ENDOLEAK REPAIR USING AN ANCHORING DEVICE

Pham Minh Tuan, MD, Hiroshi Ohtake, MD, PhD, Seguchi Ryuta, MD, Go Watanabe, MD, PhD
Department of General and Cardiothoracic Surgery, Kanazawa University

Corresponding Author:
Pham Minh Tuan, MD
Department of General and Cardiothoracic Surgery, Kanazawa University
13-1, Takara-machi, Kanazawa, Japan, 920-8641
Tel: +81-76-265-2355; Fax: +81-76-222-6833; Email: ngminhtuan82@yahoo.com

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SUMMARY

Objective: Type I endoleaks comprise one of the most frequent and life-threatening complications of thoracic endovascular aortic repair (TEVAR). This study aimed at assessing the use of suture-anchoring devices for repairing type I endoleaks.

Method: The descending aortic aneurysm model (saccular type) was performed by side-to-end anastomosis to a Dacron graft. A Matsui-Kitamura stent graft was deployed to create a proximal type I endoleak. Approximately 5 mm above the upper rim of the anastomosis, the aorta was punctured by the pistol of the suture-anchoring device with a T-shaped bar under fluoroscopy. Sutures were applied until angiography showed the absence of a type I endoleak. During the process, 2 pressure measurements were used to perform continuous assessments of aortic pressure and intra-aneurysm sac pressure.

Results: An average of 5 ± 1 anchoring shots was used to eliminate type I endoleaks. The device performed well and no complications were observed. The mean intra-sac pressures before stent graft deployment, during endoleak maintenance, and post-repair were 118 ± 5, 61 ± 4, and 26 ± 5 mmHg, respectively. The post-repair pressure was significantly decreased ($p < 0.001$) (Student's *t* test).

Conclusion: Despite some anatomic and clinical limitations identified during the experiments, the effectiveness of the suture-anchoring device was confirmed. Further improvement of the device will soon lead to its use as a less invasive endoleak repair procedure.

KEYWORDS
Thoracic aneurysm, thoracic aneurysm repair, endovascular therapy, endoleak post-TEVAR, meniscal repair

INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) is an advanced technique that has been used since the 1990s and involves the repair of the thoracic aortic aneurysm (TAA) using a stent graft to prevent TAA rupture. TEVAR does not require thoracotomy or extracorporeal support. TEVAR was initially developed to treat patients with poor tolerance for surgery; however, based on the results of many clinical trials, it is now widely used in the treatment of patients who are appropriate candidates for stent graft therapy [3, 5, 23].

However, some fatal complications associated with TEVAR have been reported [6, 7]. One of the most dangerous complications associated with this technique is endoleak [8, 13, 21], which is classified into 5 categories based on the source of the blood flow [20]. Type I endoleak refers to direct blood flow into the aneurysm because of incomplete sealing of the graft [8, 9, 10]. Type I endoleak, which was reported postoperatively in approximately 8–16% of cases [3, 5, 23], is caused by an inadequate landing zone, curvature of the thoracic aorta, device migration, or dilatation of the aneurysm.

Several studies have reported a high frequency of rupture in unsuccessful type I endoleak repair procedures. This leak is virulent and patients are generally not protected against aneurysm rupture. Therefore, type I endoleaks should be repaired immediately after diagnosis.

There are several methods for the treatment of type I endoleak: additional ballooning, additional TEVAR [13, 19], coil embolization [17, 18], the use of suturing devices [1], or even open surgery conversion [7]. However, each method has its limitations. Specifically, in distal aortic arch aneurysms, additional TEVAR for proximal type I endoleaks is complicated by the difficulty in obtaining a sufficiently large landing zone because of the short distance between the supra-aortic arteries [11]; coil embolization requires catheter manipulation near the ostium of the supra-aortic arteries, which is associated with a risk of cerebral infarction. Therefore, a new method needs to be developed for type I endoleak repair to overcome the disadvantages of previous techniques. In the present study, we developed a new technique using an anchoring device for experimental repair of type I endoleaks and assessed its effectiveness.

METHODS

Animal preparation

Eleven pigs weighing 28.2 ± 2.5 kg were used for experiments. The animals were intubated with normal endotracheal tubes. General anesthesia was administered and maintained with halothane, propofol, and nitrous oxide (50%). Ringer's lactate solution was administered intravenously. Heart rate measurements, electrocardiography, and direct arterial pressure measurements were performed continuously via the right carotid artery. To obtain intraoperative aortograms (Siemens AG, Wittelsbacherplatz 2, DE 80333 Munich, Germany), an angiographic catheter (SZ4123; Medikit Co, Ltd, Tokyo, Japan) was inserted into the ascending aorta via the left carotid artery. All the pigs were placed in the right lateral position on the plastic operating table. A posterolateral thoracotomy was performed at the fourth intercostal space to expose the descending aorta.

