Original Article

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First Use of the Manta Closure Device in Ruptured Abdominal Aortic Aneurysm Patients and its Potential Usage for Urgent Endovascular Procedures: A Short Report

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Arterial closure after endovascular procedures can be managed by manual compression, fascia suture, closure devices or surgical cut-down with direct vessel suture. We describe the first successful usage of the Manta closure device for large access closure in three cases of ruptured abdominal aortic aneurysm. This large-bore access closure device has the potential for use in other endovascular procedures and might be especially beneficial in emergent endovascular surgery.

Keywords: *Closure Device; Endovascular; EVAR; Vascular Access*

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INTRODUCTION

Correct closure of a large-bore access at the end of an endovascular procedure is of high importance, especially in emergency procedures such as endovascular aortic repair (EVAR) for ruptured abdominal aortic aneurysm (rAAA). However, this may be challenging and complications, such as excess bleeding, might cause further delay as well as increase the risk of infections. In an acute setting, time is of the essence in the hemodynamically unstable patient [1]. During EVAR and other procedures, such as thoracic endo-grafts and transfemoral valve replacements, there are several closure devices used for large-bore access. The majority of devices have relatively low failure rates and are considered safer than manual compression, but require considerable pre-procedural preparation before being used [2]. Other vessel closure possibilities are fascia suture and the surgical cut-down procedure [3]. All these procedures have pros and cons but the optimal access closure in urgent procedures should be fast, simple and have a low failure rate [1]. Manta (Essential Medical Inc, Malvern, USA) is a recently developed percutaneous closure device intended for large-bore access sheaths between 10 and 25 Fr. It consists of a delivery system attached to a closure unit consisting of a sheath with introducer and a puncture location dilator. The closure unit works by using an intraluminal toggle that seals the vessel from the inside which is then connected by a polyester suture to an extravascular hemostatic bovine collagen pad with a fluoroscopically visible lock. The components of the closure unit will all be reabsorbed within 6 months, except for the stainless-steel suture

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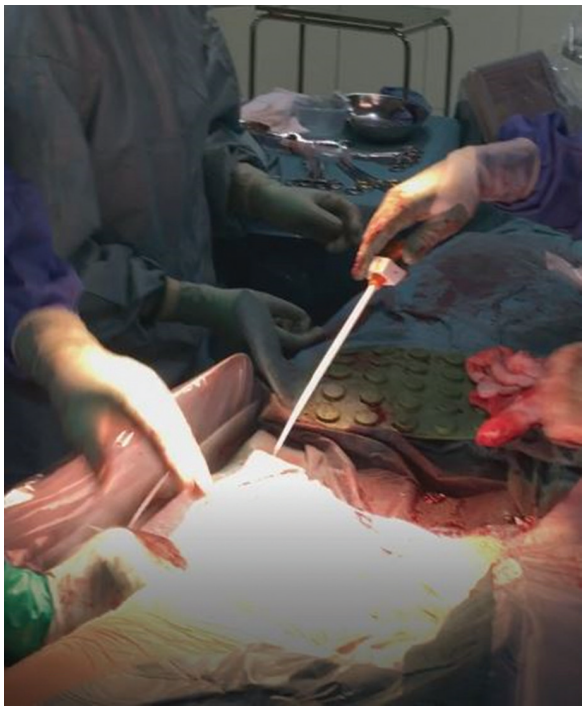

Figure 1 Manta sheath introduced on a wire at the end of the procedure.

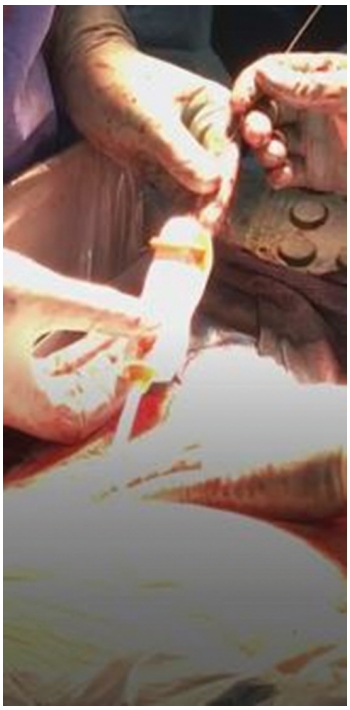

Figure 2 Manta device deployment.

lock which allows for future x-ray identification of the puncture site [4]. We describe three consecutive cases of rAAA treated by EVAR, where the EVAR procedure was terminated successfully with bilateral femoral access closure using the Manta closure device.

