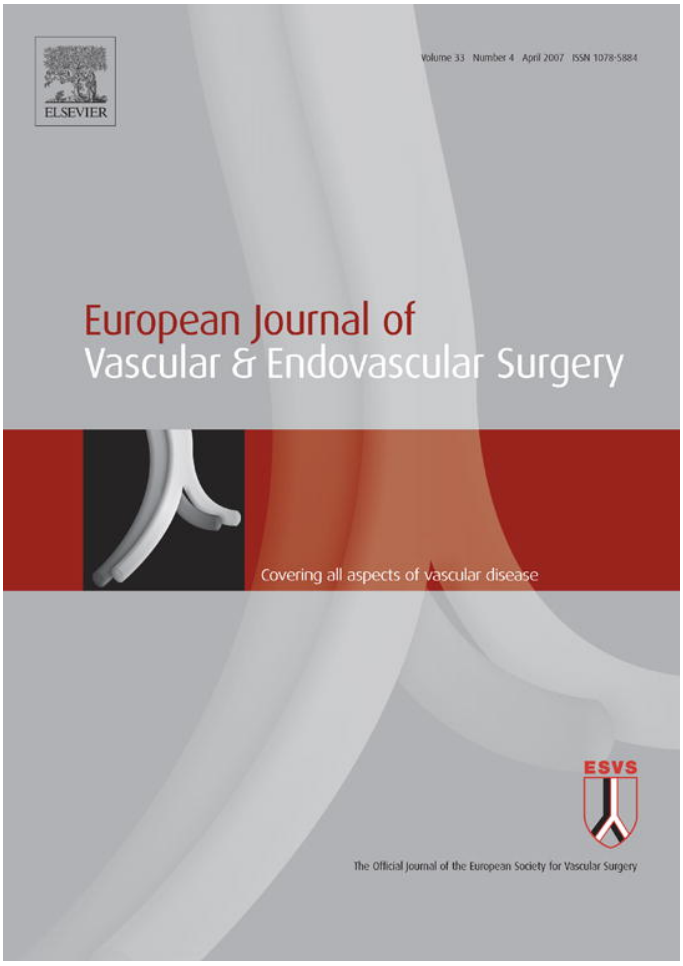
ELSEVIER
Volume 33 Number 4 April 2007 ISSN 1078-5884
European Journal of
Vascular & Endovascular Surgery
Covering all aspects of vascular disease
ESVS
The Official Journal of the European Society for Vascular Surgery

Eur J Vasc Endovasc Surg 33, 408–411 (2007)
doi:10.1016/j.ejvs.2006.10.019, available online at http://www.sciencedirect.com on ScienceDirect

Intravascular Stapler for ''Open'' Aortic Surgery: Preliminary Results

E.G. Shifrin,[1*] W.S. Moore,[2] P.R.F. Bell,[3] R. Kolvenbach[4] and E.I. Daniline[5]

[1]*Department of Vascular Surgery, Assuta Hospital, Tel-Aviv, Israel,* [2]*Division of Vascular Surgery, UCLA, CA, USA,* [3]*Department of Surgery, University of Leicester, UK,* [4]*Department of Vascular Surgery, Augusta Hospital, Dusseldorf, Germany, and* [5]*Department of Vascular Surgery, Central Clinical Hospital, Moscow, Russian Federation*

Objectives. *The aim of this study was to assess the efficacy of a new stapling device using a pig model.*
Methods. *Straight 12 mm Gore-Tex grafts were inserted end to end into the aorta of 12 pigs. One anastomosis was performed with the stapler and the other using 4/0 prolene sutures and 13 mm needles. The animals were sacrificed at one week, one and three months and all grafts underwent histological examination. Leakage from the anastomoses was assessed in a separate specially designed circulation model using saline as a perfusate.*
Results. *The stapled anastomoses took 1.0 ± 0.25 minutes to complete while suturing took 8.5 ± 1.5 minutes. There was no difference in the histology between the two types of anastomosis. The leak rate was six times greater at the sutured compared to the stapled anastomosis.*
Conclusion. *The use of stapled anastomoses may allow a significant shortening of aortic cross clamping time, reduce anastomotic leakage and may be particularly useful in laparoscopic aortic repair. A randomised trial is required to assess the efficacy of this device.*

Keywords: Aorta; Aneurysm repair; Stapler; Circulation model; Pigs; Patients.