Establishment of the saccular-type thoracic aortic aneurysm model

Heparin (50 UI/kg) was administered intravenously. After 3 min, the descending aorta was clamped and a longitudinal incision was made. A Dacron graft (Hemashield Gold; Boston Scientific Co, Ltd, Natick, MA; diameter, 14 mm; length, 2 cm) with one end closed was anastomosed end-to-side to the descending aorta with nonabsorbable 5-0 prolene (Ethicon Inc, Somerville, NJ, USA) to produce a saccular-type aneurysm model (Figure 2-A).

Systemic and intra-sac pressure monitoring

An arterial catheter was placed into the right carotid artery to measure the systemic blood pressure. A pressure monitoring catheter (Arterial Monitoring Kit VO1706TSPL03; Edwards Lifescience, USA) was placed into the saccular-type aneurysm to measure intra-sac pressure.

Stent graft system and deployment procedure

In the present study, a Matsui-Kitamura stent graft (diameter, 12 mm; length, 6 mm) (MKSG; Cathex, Kanazawa, Japan) was used (Figures 2-B and 2-C). The M-K stent, which comprises the framework for the MKSG, is made from a single self-expandable braided 0.30–0.40-mm-diameter nitinol wire (Memoalloy; Tokin, Tokyo, Japan) covered with a crimped woven graft made of polyester fabric with a porosity of 200 $mL \cdot min^{-1} \cdot cm^{-2}$. For stent graft anchoring, a 5-mm bare stent area was established on the proximal side alone. The graft was attached to the M-K stent at the bilateral edges with 5-0 interrupted polypropylene sutures. A special designed preloader-type introducer (Medikit Co, Ltd, Tokyo, Japan) was also used to load the device into the sheath. With regard to the stent graft selection, the diameter of the stent graft was set to 120% of the proximal site landing zone.

The abdominal aorta was exposed by small laparotomy. The purse string suture was made and a small aortotomy was performed. The guide wire was inserted through the small aortotomy and a 12F sheath (Supersheath; Medikit Co Ltd, Tokyo, Japan) was inserted. Under fluoroscopy, the MKSG was placed in the sheath, advanced with the help of a pusher rod and deployed into the aortic lumen. The position of the MKSG was adjusted to create a typical type I endoleak.

Type I endoleak repair using the anchoring device

The components of the anchoring device included a T-shaped bar suture and a shooting device (Figure 3). The T-shaped bar suture consists of a short, rigid plastic bar attached to a long plastic line. The shooting device (*Tag Gun,* Banok 503X; Mitchell Co., Ltd., Japan), a regular commercial tag-gun, consists of a body and a thin gutter-needle. The needle was sharpened with a 5° tip, 0.8 mm in diameter and 18 mm in length. The plastic bar is inserted into the gutter-needle of the pistol. When the trigger is pulled, the bar is deployed into the aortic lumen by a tiny pusher inside the gutter-needle. Each bar was anchored by tensioning and clipping (Ligaclip®MCA, Ethicon Endo-surgery, Inc, USA) of the outside part of the plastic line [14–16] (Figure 1).

In the experiments, the anchoring device was delivered directly into the thoracic cavity. The location

of the type I endoleak was determined fluoroscopically, and the thoracic aorta was subsequently punctured by the gutter-needle. Several bars were delivered and anchored until angiography showed disappearance of the type I endoleak (Figure 5).

Measurement

During the procedure, pre- and post-deployment hemodynamic conditions including intra-sac pressure were recorded (Monitor Nihon Kohden RMT-1000 Laboratory Polygraph System, Tokyo, Japan). The number of anchoring sutures required to eliminate the type I endoleak was counted. After the procedures were completed, all pigs were euthanized according to the "Guidelines for the Care and Use of Laboratory Animals" at the Takara-machi Campus, Kanazawa University, and the portion of the thoracic aorta including the stent graft was harvested for further investigation.

Statistical analysis

Data are expressed as mean and standard deviation. Continuous variables were compared using the Student's *t* test for independent variables. Categorical variables were compared using Fisher's exact test. Differences were considered significant when the 2-tailed *P* value was <0.05.

RESULTS

All procedures were performed according to the described protocol with no hemodynamic complications and little bleeding from the puncture site. An average of 5 ± 1 anchoring shots was used to eliminate the type I endoleak. The mean intra-sac pressures before stent graft deployment, during endoleak maintenance, and post-repair were 118 ± 5, 61 ± 4, and 26 ± 5 mmHg, respectively. Intra-sac measurements showed a significant decrease in pressure post-repair compared to the pressure during the type I endoleak ($P < 0.001$) (Figure 4).

All animals were still alive after the experiments. The harvested aortic portions containing the MKSG showed no significant changes. Morphological assessment showed the T-shaped plastic bar sutures penetrating both the stent graft and the aortic wall to provide gap closure between them (Figure 6); however, no erosion through the other side of the aorta was observed. These results indicated that the type I endoleak was completely repaired. The suture-anchoring device (pistol and T-shaped plastic bar) was used successfully and the results showed that this is an effective method for the management of type I endoleak.

