www.sitesymposium.org

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Next issue
November 2014

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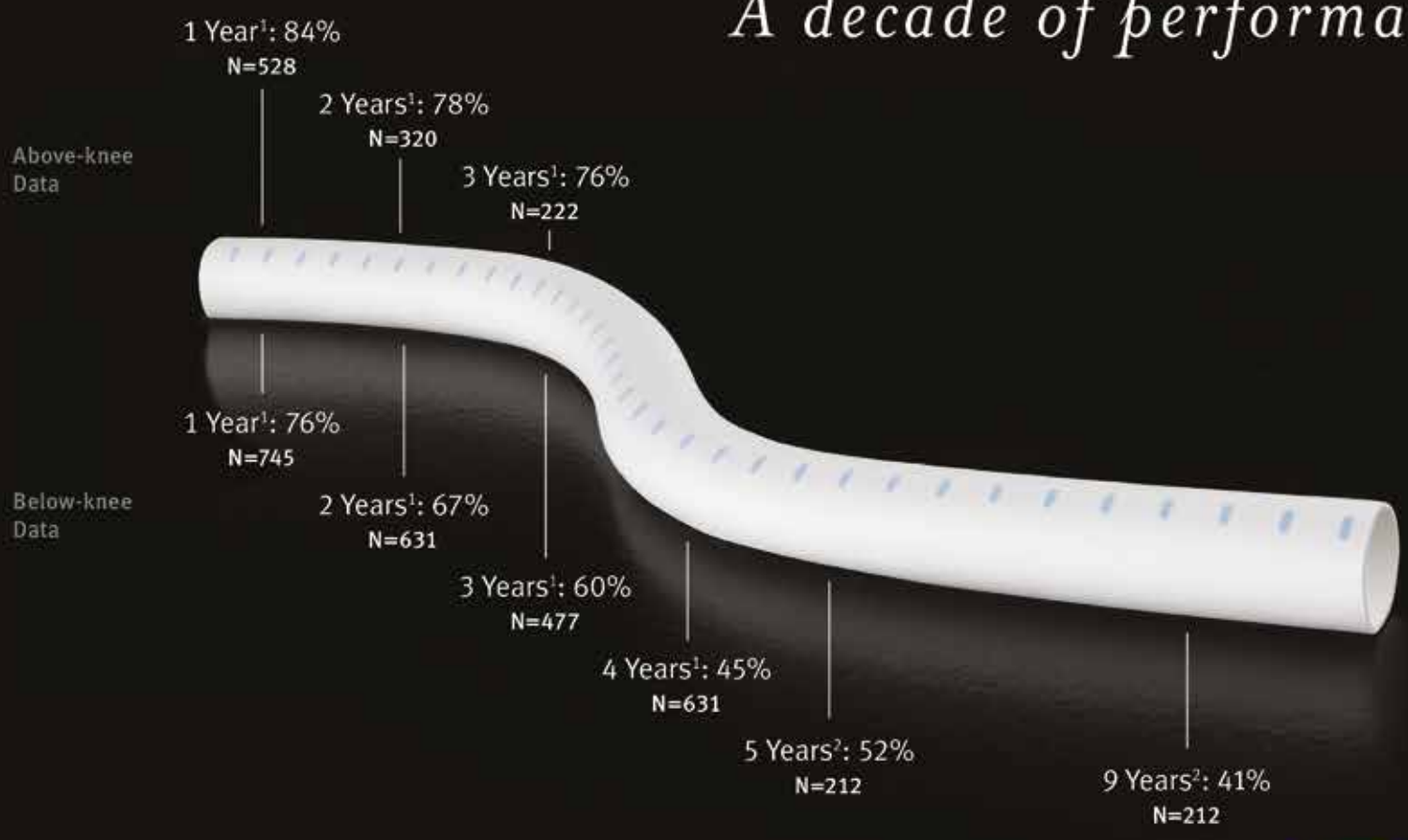

Overall weighted average primary patency

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- 100,000+ devices implanted
- 30+ clinical publications
- 93% 9-year limb salvage[2]
- 1629 limbs studied
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- 33% reduction in 3-year cumulative cost compared to standard ePTFE[4]
- 50% reduction in the risk of graft occlusion compared to standard ePTFE in CLI patients[3]

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goremedical.com/propatenperformance

* As compared to clinical studies listed on clinicaltrials.gov for peripheral arterial bypass.

1. Overall weighted average primary patency is based on data from 11 peer-reviewed publications meeting pre-determined inclusion criteria. Visit goremedical.com/propatenperformance to see inclusion criteria, explore the data, see publications, and request reprints.
2. Monaca V, Battaglia G, Turiano SA, Tringale R, Catalfamo S. Sub popliteal revascularization. Criteria analysis for use of E-P.T.F.E. (Propaten®) as first choice conduit. *Italian Journal of Vascular & Endovascular Surgery*. In press.
3. Lindholt JS, Gottschalksen B, Johannesen N, *et al*. The Scandinavian Propaten® Trial – 1-year patency of PTFE vascular prostheses with heparin-bonded luminal surfaces compared to ordinary pure PTFE vascular prostheses – a randomised clinical controlled multi-centre trial. *European Journal of Vascular & Endovascular Surgery* 2011;41(5):668-673.
4. Value in Performance. W. L. Gore & Associates, Inc. Web site. www.goremedical.com/resources/dam/assets/AQ0599-EN2.pdf. Published September 2012. Accessed September 30, 2013.

