Automated anastomotic devices are used routinely in gastrointestinal and thoracic surgery but not in traditional vascular bypass grafting. Experimental studies of the use of an automated system for the construction of an aortic anastomosis are rare and do not translate into daily practice. Manual suturing remains the gold standard, mainly because of the difficulty of handling these automated devices in the operative field.

We report here the preliminary results of a new device that was developed to decrease clamping time and to facilitate construction of an end-to-end arterial anastomosis when performing laparoscopic aortic revascularization or an end-to-end arterial anastomosis in a small confined space through a mini-laparotomy. This new device is simpler to use than the robotic support proposed for laparoscopic revascularization.
aortic anastomosis\textsuperscript{9,10} and different from all the stapling devices already developed.\textsuperscript{5,11} It is built on the same principle as the Viabahn Open Revascularization Technique (VORTEC) developed by Donas et al\textsuperscript{12,13} and applied also to the recently available Gore Hybrid Vascular Graft (W. L. Gore and Associates, Flagstaff, Ariz). Our automated system adds to this a bare spiked stent for a true end-to-end anastomosis without the limitation of a dedicated vascular graft and with an optimal fixation of the prosthetic graft to the artery. This article presents our preliminary experience using this novel sutureless stenting system for open arterial anastomosis with investigation of its tensile strength, watertight capability, and patency.

MATERIALS AND METHODS

The device is a connector made from a bare stainless steel stent, 20 mm in length, with a nominal diameter of 7 mm, with spikes on its outer surface to allow the vascular prosthesis to anchor to the arterial wall, resulting in a telescoping anastomosis (Fig 1). For these experiments, the stent, crimped on a balloon with the spikes retracted, was first introduced into a polytetrafluoroethylene (PTFE), Gore-Tex Ultra Thin graft (W. L. Gore) or into a polyethylene terephthalate (PET), Bard Dialine Prosthesis II graft (Bard Peripheral Vascular, Inc, Tempe, Ariz) with the connector protruding 5 mm at the extremity of the vascular graft. An OPTA Pro angioplasty balloon (Cordis, Miami Lakes, Fla) with a diameter corresponding to that of the vascular prosthesis completed the system. Once in place, the stent covers a length of 15 mm in the prosthesis and 5 mm in the artery. In this model, the length of the spikes was 1 mm, which corresponds to the average thickness of the infrarenal aorta of pigs weighing 30 to 35 kg. The experiment was conducted in three phases:

1. A study on cadaveric arteries was performed to assess the feasibility of the procedure. Four anastomoses using the system were completed on a femoral artery using a PTFE prosthesis with measurement of the penetration of the spikes into the layers of the arterial wall.

2. In vitro tests using tensile tests and leak tests were conducted in 14 anastomoses; 7 automated anastomoses and 7 sutured anastomoses with a PTFE graft ($n = 7$) or a PET graft ($n = 1$) on a segment of porcine aorta or a Spandex (Devra A, US Patent 5303,882, 1994) tube with diameters of 6 and 7 mm. Spandex is a thermoplastic polyurethane elastomer with compliance similar to that of arteries.\textsuperscript{14} An electromagnetic-coupled tension meter (Dynamometer; Mark-10, Long Island, NY) was used to compare the tensile strength quantified in Newtons (N) of the automated anastomoses with that of the sutured anastomoses. The sealing of the anastomosis was also tested using a pump system with a pulsatile pressure up to 250 mm Hg in a water-filled closed circuit.

3. An in vivo study was conducted in seven pigs (weight, 27 to 30 kg). This study was approved by the Ethical Committee on Animal Experiments of the Institut Mutualiste Montsouris (Paris, France) and of the ‘Université de la Méditerranée’ and Protomed, a company based within the medical school. Because of the reported risk of aortic thrombosis in the porcine model,\textsuperscript{15} clopidogrel (2.5 mg/kg) was given to all animals 2 days before the procedure, followed by 1.0 mg/kg daily. The pigs also received 100 IU/kg of unfractionated heparin immediately before aortic clamping.