DISCUSSION

Endovascular aortic repair, one of the most important techniques for the repair of aortic aneurysms developed in the past 30 years, was first described by Parodi et al. in 1991 for the treatment of abdominal aortic aneurysms. The potential benefits of endovascular therapy include the avoidance of long thoracic and/or abdominal incisions, no aortic cross-clamping, less blood loss, lower incidence of organ ischemia, fewer episodes of respiratory dependency, and quicker recovery [3, 5, 21]. TEVAR improves long-term survival in patients with descending TAA. It is currently the first choice for patients who are considered ineligible for surgery, but has become a suitable alternative to open surgery for appropriate candidates. TEVAR has been increasingly used for other aortic pathologies such as complicated type B dissection, traumatic aortic transection, and aneurysmal disease extending into the arch. Despite recent advances in TEVAR, endoleaks remain the Achilles heel of the technique. Among these complications, type I endoleak is defined as the most life threatening [7, 9, 12].

Despite development of the device, endoleaks after TEVAR were not uncommon in many series. Although perioperative type I endoleaks have gradually improved by the development of devices and techniques, it has been reported with relatively high incidence of 8–16% [3, 22, 23]. Delayed type I endoleaks may be seen in follow-up studies if the device is deployed into a diseased segment of the aorta that dilates over time. The type I endoleak is a complication of endovascular stent grafting procedures that is defined as persistent blood flow outside the lumen of the endograft. Spontaneous closure of endoleaks is rare. In most endoleaks, the aneurysmal sac remains exposed to systemic pressure, predisposing patients to aneurysmal rupture [7, 21]. Thus, type I endoleaks should be treated aggressively after detection [22].

Extensive efforts have been made by clinicians to resolve these problems. During the additional TEVAR procedure, accurate placement in the arch can be very challenging, and even a tiny distal migration during deployment of the stent graft can result in inadequate proximal fixation. In 2005, Golzarian J. showed that 7 of 22 follow-up patients had remaining type I endoleaks after additional intervention [10]. Another study by Parmer indicated that type I endoleaks were detected in 11.6% of patients after TEVAR. These patients were treated with additional endovascular techniques; however, 12% (1/8 patients) had residual endoleaks. The virulence of type I endoleaks was demonstrated in 12% of patients who experienced fatal aneurysm rupture after an unsuccessful attempt at endoleak repair. To obtain stronger proximal radial force, Palmaz stent placement was performed, but the result was unsatisfactory. In some cases, postoperative dissection of the proximal aorta was reported. Placement of a proximal cuff or an additional TEVAR can further complicate the repair [19]. In some cases, debranching of the supra-aortic arteries was attempted to produce an adequate landing zone [11–13]. Furthermore, the Chimney graft technique or branched stent-grafts have been developed to prevent proximal type I endoleaks. However, it is relative risky because it can cause severe complications such as cerebral infarction by prolongation to the proximal zone. Although endovascular anchoring devices continue to develop, clinical difficulties remain. Because these methods all have limitations and most are associated with complications, aggressive intervention should be carefully considered in these cases. Thus, development of novel repair methods for type I endoleaks is essential. In the present study, we developed a new technique to overcome the shortcomings of the earlier methods.

Our results show that the anchoring suture device using a T-shaped plastic bar was effective for the repair of type I endoleaks after endovascular therapy for TAA. Locating the position of the type I endoleak under fluoroscopy was very useful for ensuring precise punctures by the anchoring device. The aorta was punctured by the pistol and the T-shaped plastic bars were delivered and then fixed by hemoclips. While the aorta was punctured, angiography was used to detect the endoleak and accurately locate additional punctures. The results of our experiments showed that an average of 4.75 anchoring shots by the pistol was needed to completely repair type I endoleaks. The effectiveness of each step was carefully assessed to ensure that our procedure was performed quickly and precisely. The presence of endoleaks indicated a gap between the aortic wall and the stent graft that enabled the blood to flow into the aneurysm sac from the aorta as observed by angiography. Therefore, the intra-sac pressure was

transmitted through that route and maintained at an average of 61.4 mmHg. However, after the placement of the anchoring device under fluoroscopy, the intra-sac pressure decreased to an average of 26 mmHg, which coincided with the disappearance of the endoleak as determined by angiography. The pressure measurements showed a significant decrease in the mean intra-sac pressure during the endoleak and after its complete repair ($P < 0.001$) (*Student's t test*). This device was shown to repair type I endoleaks both quickly and effectively with only 5 anchoring shots in average. The accuracy of the technique led to procedural success with no hemodynamic complications.

In addition, during the procedure, there was no need for an additional landing zone as with TEVAR. Even in distal aortic arch aneurysm models, in which the aneurysm was close to the left subclavian artery, this procedure was successful. Furthermore, the pistol and the T-shaped plastic bars were always under control, and the T-shaped plastic bars were delivered into the aortic lumen, which reduced the risk of erosion through the other side of the aorta and eliminated the risk of nontargeted embolization of the cerebral circulation.