Introduction

Abdominal aortic aneurysms (AAA) are one of the leading causes of death in males older than 55 years and was responsible for 16,000 deaths in the United States alone in 1990.[1] The rising incidence of AAA has been paralleled by improvements in anaesthesia and surgical techniques which have contributed to a decrease in morbidity and mortality associated with elective aneurysm repair. Most surgeons report a perioperative mortality of about 5%, a figure which contrasts dramatically with the high mortality of 30–70% for emergency repair of ruptured aneurysms.[2] Other factors which have contributed to the decrease in complications are timely diagnosis followed by elective repair of the aneurysm and improvements in surgical technique which in turn have significantly reduce the rate of post operative complications especially in high risk elderly patients.

A major goal in the design of any new instrument used to treat aortic aneurysm is to improve the morbidity and mortality which is known to be related to the length of time the aorta is cross clamped.[3] Any technique which can reduce cross clamping time and simplify the procedure should result in a significant improvement in M/M. With these objectives in mind a novel vascular stapler has been developed (ES Vascular Ltd, Haifa, Israel) which we have now tested experimentally in vitro and in vivo. This paper presents the experimental data that we have obtained.

Methods

The stapler

The stapler consists of two parts, a head and a handle. The head contains a round cassette which holds 10 staples. The special feature of the staples is that each one has an opening at both ends which allows a two-point fixation of the graft to the aortic wall so that the graft is fixed at 20 points which are stapled simultaneously by single compression of the handle. A circular clamp is also required to achieve an

*Corresponding author. E.G. Shifrin, MD PhD, Department of Vascular Surgery, Assuta Hospital, 64 Ha'Shahar Street, Raanana 43565, Israel.
E-mail address: shifrin_e@yahoo.com

1078–5884/000408 + 04 $32.00/0

external grip of the aorta and enable the stapler to attach the graft to the aortic wall. The way in which the stapler is used is shown in Fig. 1.

In vitro experiment

The physiological circulation model was created (IL 147954, 03.02.2002) in order to check the efficacy of the anastomoses (Fig. 2). Six aortas were removed from pigs and attached end to end to straight 16-mm PTFE grafts. One anastomosis was stapled and the other sutured using continuous 4/0 Prolene and a 13-mm needle. Both ends of the aorta were connected to the pump which allowed us to alter the systemic perfusion pressure by raising the peripheral resistance to assess leakage from both anastomoses at various pressures. Saline was used as the perfusion fluid and the leakage assessed as the volume of fluid collected at each anastomosis. Blood was not used because of the problems this would have created with thrombosis. In addition it was felt that saline would offer the most severe test of the soundness of the anastomosis.

In vivo experiment

Twelve pigs weighing 103−107 kg were used for these experiments. The abdominal aorta of each pig had an internal diameter of about 12 mm and a special stapler was built for these experiments. Animal care complied with the Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, Commission of Life Sciences, National Research Council, Washington, National Academy Press, 1996. All procedures were carried out under general anaesthesia with endotracheal intubation.

The surgical procedure consisted of mobilising the aorta in the standard fashion through a transperitoneal approach, clamping it below the renal arteries. The circular clamp to hold the aorta was then placed

