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Editor's Choice - A Randomized Controlled Trial of the Fascia Suture Technique Compared with a Suture-mediated Closure Device for Femoral Arterial Closure after Endovascular Aortic Repair CME

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WHAT THIS PAPER ADDS

This is the first randomized trial including two centers comparing the fascia suture technique with a suture-mediated closure device in patients having endovascular treatment of aortic aneurysms and dissections. The study brings information about access closure time and cost and also the complication rate for both techniques and independent risk factors for failure.

Objectives: The aim was to investigate whether the fascia suture technique (FST) can reduce access closure time and procedural costs compared with the Prostar technique (Prostar) in patients undergoing endovascular aortic repair and to evaluate the short- and mid-term outcomes of both techniques.

Methods: In this two center trial, 100 patients were randomized to access closure by either FST or Prostar between June 2006 and December 2009. The primary endpoint was access closure time. Secondary outcome measures included access related costs and evaluation of the short- and mid-term complications. Evaluation was performed peri- and post-operatively, at discharge, at 30 days and at 6 months follow up.

Results: The median access closure time was 12.4 minutes for FST and 19.9 minutes for Prostar ($p < .001$). Prostar required a 54% greater procedure time than FST, mean ratio 1.54 (95% CI 1.25–1.90, $p < .001$) according to regression analysis. Adjusted for operator experience the mean ratio was 1.30 (95% CI 1.09–1.55, $p = .005$) and for patient body mass index 1.59 (95% CI 1.28–1.96, $p < .001$). The technical failure rate for operators at proficiency level was 5% (2/40) compared with 28% (17/59) for those at the basic level ($p = .003$). The proficiency level group had a technical failure rate of 4% (1/26) for FST and 7% (1/14) for Prostar, $p = 1.00$, while corresponding rates for the basic level group were 27% (6/22) for FST and 30% (11/37) for Prostar ($p = .84$). There was a significant difference in cost in favor of FST, with a median difference of €800 (95% CI 710–927, $p < .001$).

Conclusions: In aortic endovascular repair FST is a faster and cheaper technique than the Prostar technique.

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Endovascular repair of abdominal aortic aneurysm (EVAR) was established in the late 1990s and randomized trials have indicated a short-term benefit for EVAR compared with open repair.[1,2] A percutaneous access for endovascular aneurysm repair (P-EVAR) utilizing a suture mediated closure device (SMCD) was first described in 1999 by Haas et al.[3] P-EVAR may reduce surgery time and decrease time to ambulation[4] but the procedural cost may increase.[5] The overall success rate for percutaneous closure is reported to be 89–95%[4,6–11] with a 6 month complication rate of about 2%.[6] Obesity, femoral calcification, tortuous iliac arteries and scarred groins have been proposed as risk factors for complications.[7,11–13]

The fascia suture technique (FST) was described by Diethrich[14] in 1997 and was evaluated by this group in 2006.[15] With this technique, access closure can be provided without exposure of the vessel. The method requires a

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dissection to the femoral fascia and is not percutaneous. The overall reported success rate is in the same range as for SMCD. Reported studies are, however, retrospective and mid-term results are not fully documented, or FST has been combined with external compression.[15—18] Uncertainty exists about how well FST compares with other techniques and no randomized studies have been performed previously.

The aim of this study was to investigate whether FST reduces the time and cost of the procedure in comparison to pre-suturing using the Prostar XL percutaneous Vascular Surgical system (Abbott Laboratories, Redwood City, CA, USA) and to evaluate the short- and mid-term outcome of both techniques.

METHODS

Study design

From June 2006 to December 2009 a prospective, randomized, two center trial was performed in EVAR or thoracic endovascular aortic repair for aneurysm or dissection. The primary endpoint was procedure time for access closure for FST and Prostar. Secondary outcome measures included access related costs and evaluation of short- and mid-term complications of both techniques.

Patients planned for endovascular treatment with a need of at least a 16F (outer diameter) introducer/stent graft system in the main femoral access site were included. Exclusions included the need for aorto-uni-ilac (AUI) stentgrafts with femoro-femoral or other bypass involving the main femoral access site, femoral aneurysms, ruptured aneurysms, emergency operations when pre-operative ultrasound was not performed, ongoing anticoagulation, and patients previously included in the trial or patients not considered likely to attend follow up. Availability of physicians with experience of both closure techniques, "closure license," was mandatory.