Our new device and T-Fix method [1] both successfully eliminated type I endoleaks without complications. However, our device has several benefits compared with the T-Fix suture method. All of the steps of the T-Fix method, including needle delivery, suturing, and suture ligation, were performed manually and required more time. In contrast, in our method, the T-shaped bars were quickly delivered into the aortic lumen by the pushing system of the pistol as the trigger was pulled and then anchored by simple stapling. Thus, the T-shaped bars could be delivered continuously until the leakage was completely remedied in a short amount of time.

In this study, the device consisted of regular commercial products (the tag gun and the plastic bar) rather than medical prototypes to prove the concept. Our aim was to evaluate device effectiveness. A thoracotomy was then performed to deliver the pistol and a simple saccular-type aneurysm model was designed for the experiments. In future work, a medical-grade device will be developed to minimize invasiveness. We will further develop the pistol into a longer and thinner gutter-needle. A longer needle may enable performance success using a video-assisted thoracoscopic method instead of a thoracotomy. A thinner needle results in smaller puncture holes, which decreases the unexpected invasion to the aorta. We also consider the material of the T-shaped bar to be adaptable to the aorta. The design of the T-shaped bar may include many tiny spikes on the outer part that may enable stronger fixation of the T-shaped bars to the aortic wall and the hemoclips, which improves the long-term mechanical stability of the T-shaped bars. These advances will lead to significant improvements in type I endoleak repair techniques. Moreover, further experiments with fusiform aneurysms will be performed for additional assessment of the anchoring device's effectiveness.

We successfully used a suture-anchoring device for repairing type I endoleaks without complications. The ability of this device to overcome anatomic and clinical limitations will result in a less invasive and effective type I endoleak repair method.

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Figure 1: Device in use
A. Descending aortic aneurysm
B. M-K stent graft placement with type I endoleak
C, D. Shooting device: the gutter-needle delivers a T-shaped plastic bar into the aortic lumen
E. The T-shaped plastic bar was gently pulled and clipped on the outside part, enabling the attachment of the stent graft to the aortic wall
F. Several sutures were performed until no type I endoleak was detected by angiography