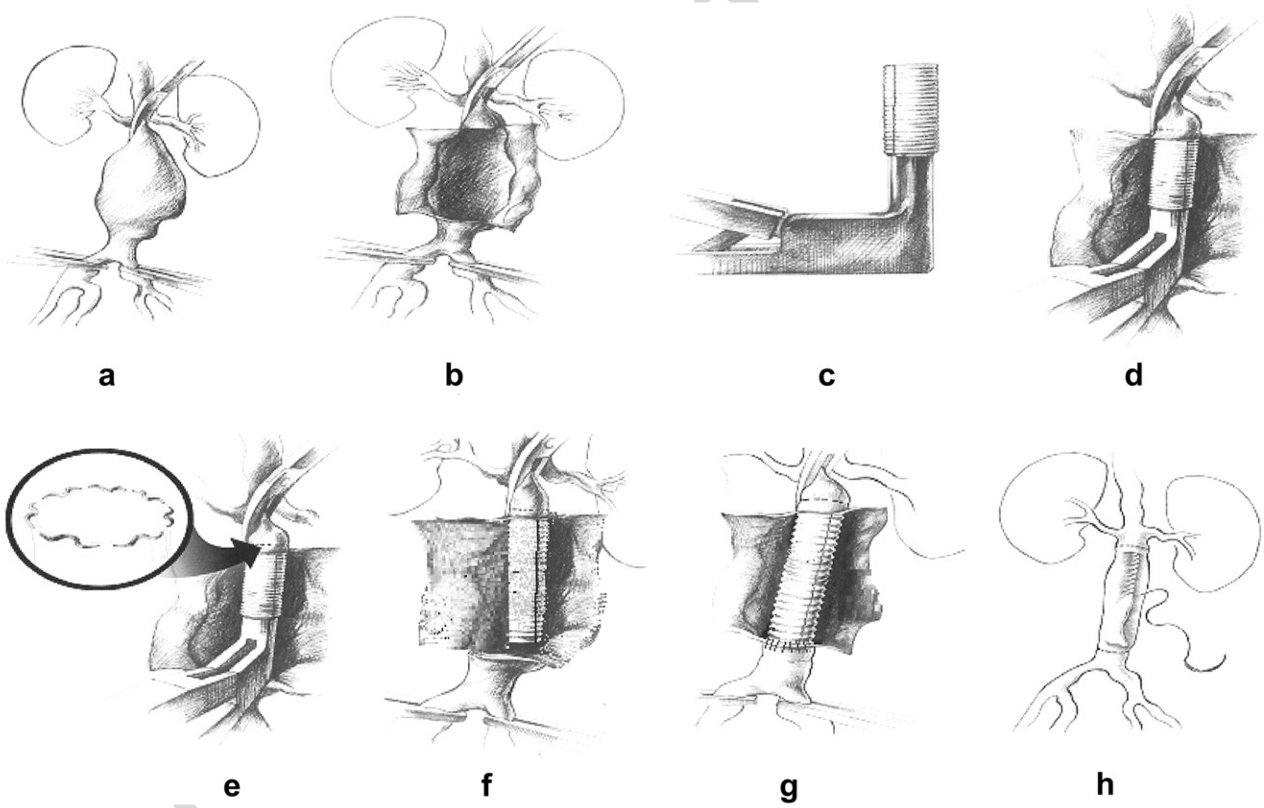

Fig. 1. Diagrammatic presentation and use of vascular stapler (a) The abdominal aorta is separated from the surrounding tissues and clamped. (b) The abdominal aorta is opened below the renal arteries. (c) A graft is ‘‘dressed up’’ on the head of the stapler and fixed. (d) A stapler and a graft is inserted into the aorta, fixed in place and stapled to the aortic wall by squeezing the handle. (e) The 10 staples are placed in circular manner. (f) The stapler is removed and the ‘‘sealing’’ of the anastomosis is tested by temporary aortic declamping. (g) The aorta is clamped again and the remaining anastomosis constructed with a regular Prolene suture, the aorta is declamped and haemostasis secured. (h) The graft is covered with aneurysmal sac.