All the pigs were operated on under general anesthesia with endotracheal intubation. The aorta was approached using a median laparotomy of $<10$ cm in length. The proximal anastomosis of the prosthetic graft (PTFE, $n = 5$; PET, $n = 2$) was performed on the
infrarenal aorta using the connector crimped on a balloon catheter. The anastomotic device was inserted into the prosthetic graft and introduced into a 20F sheath. After the aorta was clamped, the anterior wall was opened transversally and the device introduced. The balloon was inflated, deploying the stent over 5 mm of the artery and 15 mm of the graft. No angiography was needed during this procedure, but for the purpose of the study, completion angiography was done in all in vivo experiments. For these 7 procedures, the design of the spikes inserted on the outer surface of the connector were reinforced on the fold at their base to penetrate perpendicularly all the layers of the arterial wall when spreading out. Impaction of the spiked stent was obtained by inflation of the angioplasty balloon. No stay suture was used during the procedure.

After completion of the automated aortic anastomosis, the distal anastomosis of the prosthetic graft was handsewn on the aortic bifurcation using a 6-0 polypropylene suture (Fig 2). After declamping the aorta and stabilization of the pigs’ hemodynamics, the seal of the anastomoses was tested by increasing the arterial pressure up to 175 mm Hg for 10 minutes with intravenous adrenalin. The time needed to complete each automated and sutured anastomosis was recorded, and the patency of the anastomoses was confirmed by angiography.

Fig 2. Implantation of the device in the pig aorta. A, Operative view of the sutureless anastomosis being completed with the aorta clamped. B, Completion angiography of the aortic graft with the spiked stent in place and the distal handmade anastomosis on the aortic bifurcation. C, Picture of the anastomotic device inserted into the prosthetic graft and introduced into a 20F sheath before aortic implantation.

Fig 3. In vitro tests for tensile strength quantified in Newtons (N). The median force needed to rupture the automated anastomoses was 18.3 N, with no significant difference with that needed to disrupt the sutured anastomoses (19.5 N, Mann-Whitney U test, \( P = .33 \)).

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All the animals were euthanized at various intervals for macroscopic and histologic studies of the aorta, connector, and prosthesis. Immediate explantation was done in two pigs, followed by explantation in the five remaining pigs, which were humanely killed at 15 days (2 pigs), 30 days (2 pigs), and 42 days (1 pig). Longitudinal sections of the explanted aorta were stained with hematoxylin and eosin for histologic examination.

Statistical analysis. Statistical analysis was performed with SPSS 19 software (SPSS Inc, Chicago, Ill). The averages of the data are expressed as median with the interquartile range (IQR). Differences between sutureless and sutured anastomosis groups were analyzed with the Mann-Whitney U test because the data were few and not normally distributed.
RESULTS

Experiments with cadaveric human femoral arteries. During the four experiments in cadaveric specimens, no rupture of the femoral artery occurred when inserting the connector and all anastomoses were achieved with success. The spikes penetrated the arterial wall layers without fracture, and the stent was uniformly applied with success. The spikes penetrated the arterial wall layers inserting the connector and all anastomoses were achieved with success. The median anastomosis time using the sutureless device was 2.4 minutes (interquartile range [IQR], 1.4-3.3 minutes), which was significantly shorter than the 17.1 minutes (IQR, 15.1-17.2 minutes) required for the sutured aortic anastomosis in the same animals (Mann-Whitney U test, \( P = .002 \)).

In vitro bench tests showed that when using PTFE prostheses with the connector system, the median force needed to rupture the automated anastomoses was 18.3 N (IQR, 17.7-19.9 N) with no significant difference from that needed to disrupt the handmade anastomoses (19.5 N; IQR, 17.9-20.2 N; Mann-Whitney U test, \( P = .33 \); Fig 3). Macroscopic observation of the automated anastomosis demonstrated a lack of complete penetration of some spikes in the vascular prostheses and in the segment of porcine aorta in two cases. Changes were made to the spikes for the in vivo experiments. During these in vitro tests, there was no leakage of the automated anastomoses when using a 180 to 250 mm Hg pulsatile pressure.