Figure1

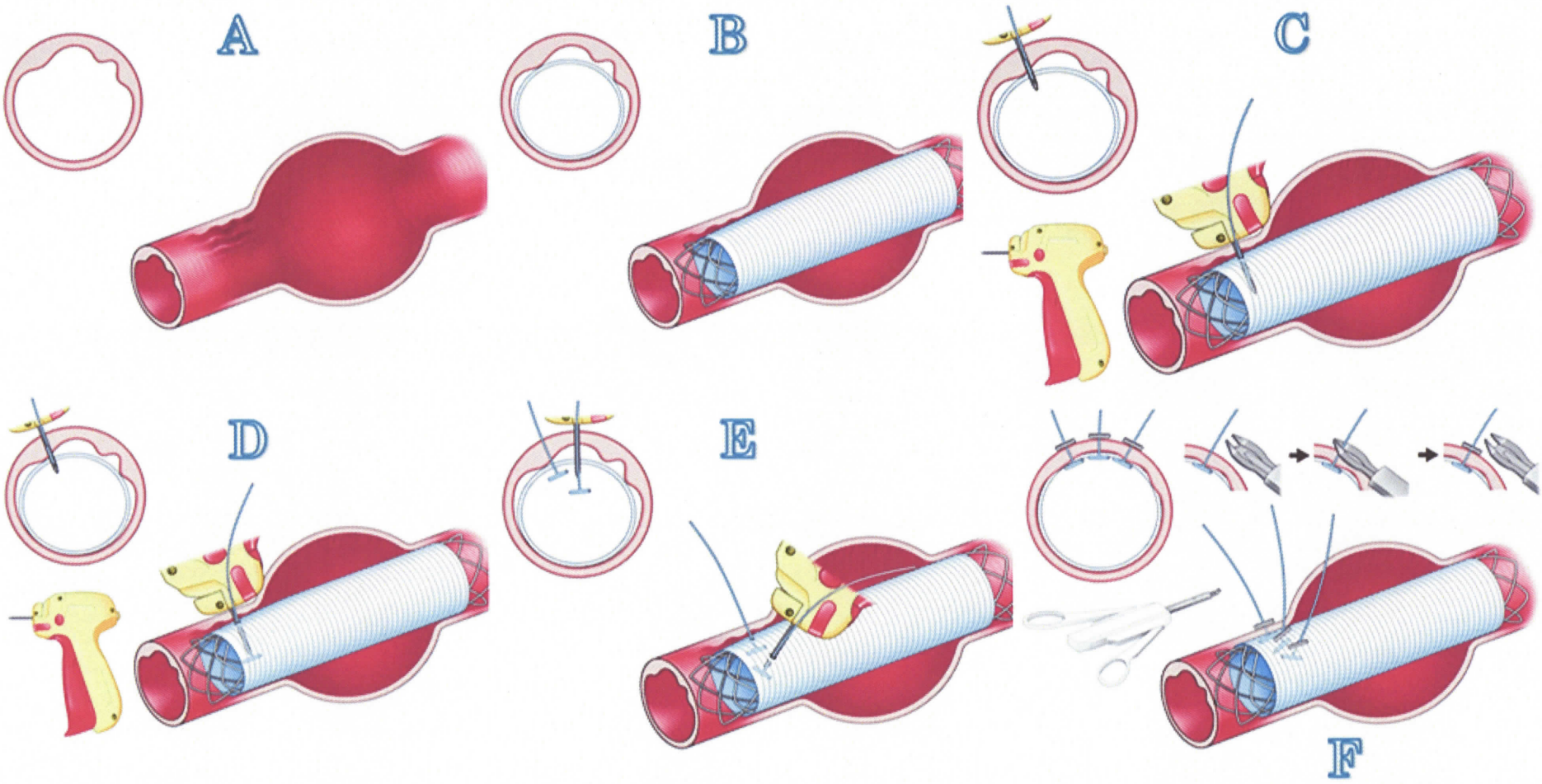

Figure 2:
A. <red arrow> Saccular-type aneurysm model generated by the end-to-side anastomosis of a Dacron graft to the descending aorta using nonabsorbable 5-0 prolene
B. <yellow arrow> Aorta
C. M-K stent graft

Figure 2

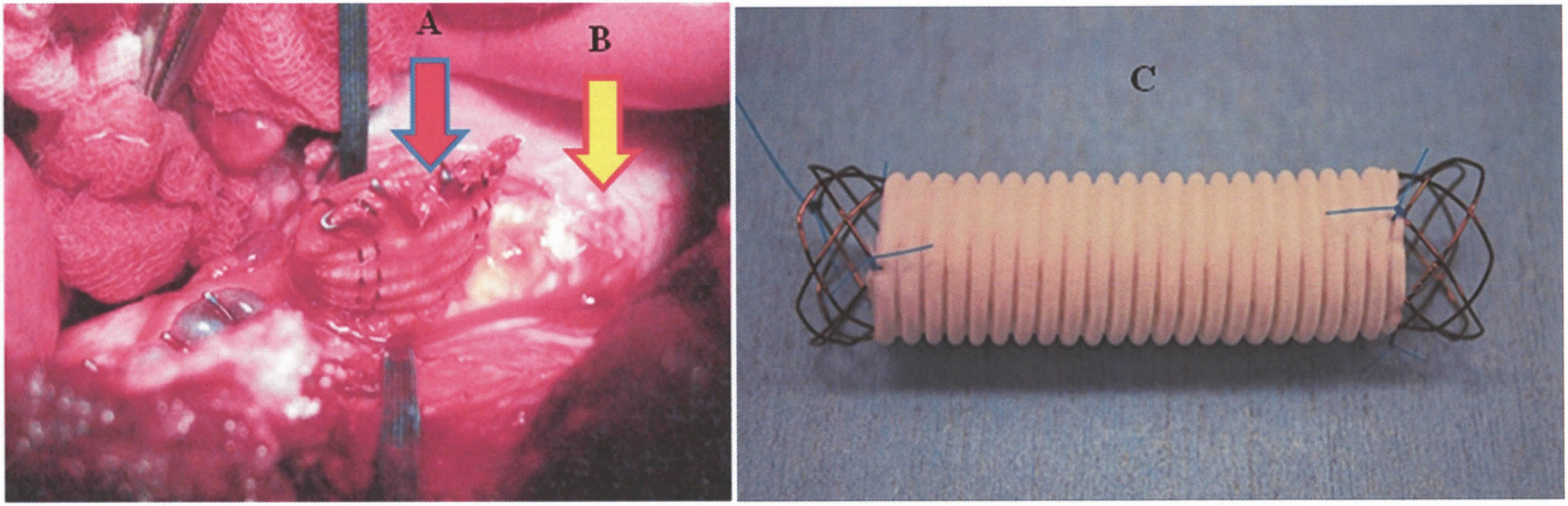

Figure 3:
When the trigger is pulled, the plastic bar is deployed into the aortic lumen by a tiny pusher inside the gutter-needle. Each plastic bar is anchored by tensioning and clipping the outside part of the plastic line, which fixes the plastic bar in place. Several sutures were used to ensure attachment of the stent graft to the aortic wall

1. <yellow arrow>: gutter-needle
2. <red arrow>: T-shaped plastic bars
3. <white arrow>: the T-shaped plastic bar being deployed by the gutter-needle
4. Aorta with M-K stent graft after deployment, maintaining the type I endoleak
5. T-shaped plastic bar
6. Thoracic aortic aneurysm
7. Hemoclips