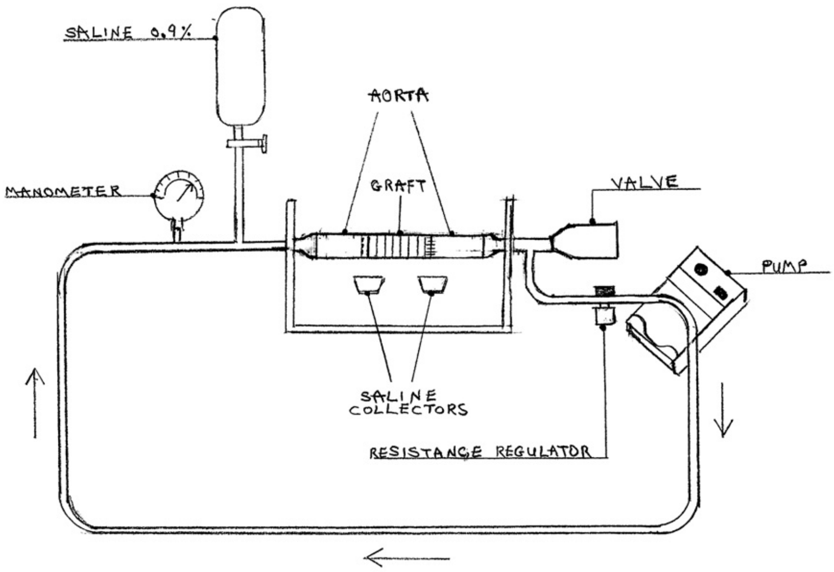

Fig. 2. Schematic presentation of circulation model.

around the vessel and the stapler already carrying the 12-mm PTFE graft inserted into the lumen as shown in Fig. 2. The external clamp grips the aorta and graft which is then stapled into place with a single squeeze of the handle. The stapler is then removed and the lower anastomosis constructed in the usual manner with standard sutures. The time taken to complete the stapled anastomosis was measured from the moment the aorta was opened to the time the stapler was removed and for the sutured anastomosis it began with the start of the suturing process.

Results

In vitro study

The results of this study showed that leakage of saline from the sutured anastomosis was six times greater than for the stapled anastomosis over a 20 minute measurement period. These results are shown in Table 1.

Table 1. "Leakage" of Saline at each anastomosis at various pressures in the circulation model

Pressure	Prolene suture	Stapling
A. Stapling of proximal and Prolene suture of distal anastomoses		
100 mmHg	100 ml	15 ml
140 mmHg	150 ml	20 ml
220 mmHg	320 ml	40 ml
B. Prolene suture of proximal and stapling of distal anastomoses		
100 mmHg	150 ml	20 ml
140 mmHg	220 ml	30 ml
220 mmHg	380 ml	35 ml

In vivo study

The total aortic cross clamping time for the stapled anastomosis was 1.0 ± 0.25 minutes on average while the sutured anastomosis took 8.5 ± 1.5 minutes. All twelve pigs survived the procedure and were sacrificed by lethal injection of thiopental at one week and one and three months.

On macroscopic examination of the grafts they looked identical and there were no signs of thrombosis or other defects on the anastomosis. Microscopic examination was also almost identical and showed chronic inflammation with some foreign body reaction, the only difference being some mild thickening of the intima in the area of the sutures.

Cadaveric experiments

The mean detachment force was higher for the staples than the sutures but this was not statistically significant. These results are summaries in Table 2.

Discussion

The aorta at the thoracic and abdominal levels is cross clamped mostly for surgical treatment of aneurysmal and aortic occlusive disease. Significant predictors of outcome, particularly in high risk cases, include the total aortic clamping time and the complications that result from the pathophysiological disturbances that occur during cross clamping. This is particularly important in ruptured aneurysms.[2,4] Prolonged

Table 2. Detachment summary (Cadaveric Study)

	Staples		Sutures		P-value
	n	Avr ± STD (range) (kg)	n	Avr ± STD (range) (kg)	
Distal	2	9.0 ± 1.41 (8−10)	6	7.5 ± 0.62 (7−8.5)	
Proximal	8	8.2 ± 0.77 (7.1−9)	1	9.0	
Overall	10	8.3 ± 0.90 (7.1−10)	7	7.7 ± 0.80 (7−9)	0.200

clamping leads to the accumulation of vaso-active substances, changes in systemic vascular resistance[5] and altered haemodynamic responses.[6,7] These changes are even more apparent when concomitant renal or visceral revascularisation is required.[8]

Over a decade has passed since the original report of Parodi *et al*.[9] on the clinical use of endovascular (EV) stent grafts to treat an AAA. There is a lower perioperative mortality associated with elective endovascular aneurysm repair compared to open surgery. However, the durability of endovascular aneurysm repair appears less favourable than that of conventional surgery.[10]

For younger patients with a lower operative mortality open repair is probably still the procedure of choice. In addition 30−40% of cases are unsuitable for EVAR unless branched graft technology is used and this is not yet in widespread usage and probably will not be in the long term. Open repair will therefore still be required in many cases and any method that can simplify the procedure and improve the results is worth developing. Placing sutures in the aortic wall can be difficult particularly if the aorta is calcified or if it is friable. Using a stapling technique may avoid some of the problems that occur with sutures. Implicit in the technique is that the circular instrument required to exert counter pressure has to go around the aorta and this may pose problems, however these problems should be counteracted by the simplicity of using this device which should shorten clamp times and reduce the complications that are caused by clamping although this difference remains to be proven.

