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Novel device, a temporary guidewire fixator

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Abstract

A novel device for distal fixation of a guidewire was tested in regards to deployment and retrieval, deposition in the blood stream and force of fixation in a pig model. Eleven pigs were subjected to full anaesthesia and heparinized to active clotting time 250–350 s. Uninterrupted blood flow during 4 h deposition was assessed by angiography and inspected for thrombus deposition upon retrieval. The force of fixation was investigated up to the level of loss of fixation (displacement force). The device was successfully deployed and retrieved in over 40 cases. In one case, an alternative method for bailout retrieval was used. Deposition for 4 h was performed, and uninterrupted blood flow was verified by angiography. No instances of arterial occlusion or thrombosis were detected. The median dislocation force was 7.6 N. No arterial rupture or dissection was detected following the loss of fixation. As a conclusion, the device was considered safe and functional in this animal test model.

Keywords

Guidewire, fixator, animal test, retrieval, dislocation force, fenestrated endovascular aneurysm repair

Introduction

Endovascular therapy has developed rapidly during the last 20 years. A majority of formally surgical vascular procedures is now performed by endovascular techniques.[1–4] Endovascular techniques are increasingly used in complex situations and challenging anatomy, with combination of multiple wires, accesses and hybrid procedures.

A well recognized problem during visceral and aortic arch catheterisation is the difficulty in achieving stable wire position in challenging and tortuous anatomy, and the risk of losing a position during parallel endovascular work in the aorta. This problem can be encountered during carotid catheterisation, during stentgraft treatment in the branched part of the aorta, during visceral catheterisation for treatment of occlusive arterial lesions and during attempts for treatment of gastrointestinal or trauma haemorrhage. Unstable wire position may increase the risk of complications, due to prolonged procedure, dissection and procedure failure.

In this report, a novel device is presented that achieves stable position in a blood vessel through the use of a guidewire fixator. The device was iteratively designed to withstand a dislocating force of at least 3 N. This force represents a limited traction that does not induce arterial trauma during repeated testing in bench tests of post-mortem harvested animal arteries.

The aim of the study was to investigate safety and performance of the device in a pig model.

Materials and methods

Device description

The Liungman Guidewire Fixator (LGF) is designed to secure guidewire position in an artery, while allowing continuous blood flow.

The device is an integrated assembly of three essential elements: (A) a fixating element, (B) a guidewire and (C) a retrieval catheter (Figure 1).

The fixator consists of a Nitinol mesh of wires fixed at the ends and expandable to a pre-set diameter, available in sizes of 8, 11 or 14 mm, aimed to suit arteries with a diameter between 5 and 13 mm. The initial size fitting is designed so that the LGF size should be at

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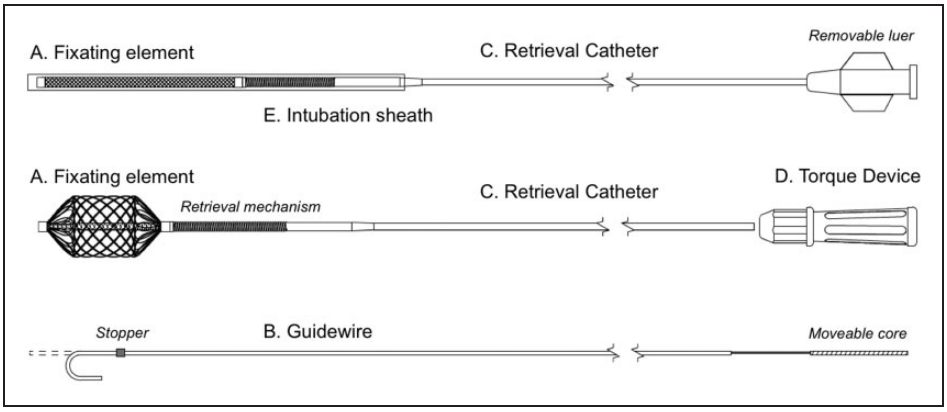

Figure 1. Liungman Guidewire Fixator assembly.