Figure 3

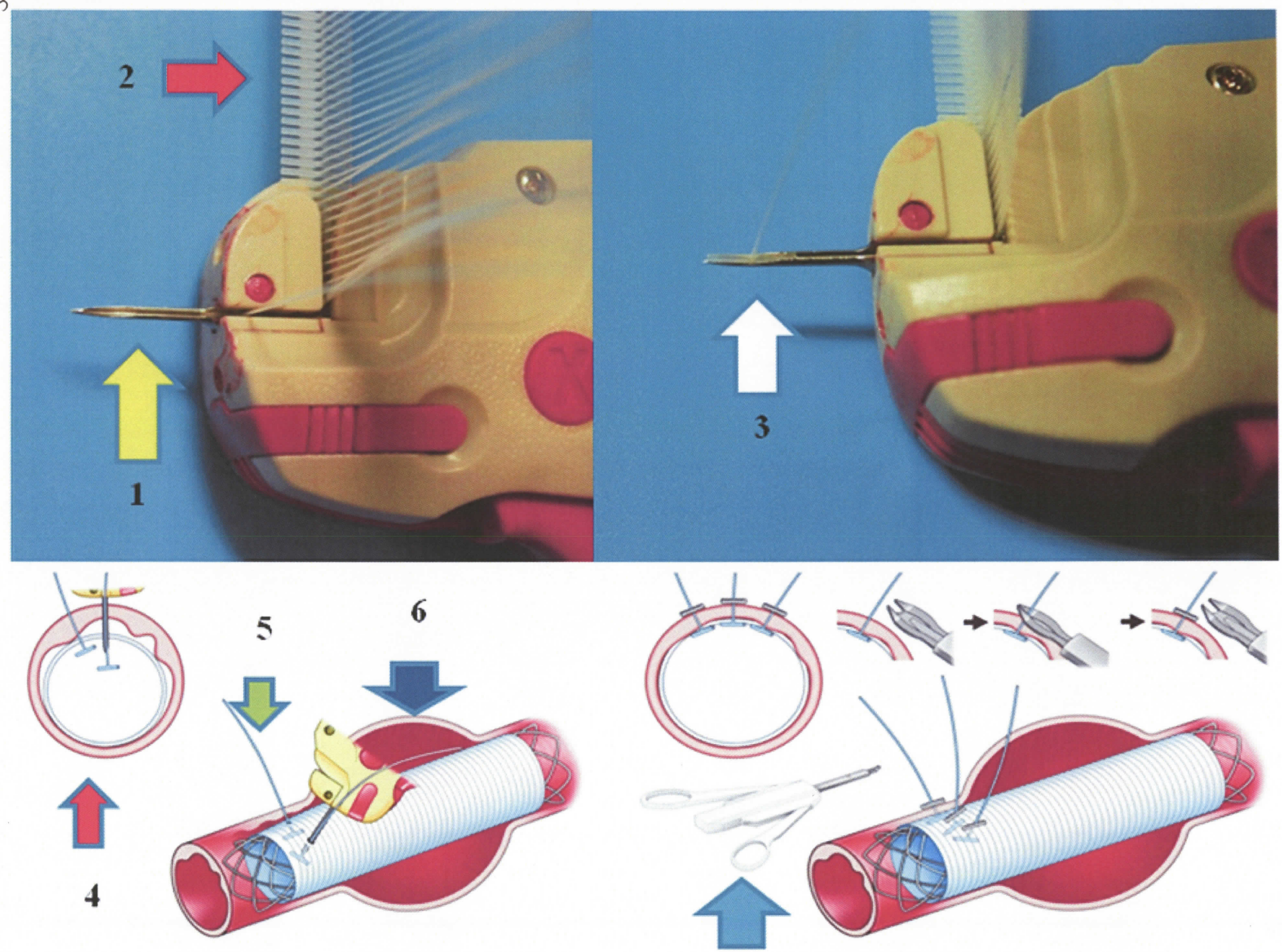

Figure 4:
Intra-sac pressure decreased significantly after the repair compared to that measured during the type I endoleak. Statistical evaluation was performed between the 2 groups by 2-tailed t test and measured ($P < 0.01$)