In this study we have shown that the time taken to insert the staples is significantly shorten than that taken to suture the graft which should in itself help with the procedure from a technical point of view. Cadaveric studies have shown that the staples are as secure as sutures and the anastomosis leaks less. It could be argued that the test used in this study is artificial in that saline was used rather than blood and blood usually thromboses closing most suture holes anyway. We used saline as a severe test of leakage and showed quite clearly that the stapled anastomoses gave better results. It could also be argued that errors occurred in collecting the saline from the two anastomoses, this is unlikely as the differences were large and repeatable. The importance of this device in patients requiring open repair needs to be determined by a randomised clinical study but the device has been inserted into ten patients without difficulty and this will be the subject of a different publication. Possibly the main area where this device will have an impact is in laparoscopic aortic surgery where suturing is a major problem.[11] Other stapling devices have been used in the past.[12] We feel that the device described here works well in the pig model and our experience with human cases has confirmed this view. We also feel that it will be possible to take this forward to laparoscopic surgery in the near future.

References

1 United States Public Health Service. Vital statistics of the US, vol. II. Mortality, Part A. Department of Health and Human Service, 1990: Washington DC: US Government Publication.

2 Gloviczki P, Noel AA, Cherry KJ. A high morbidity and mortality of contemporary open surgical repairs of ruptured AAA. The 28th Veith Symposium, V1 1.1, NY, November 2001.

3 Hatori N, Yoshizu H, Shimizu M, Hinokiyama K, Takeshima S, Kimura T *et al*. Prognostic factors in the surgical treatment of ruptured abdominal aortic aneurysms. *Surg Today* 2000;(30): 9785−9790.

4 Ellis JE, Roizen MF, Youngberg JA. Anaesthesia for abdominal aortic revascularisation. In: Youngberg JA, ed. *Cardiac, Vascular and Thoracic Anaesthesia*. New York: Churchill Livingstone; 2000:538−566.

5 Gelman S. The pathophysiology of aortic clamping and unclamping. *Anaesthesiology* 1995;**82**:1026−1060.

6 Nypaver TJ, Shepard AD, Reddy DJ, Elliot Jr JP, Ernst CB. Supraceliac aortic cross clamping: determinants of outcome in elective aorticreconstruction. *J Vasc Surg* 1993;**17**:868−876.

7 Deb S, Martin B, Sun L, Barris D, Wherry D, Pikpulis E *et al*. Comparison of Titanium vascular closure staples with suture repair of the thoracic aorta in swine. *Chest* 2000;**118**:1762−1768.

8 Svensson LG, Crawford ES, Hess KR, Coselli JS, Safi HJ. Experience with 1509 patients undergoing thoracoabdominal aortic operations. *J Vasc Surg* 1993;**17**:357−370.

9 Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Ann Vasc Surg* 1991;**5**:491−499.

10 EVAR Trial Participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR Trial 1): randomised controlled trial. *Lancet* 2005 June 25-July 1;**365**(9478):2179−2186.

11 Wassiljew S, Kolvenbach R, Puerschel A, Schwierz E *et al*. Total laparoscopic iliac artery aneurysm repair using endoscopic techniques with endovascular balloon occlusion. *Eur J Vasc Endovasc Surg* 2006;**32**(3):270−273.

12 Yoshida K, Ohtake H, Kimura K, Watabi G. Experimental study on the aortic anastomosis using a circular stapling device in the porcine model. *Eur J Vasc Endovasc Surg* 2006; **31**(6):575−580.

Accepted 17 October 2006
Available online 28 November 2006