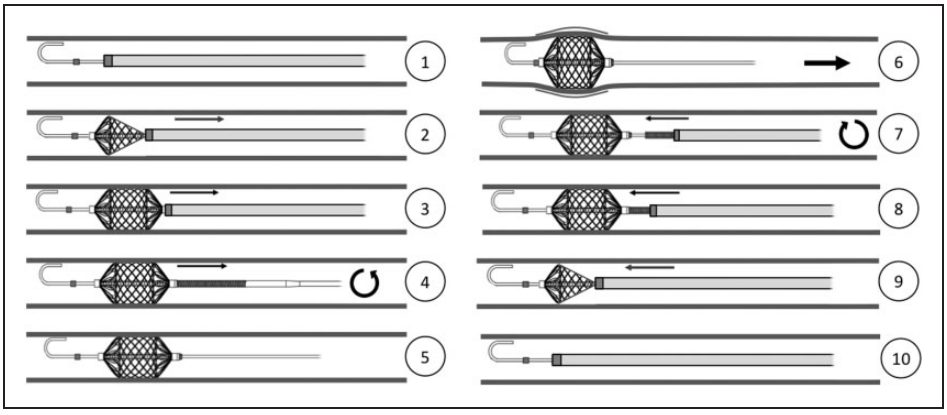

Figure 2. Delivery and retrieval of the LGF.

least 1 mm larger than the arterial diameter in order for the fixator to make contact with the arterial wall.

Once deployed, the self-expanding fixator produces a limited radial force against the vessel wall to prevent slippage. Once tension is applied on the guidewire, the fixator is compressed longitudinally and consequently expanded radially, see step 6 (Figure 2). As a safety feature, the fixator is prevented to expand above a pre-set size. At the end of the fixator, a novel screw mechanism is attached to allow deployment and retrieval at an angle. The essential element is a spring nut that fits onto a fixed bolt on the fixator. The capacity to catch and release at an angle is a unique quality of this retrieval mechanism that is made possible by the pliability of the spring.

The guidewire (B) is provided with a 0.044″ stopper 3 cm from the distal end and runs freely central in the fixator. The guidewire is a 0.035″ hollow hypotube with a central movable/removable stiff core wire. When the stiff core wire is removed, the guidewire assumes extreme pliability and can be redirected in any direction, and in a sharp 180° turn.

The retrieval catheter (C) is used to deliver and retrieve the fixator to and from a desired position in the target artery through a 7 F guiding sheath, steps 1–3 (Figure 2). The fixator is released by counter clockwise rotation of the retrieval catheter, steps 4 and 5 (Figure 2). Upon release, the retrieval catheter is retracted completely to be used again for retrieval. Upon retrieval, the catheter is used to catch and load the fixator back into the guiding sheath, steps 7–10 (Figure 2).

The system also includes a transparent intubation sheath (E) and a torque device (D) for increasing the grip of the retrieval catheter (Figure 1).

Once the guidewire and fixator are positioned in an artery, the internal stiffness of the guidewire and core, along with the possibility to apply tension will assist the surgeon to retain guidewire position while inserting bulkier devices or performing parallel procedures.

Animals and anaesthesia

The safety and performance testing was conducted in a pig model. Ethical approval from the committee of

animal research ethics, Uppsala University was granted on April 01, 2013.

Eleven pigs, Swedish landrace, weighing 60–95 kg were subjected to general anaesthesia. Induction of anaesthesia was achieved with a combination of Rompun (2.2 mg/kg) and Zoletil (6 mg/kg) through an s.c. injection in the back of the neck. The animals were intubated, or the airway was entered through a tracheostomy, depending on size-related anatomic conditions. Anaesthesia and analgesia were maintained through a combination of Ketaminol (4 g/1000 mL), Fentanyl (0.5 mg/1000 mL) and Midazolan (15 mg/1000 mL) via infusion at a rate of 8 mL/kg and hour. Bilateral arterial access to the common femoral arteries was achieved through cut down groin incisions. Blood pressure (BP) was monitored throughout the procedure in all animals and kept within the accepted range of 85 to 130 mm Hg systoli BP.

At the termination of the procedure, during anaesthesia, the animals were sacrificed by the use of potassium chloride solution injected i.v.