Figure 4

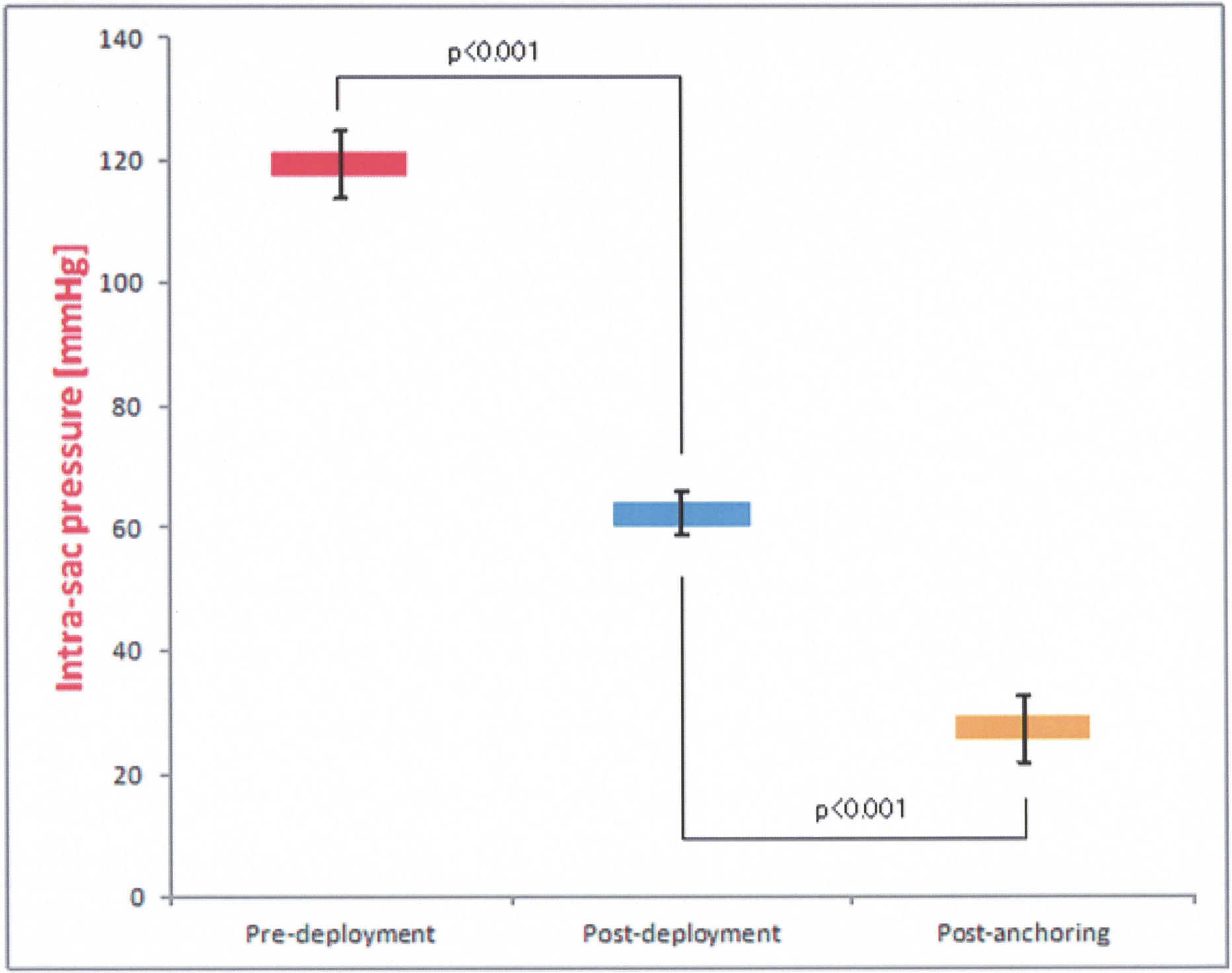
140
120
100
80
60
40
20
0
Intra-sac pressure [mmHg]
p<0.001
p<0.001
Pre-deployment
Post-deployment
Post-anchoring

Figure 5:
Angiography images:
A. Preoperative angiography image showing a type I endoleak (arrow)
B. Postoperative angiography image showing no type I endoleak, indicating complete repair