In vivo experiments. In vivo experiments were performed in seven pigs. The automated proximal aortic anastomoses showed no leakage. The median time for completion of the successful aortic anastomoses using the sutureless device was 2.4 minutes (IQR, 1.4-3.3 minutes), which was significantly shorter than the 17.0 minutes (IQR, 15.1-17.2 minutes) required for the handmade aortic anastomotic in the same animals (\( P = .002 \); Fig 4).

Four pigs needed only one attempt for successful completion of the automated anastomosis, two pigs needed two attempts, and one pig needed three attempts. In one pig, the first attempt failed due to perforation of the balloon. In the second pig, the stent moved up a few millimeters, making it difficult to balloon-dilate the stent. In these two cases, the second attempt was successful. Three attempts were necessary in the third pig due to a small perforation of the aorta that was successfully covered by the stent with a change of the ancillary connector. The median duration of aortic clamping was 24.6 minutes (IQR, 23.6-28.4 minutes) to complete both anastomoses.

A systematic angiogram was performed in all cases at the end of the procedure and showed a patent aortic graft without stenosis of the sutureless anastomosis. After increasing the arterial pressure up to 175 mm Hg, we observed no leakage from the anastomoses. One pig died of septic shock due to aspergillosis at 42 days, with a septic clot in the abdominal aorta but an intact aortic anastomosis. In all animals, specimens of the aorta showed that the inner surface of the aortic wall, the connector, and the prosthesis were covered with a thin layer of fibroblast ingrowth, without intimal hyperplasia and with all the spikes penetrating the arterial wall without fracture or bending (Fig 5).

DISCUSSION

In this study, we demonstrated the safety and feasibility of an automated aortic anastomosis between the porcine aorta and a vascular graft using a simple connector and an angioplasty balloon. These components confer simplicity of use and efficacy as outlined below.

The feasibility of the technique using this automated anastomotic system has been demonstrated in human cadaveric femoral arteries and in in vitro studies with comparable tensile strength between handsewn and automated anastomoses that resist high breaking forces. The ease and short time for completion of the aortic anastomosis in pigs using a midline incision should in itself be an important result, especially when considering the potential for laparoscopic or minilaparotomy aortic surgery if the device could be miniaturized to be inserted through a 10-mm diameter trocar.16-18 In this study, the distal anastomosis of the aortic bypass was handsewn to compare the strength and the time needed for both anastomoses, but an automated anastomosis using this system can be completed for both ends by inserting another spiked stent distally through the graft.

Obtaining a fast mechanical aortic anastomosis has attracted many previous preliminary experimental works.1-8 Following this evolving technology, Kolvenbach et al19 reported the first clinical series using the Open Aortic Stapler (ES Vascular Ltd, Haifa, Israel), a vascular stapling system that received a Conformité Européene mark in 2008. With this device, the average time for completion of the aortic stapling in a study of 10 volunteers was 10.2 minutes, but the anastomosis had to be strengthened by sutures. Thus, the timesaving achieved was minimal. Another automated anastomotic system, the HDH device (HDHMedical, Haifa, Israel), is based on a ring studded with spikes. This device has to be secured before its application to a dedicated vascular prosthesis, making its use cumbersome, with very few clinical applications until now.
Millon et al\textsuperscript{4} described a semiautomatic and dynamometric suture system, SuDyn (PROTOMED SA, Marseille, France), which uses needle and thread and acts as a substitute for knot tying. The system automatically locks the suture thread and cuts it. It was tested in human cadaveric arteries and in six pigs. No in vitro studies of tensile strength and leakage with the use of this system have been published, and after increasing the arterial pressure up to 200 mm Hg in six pigs, a leakage was observed from two anastomoses. Mean time for completion of the anastomosis was 38\textpm8 minutes, with no improvement in the course of the study.

After the Millon study, Alimi et al\textsuperscript{2} described a new clampless device composed of a vascular graft and a connector made of stainless steel covered with PTFE. The connector, which remains inside the aorta, has a side opening connected to a PTFE graft forming an end-to-side anastomosis. No bench test or in vitro studies for tensile strength have been reported with this device, which is limited to end-to-side anastomosis with a dedicated PTFE graft.