Investigators

The endovascular procedure and testing were performed by one of two independent investigators, Prof. Anders Wanhainen or Ass. Prof. Kevin Mani, both of whom share extensive experience of peripheral and aortic endovascular procedures.

Access procedure

The femoral arteries were accessed in a conventional manner on both left and right side. The renal arteries, the superior mesenteric artery and the coeliac trunck, were identified and catheterized with conventional technique, and a 7 F, 45 or 55 cm guide sheath (Destination, Terumo) was inserted. The guidewire was then replaced by the LGF guidewire upon, which the fixator was deployed and retrieved using the retrieval catheter. All introducers and catheters left in the aorta or target arteries were supplied with continuous saline infusion at low-flow rate, less than 0.2 mL/min to avoid coagulation and clotting.

Fluoroscopy and angiography

A C-arm Philips BV300 with a conventional image intensifier was used to document the findings during the investigation. Intermediate magnification was used to detect thrombosis and arterial injury.

Heparinisation

Twenty to forty thousand units of unfractionated heparin was distributed immediately prior to the arterial access as a bolus, and heparin was then distributed hourly to achieve an active clotting time (ACT), between 300 and 350 s. The dose level was chosen to acquire an ACT level comparable to the routine levels used in man during major endovascular procedures of long duration, 250–300 s.[5]

Measurements of arterial size

The measurements of the arterial diameter during the present investigation were done using an external reference scale (a centimetre scale pigtail catheter) and analysis of angiograms.

Deployment and retrieval

The LGF was positioned into the target artery under fluoroscopy (Figure 3). Reposition and catch were

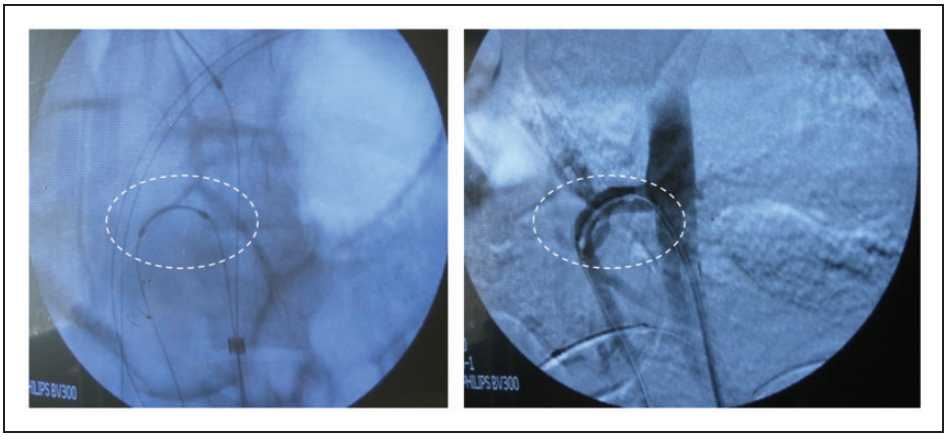

Figure 3. A 14 mm LGF positioned in the superior mesenteric artery. Left: LGF indicated under fluoroscopy. Right: LGF indicated under digital subtraction angiography.

repeated in various positions during the experiment series in the 11 pigs using 4 targeted arteries in each animal, the 2 renal arteries, the superior mesenteric artery and the coeliac trunc.

Deposition in the blood stream

The device was delivered to the designated target artery according to the method previously described. The device was then left in the position of fixation for a minimum of 4 h, and angiography was repeated hourly to verify uninterrupted arterial blood flow (Figure 4). At the end of the testing, the fixator was removed, and the artery was inspected through fluoroscopy to verify any dissection, thrombus formation, ruptures or other vascular trauma. The fixator was also visually inspected for any thrombus formation or device damage.

Test for force of fixation

A digital electronic force gauge, HF-50 was used to evaluate the force necessary for fixator dislocation. With the fixator in position in the target artery, the guidewire was attached to the force gauge. At manual incremental steps of traction, the dislocation force was determined for each device in the different arteries.

A total of 40 dislocating force measurements were performed in the series of testing. After dislocation, the artery was investigated for any sign of rupture or dissection by angiography.