Figure 5

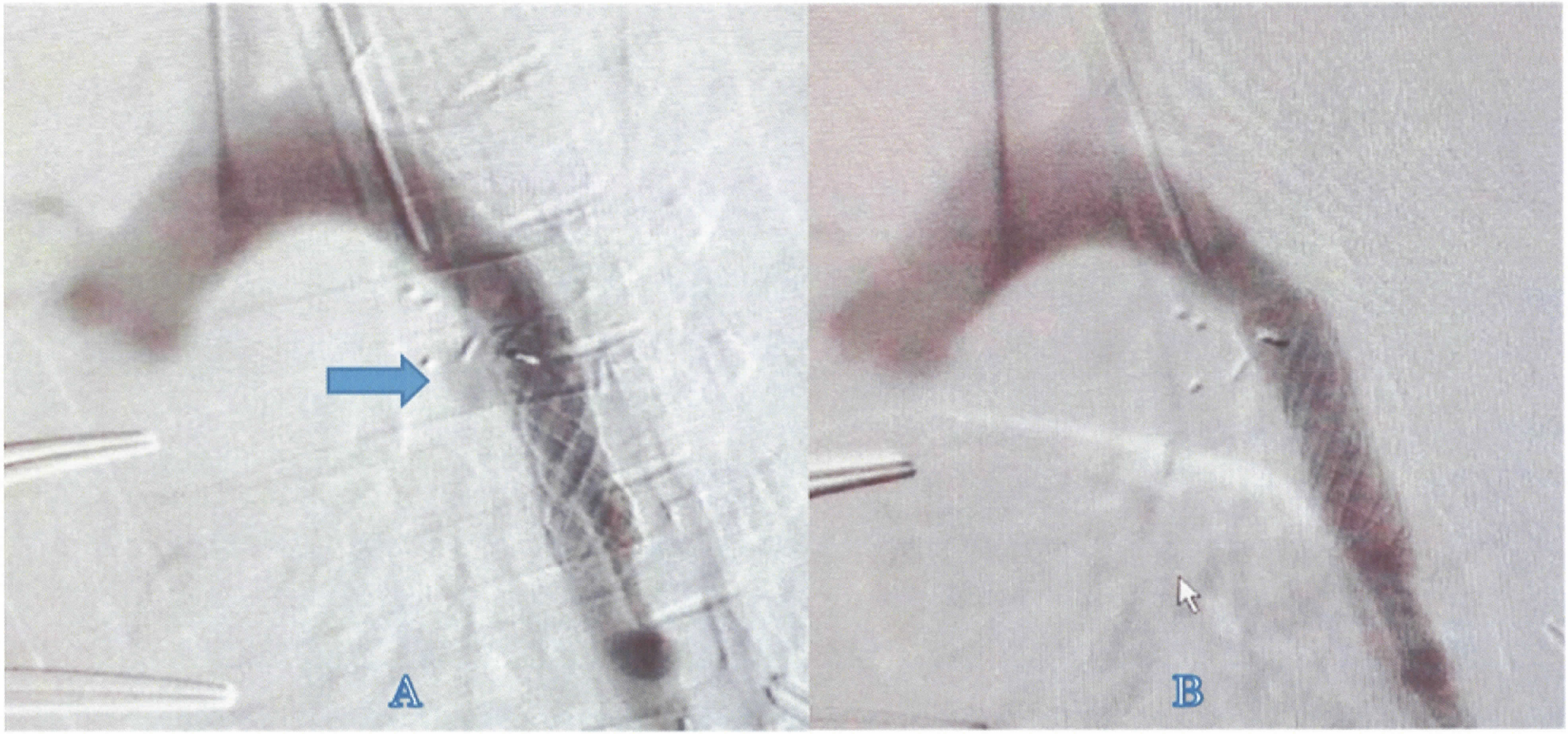

Figure 6:
The harvested aortic portions containing the MK stent graft showed no significant changes. Morphological evaluation showed that the T-shaped plastic bar sutures penetrated both the stent graft and aortic wall to close the gap between them but did not erode through the other side of the aorta, indicating that the endoleak type I was completely repaired.
<yellow arrow>: T-shapes plastic bars anchored to the aortic wall by hemoclips

Figure 6

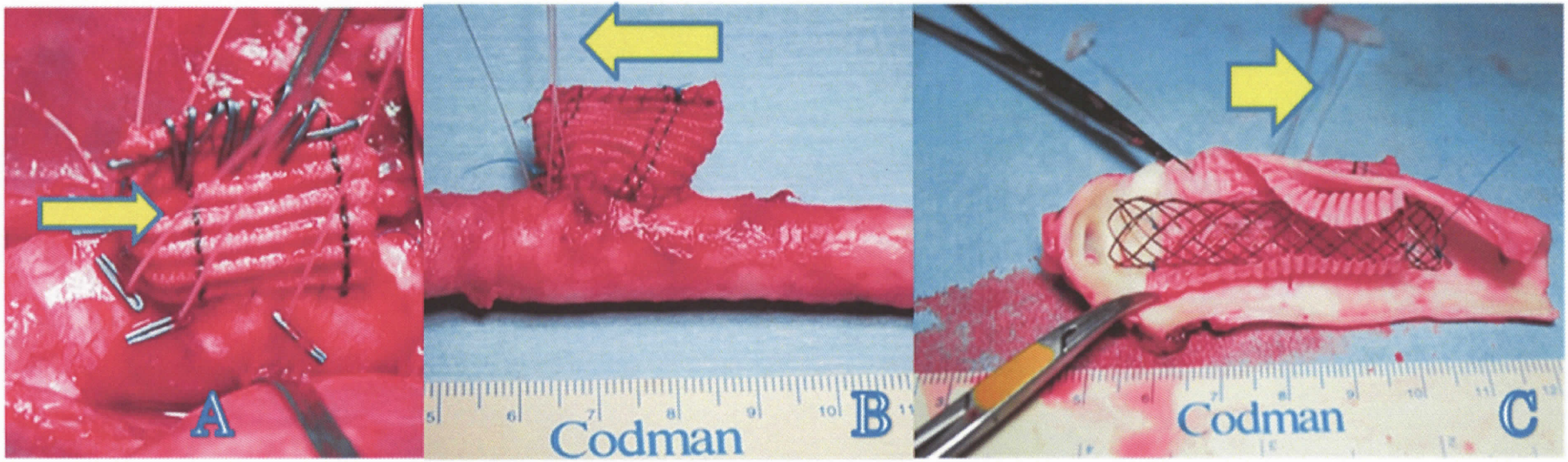

Figure 7:
An outlook image that illustrates the potential future importance of this approach:

- *A. The developed anchoring device with a longer and thinner gutter-needle*
- *B. The guide camera for the precise position of the anchoring device*
- *C. TAA has undergone TEVAR, but a proximal type I endoleak remains*

Figure 7