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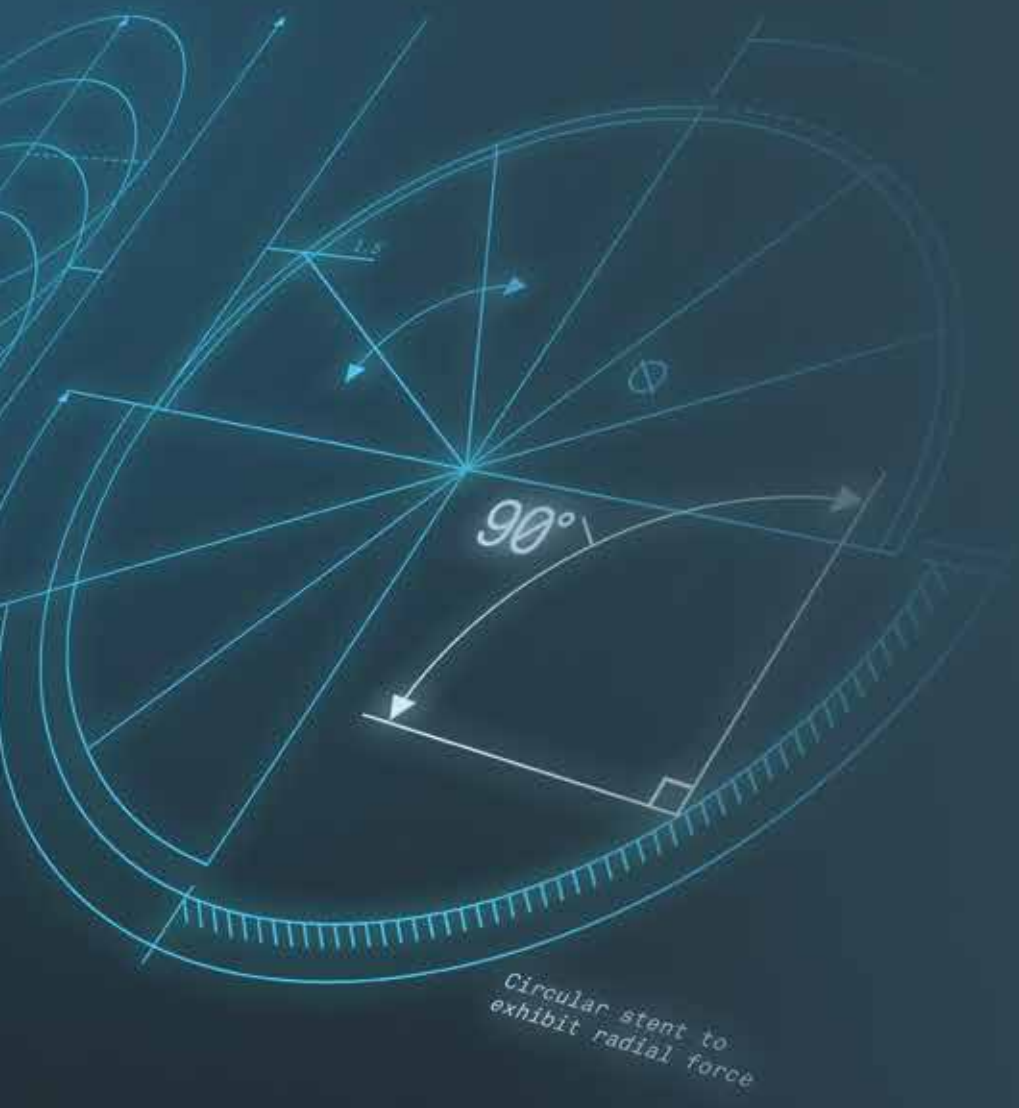

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Magnet Accelerated Cannulation* to facilitate fast and easy cannulation [3]

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Fully repositionable – ensures accurate delivery to the target [3]

Proactive sealing system – innovative ring stent technology [4]

90° Aortic Neck CE Mark – proven results within challenging anatomy [5,6]

References:
1. Data on file at Vascutek - IFU 301-130/2
2. Bungay P. The Use of the Anaconda™ Stent Graft for Abdominal Aortic Aneurysms. J Cardiovasc Surg 2012; 53(5): 571-7.
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5. Rödel S.G.J. Zeebregts C.J. Huisman. A.B. Geelkerken. R.H. Results of the Anaconda™ Endovascular Graft in Abdominal Aortic Aneurysm with a Severe Angulated Infrarenal Neck. J Vasc Surg 2014; Article in press.
6. Data on file at Vascutek.

* The Magnet Accelerated Cannulation is achieved using the Intrinsic Magnet Guidewire and the Contralateral Magnet Guidewire.

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