Results

Deployment and retrieval

Delivery was successful on first attempt in 44/44 test situations. Retrieval was successful on first attempt in 38/43 test situations, and successful within three attempts in 43/43 test situations. No signs of arterial dissection or injury were detected through angiography following the delivery and retrieval.

In four cases, the reason for additional retrieval attempts related to challenging anatomy and sharp target artery take-off angle from the aorta. In one of these cases, the retrieval required three attempts due to the challenges of accessing the fixator position with the guide sheath. In one case the normal retrieval procedure was abandoned due to technical failure of the retrieval mechanism and optional retrieval using a conventional snare (EN-snare, Merit medical) was successful on the second attempt. The optional retrieval was performed according to the description in the device Instruction for Use.

Deposition in the blood stream

A total of 39 fixators were retained in the fixated position in the arterial branches for at least 4 h. There were no cases of recorded flow disturbance during angiography runs performed hourly during the procedure. There were two cases where some thrombus deposition was detected on the fixator mesh upon retrieval, but

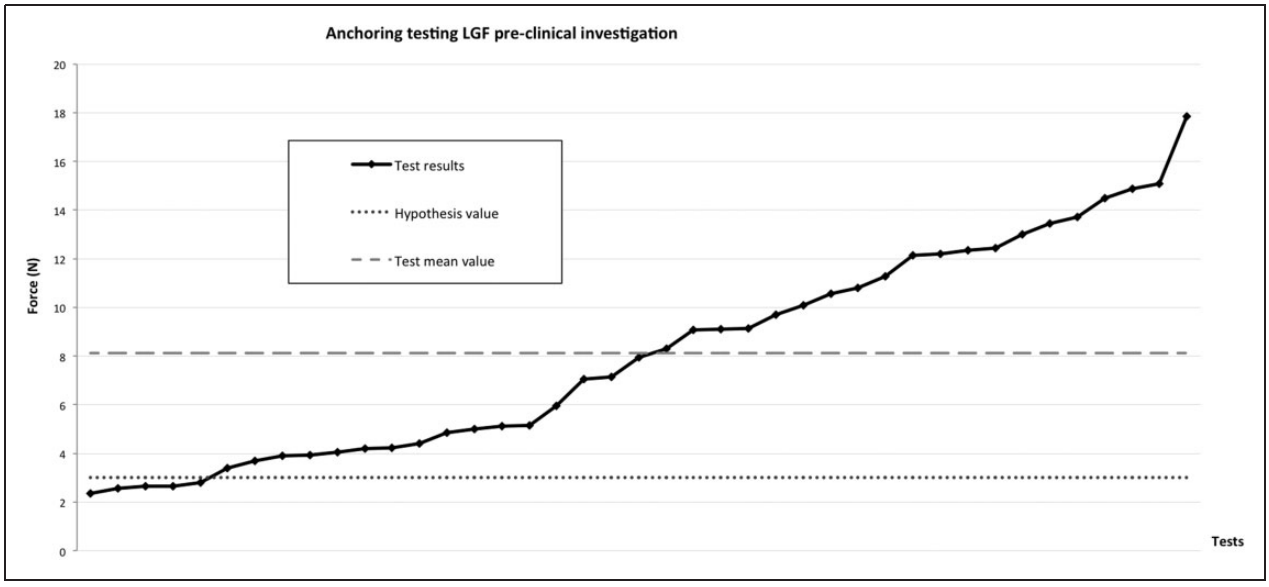

Figure 4. Anchoring force testing results.
LGF: Liungman Guidewire Fixator.

none >1 mm in size. No corresponding contrast defects were detected during repeated angiography.

In two instances, visual inspection of the artery was performed through post-mortem examination. No visual arterial damage could be detected.

Force of fixation test

The device retained position in the target artery on incremental increase of a dislocating force up to a level where the application of more force caused a sudden device loss of position.

The median force necessary to dislocate the fixator was 7.6 N with a range of 2.35–17.9 N (Figure 4). No arterial rupture or dissection was detected by angiographic runs following the loss of fixation.