Case Descriptions and Usage of the Device

After receiving a short instruction on its use, the team successfully used Manta in an elective EVAR with bilateral femoral access (12 Fr and 16 Fr sheaths, GORE stent-graft system). Thereafter, the first rAAA case in which it was used was an 87-year-old woman admitted with a three-week history of abdominal pain. On admission, due to accentuation of abdominal pain, a computed tomography (CT) was performed and revealed an 8 cm rAAA. The patient was hemodynamically stable and transferred to the hybrid operating room immediately for urgent EVAR according to our hospital routines [5]. The procedure started with percutaneous ultrasound assisted access with a 7 Fr sheath and measurement of the vessel depth as described in the Manta instructions for use (IFU). EVAR was performed successfully with a 32 mm GORE C3 system (W.L. Gore & Associates, Flagstaff, AZ, USA) with a surgical time of around 45 minutes. At the end of the procedure, Manta was used to close the femoral access using a Lunderquist wire (Cook, Bloomington, IN, USA). Manta 16 Fr was used for the 16 Fr access and Manta 14 Fr for the 12 Fr access (Figures 1 and 2). At the end of the procedure, ultrasound was conducted to ensure distal perfusion

Figure 3 Post-procedural CT with Manta in place in the left femoral artery. Marked with the arrow.

and normal flow was observed in the femoral arteries. The patient recovered without complications and the ankle-brachial index and clinical status were normal. The CT performed two days later showed open femoral arteries bilaterally with no stenosis (Figure 3).

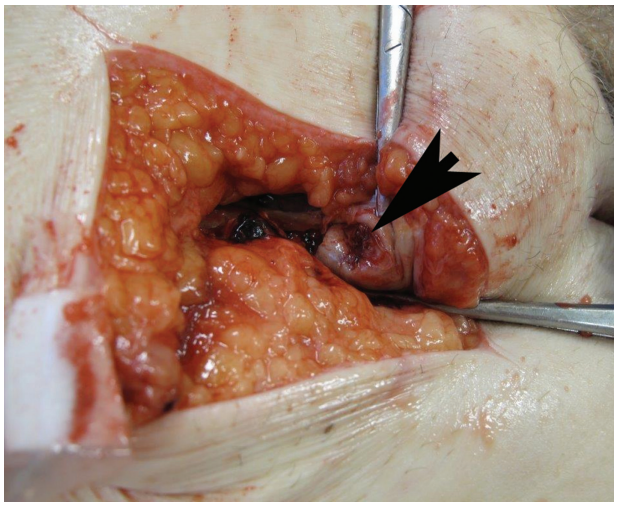

Figure 4 Autopsy photo of the femoral artery in the third patient. The arrow points to the intravascular Manta toggle.

The following day, the same procedure was performed on a 79-year-old man who presented with a 9 cm rAAA. This patient was circulatory stable with a systolic blood pressure (SBP) of 150 mmHg upon arrival which remained stable during the procedure. EVAR was successfully performed with a 6 mm Chimney graft to the left renal artery (BeGraft, Bentley InnoMed GmbH, Germany) and a 34 mm C3 GORE system. The total surgical time was 190 minutes. Manta 16 Fr and 14 Fr were used to close the bilateral femoral arterial accesses without any complications and normal clinical status. The control CT did not show any stenosis of the femoral arteries.

A third patient, with an aneurysm after a previous open aortic tube-graft reconstruction several years earlier, presented to the emergency department with abdominal pain and an SBP of 70 mmHg. CT showed a 7 cm rAAA. Delayed repair was performed 12 hours later with a Nellix 10 mm endo-graft system (Endologix, Irvine, CA, USA) and a 6 mm Chimney graft (BeGraft) to the left renal artery. The closure device was used successfully but the patient died some hours later due to multi-organ failure. Autopsy revealed the Manta toggle correctly positioned within the femoral artery (Figure 4).

During October 2017, we have used Manta in a total of 7 patients without any complications (three urgent EVAR for rAAA and four elective EVAR for AAA, using Gore and Cook endo-grafts).

DISCUSSION

The usage of closure devices has been described for rAAA, but the devices commonly used require time and preparation prior to the endovascular procedure [6]. Cut-down or fascia suture procedures are also time-consuming [3]. In this small series, we used the Manta closure device successfully to terminate the EVAR procedure in three rAAA patients, without any reported complications at the 3-month follow-up. The major advantage of the Manta closure device is that it is easy to use, fast and can be used for large-bore accesses. An important limiting factor of total percutaneous EVAR for rAAA is the need for fast closure of the femoral arterial access. Pre-procedural measurement is recommended for Manta, however not compulsory, to estimate the depth of the femoral artery for correct device placement and may be performed rapidly. There is insufficient published data regarding the failure rate of this specific device, which must be taken into account before adopting it into clinical practice. Theoretically, failure of Manta could occur and the remaining stainless-steel lock could potentially cause complications, especially in calcified arteries. This was, however, not observed in this current series. The use of the reported closure device in these three cases demonstrated that the procedure can be performed safely and rapidly, thus facilitating rapid total procedure time.

CONCLUSION

Manta can be used in urgent EVAR procedures and might have the potential to be used in other endovascular procedures where large-bore access is required.

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