In daily practice, none of these devices has been used as an alternative to manual suturing for aortic anastomosis, probably because each requires a complex technique and has no valid clinical advantage. It appears from this analysis that mechanical staplers are still not ideal because they are associated with frequent hemorrhage or oozing from the staple line and fracture of staples.\textsuperscript{20}

To improve these results, Takata et al\textsuperscript{21} described the use of a computer-controlled iDrive circular stapler in vascular surgery (Power Medical Interventions, Covidien PLC, Dublin, Ireland) designed to establish a safe anastomosis between the porcine aorta and an artificial graft. This in vitro study showed that mechanical vascular anastomosis with the iDrive was sufficiently strong and safe relative to manual suturing. But even in vitro, use of this mechanical stapler needed some special preparations for both the aorta and the artificial graft with a purse-string suture to achieve a uniform interface between the two elements, resulting in the risk of wrinkles and misfire.

When using an automated anastomotic system, the basic requirements are safety and an intuitive sense of effectiveness. Vascular surgeons already trained in peripheral arterial stenting and balloon angioplasty will need no specific training to use our system, which works as a simple balloon angioplasty without the need to go around the aorta as with a circular stapling device or with the limitation of a dedicated vascular graft hooked to the system. Our system, specifically designed for open arterial surgery, may have a more solid fixation of the prosthetic graft to the artery; however, our study was not designed to answer this question.

In our study, the histology of the in vitro specimens demonstrated that some of the spikes inserted on the outer surface of the connector and anchoring the vascular prosthesis did not penetrate all the layers of the arterial wall, probably because the spikes made from a precut portion of the stent were not strong enough on the fold at their base to penetrate the arterial wall. In addition, some of the spikes were not sufficiently perpendicular when spreading out. The manufacturing process was changed with a new design and neither fracture nor bending of the modified spikes was observed in the bench tests and in the pig aorta specimens. However, when considering future potential clinical application, extensive aortic calcification could be a limitation of

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**Fig 5.** A, Longitudinal section of the explanted pig aorta is shown at 4 weeks, with the automated anastomosis (upper part) and the sutured anastomosis (lower part). The distance between the two green arrows represents the length of the bare stent within the aorta. B, Details of the telescoping anastomosis shows the full length of the stent anchoring the prosthesis in the aortic wall. The 5-mm distance between the two red arrows represents the length of the bare stent within the aorta. C, Photomicrograph of the pig aorta shows the phantom of a spike penetrating the aortic wall with a normal wall architecture and no intimal hyperplasia.
this device, which relies on the capacity of the spikes to penetrate the aortic wall. The histology of the automated aortic anastomosis in pigs showed no inflammatory reaction, no evidence of ischemia of the aortic wall, no intimal hyperplasia, and no false aneurysm, although specimens of the anastomotic site were harvested after only a short period of time. In fact, the architecture of the connector acting as a stent was designed to preserve the vascularization of the arterial wall with a helical arrangement of spikes, which is different from other systems that crush the arterial wall or staple the wall circumferentially.11,19-21

Finally for the in vivo procedures, because of the risk of aortic thrombosis when clamping the aorta in pigs,18 we used a large dose of clopidogrel in the days before the procedure. This was specifically related to the pig model and should not be translated to the administration of a high dose of anticoagulants and antiplatelet drugs when used in humans.

CONCLUSION
We have shown in this experimental study that this sutureless anastomotic device is safe, quick, and easy to use. Before bringing it forward to any clinical use, however, there is a need for more experimental work with a longer follow-up to confirm its safety and durability.

AUTHOR CONTRIBUTIONS
Conception and design: SA, JG, JR
Analysis and interpretation: SA, JG, JR
Data collection: SA, JG, MB, PB
Writing the article: SA, JG, JR
Critical revision of the article: SA, JG, JR
Final approval of the article: SA, JG, MB, PB, JR
Statistical analysis: JR
Obtained funding: JG
Overall responsibility: JR

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