Discussion

This experimental setting investigated a new approach to the well-known difficulty to retain an acquired guidewire position during complicated endovascular work. A new endovascular device and technique have been developed to simplify the endovascular procedure, reduce procedure duration, nephrotoxic contrast dose and radiation exposure. The essential quality of the device is the ability to retain a guidewire position in a target artery during uninterrupted arterial blood flow. This quality allows parallel catheterisation to be performed in the arterial circulation with the device in position.

An example of a useful application of the device is the introduction and positioning of stentgraft by the use of distally fixated guidewires in the target arteries. The proximal ends of the guidewires are introduced, in a retrograde manner, through pre-lined catheters passing the fenestrations of a fenestrated stentgraft, prior to introducing the stentgraft. The benefit would thus be simplified catheterisation of the fenestrations and target arteries.

The major risks identified prior to the investigation were the risk of rupture, dissection, arterial thrombosis and device failure, defined as failure of deployment, retrieval or to secure the guidewire position upon moderate traction.

The experimental pig model of 60–95 kg animals was chosen because the dimension of the arteries in a pig of this size compares well to human anatomy. Generally, the porcine species have much higher propensity for clot formation in the arterial circulation (30–50 times) compared to humans.[5] The clinically used ACT is 250–300 s during complex endovascular procedures in man.[6] This level of Heparinisation compares well with 300–400 s during experimental external corporal circulation (EEC) in 60–80 kg porcine models.[7]

One difficulty with the present animal model is the size of the orifice of the target vessels such as the renal arteries. The take-off of these arteries is sometimes angulated above 90° with a narrow orifice. In spite of these difficulties, delivery and retrieval were possible in 100% of the targeted arteries. In four instances, the surgeon did not manage to catch the fixator on the first screw on attempt but needed two or three attempts. In one instance, an alternative retrieval was performed using a snare, a method that is described in the instruction for use as an optional bail out method.

A key feature of the device is the ability of the device to retain uninterrupted arterial flow to the end organ during deposition and fixation of the guidewire to the vessel wall. Deposition in the blood stream (>4 h) of the device was used to detect any adverse effect, such as thrombosis or arterial damage (dissection) caused by deposition in the circulation during uninterrupted blood flow. The angiographic evaluation of the visceral arteries were done in a single plane due to the investigative limitations in the animal laboratory lacking an operating table with opportunity to tilt the table head down, up or sideways. This shortcoming represents a limitation of the study.

The device did not cause any arterial occlusions. In two instances, minor blood clots were detected upon retrieval after 4 h deposition of the device. These clots may have been formed on the device, but no clots were visualized during the repeated angiographic runs in these vessels just minutes before removal. Therefore, the clots are likely to be the result of stagnant blood in the guide sheath used for deposition and retrieval. Consequently, the device is considered to be functional and safe for deposition in the arteries for up to at least 4 h.

No arterial ruptures or dissections detected on angiography occurred during the test series in spite of considerable dislocating force measurements of up to 18 N. A limitation of the study is acknowledged in that only two pigs were subjected to a post-mortem evaluation of the harvested target arteries. These two animals showed no sign of arterial trauma on macroscopic examination.

The force of fixation test revealed fixation of the device in accordance with the claimed force for dislocation with a median dislocating force of 7.6 N. The variation of the maximum fixation force was primarily affected by the angulation of the arterial branch and the fixator size in relation to the arterial geometry.

To have a similar force of fixation in the different fixator sizes, it is necessary to increase the fixation force for the largest device size. The lowest values were found in the 14 mm diameter device.

Finally, a clinical study will be performed in order to evaluate the eventual art specific problems regarding intra-arterial thrombosis and trauma risk in arteriosclerotic arteries of elderly vascular patients.

Conclusion

The LGF device is a novel endovascular tool that allows anchoring of a guidewire in a target vessel for prolonged period of time. The device could be safely deployed and retrieved, and prolonged intra-arterial deployment did not result in any arterial damage or adverse event. Consequently, the device will now be subjected to clinical investigation to validate applicability of the device in current clinical practice.

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Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr Krister Liungman is the founder and has ownership in Endovascular Development Ltd. that owns the intellectual rights to the LGF. Mr Linus Bosaeus is employed by Endovascular development Ltd.

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