The Regional Ethical Review Board approved the study and patient informed consent was obtained prior to enrolment. The trial is registered ISRCTN68739781. Örebro University Hospital, Sweden, funded the trial.

Participating centers

Two centers (Örebro University Hospital and Sahlgrenska University Hospital, Göteborg) participated in the trial. Operators were required to have experience of 15 FST and 15 Prostar procedures and to have reached the basic level in order to participate. The proficiency level for the closure techniques was set at 60 procedures.

Randomization

Örebro research center handled computer generated randomization, designed with equal probability (1:1 ratio) of assignment to either FST or Prostar by means of concealed allocation and stratification by center using a permuted block design. Sealed opaque envelopes imprinted with a randomization number were delivered to the hospitals. Randomization was performed in the operating room or the angiography suite when all required baseline data had been collected, femoral access had been performed, and a guidewire and an introducer (maximum 10F) had been inserted.

Sample size

A power calculation demonstrating 10 minutes difference in closure time (90% power, significance level 5%) between the groups required 22 patients in each group at each center, based on an estimated mean of 13 minutes (FST) and 23 minutes (Prostar) (SD 9), (Mann—Whitney *U* test). 90 patients were going to be enrolled, but in the end an additional 10 patients were randomized before enrolment was closed.

Access closure

Fascia suture. Technical details of the FST have been described previously.[15] After completion of the main part of the endovascular procedure, time from the intended start of closure of the femoral puncture, to completion of skin suture was recorded.

Prostar. The Prostar XL device was used in accordance with the "preclose" technique.[3] A minimum of two devices were required. The time from when the first Prostar device was inserted to when the sutures of the second Prostar device were secured (step 1) was recorded. After completion of the endovascular procedure the time for step 2 between when the sutures were released and completion of skin suture was recorded.

Procedures and follow up

Endovascular procedure. The centers used their standard protocols for endovascular repair. All patients received 5,000 units of heparin after a large bore introducer or a graft sheath had been inserted, and the activated clotting time (ACT) was monitored and kept at 200—250 seconds. No protamine was administered.

Outcome. Outcome was recorded peri-operatively, post-operatively, at discharge, at 30 days, and at 6 months follow-up. Technical success was defined as hemostasis without the need for immediate open surgical repair or external compression. Peri-operative, post-operative, and late access related (index site) complications included any event leading to an additional procedure, operative or non-operative, or the finding of a pseudoaneurysm.

Adverse events and additional procedures related to the index site at discharge and at 1 and 6 months were recorded.

Measurements. A pre-operative duplex ultrasound was performed of the common femoral artery (CFA), the distal 5 cm of the external iliac artery, the proximal 5 cm of the superficial femoral artery, and the deep femoral artery. Significant stenosis (>50%, defined as doubled flow velocity) and occlusions were recorded. Thrombosis of the common femoral vein was recorded. At 6 months

ultrasonography was repeated and any pseudoaneurysm was noted and its size determined.

The ankle—brachial pressure index (ABI) was measured in both legs pre-operatively, at discharge and at 1 and 6 months.

Cost analysis. Closure time during the primary procedure was registered in minutes and seconds. Procedure time for reoperations related to the index site was registered in minutes, and additional procedures requiring another hospital stay were recorded as number of days. The cost for the operations was calculated according to the respective hospital's price per minute of operating time, and for hospital stay the standard price per day for patients treated outside the catchment area was used. Costs for disposables, such as the Prostar device, and sutures used for closure of the index site were included. The mean of each center's prices was used for all calculations.

Statistics. Mean (SD) was used for continuous variables and the median (range) was calculated for a non-normal distribution; percentages were calculated for categorical variables. Procedure time differences were handled with the Mann—Whitney *U* test and then with linear regression to adjust for operator experience and body mass index (BMI) as potential confounders. Because of a skewed distribution, procedure time was evaluated logarithmically, which gives mean ratios as measures of association from linear regression. A mean ratio of 1 between study groups is interpreted as no association and a mean ratio of 1.5 as a 50% longer mean procedure time in one group. Differences in categorical variables between study groups were analyzed using the chi-square test or the Fischer exact test when appropriate. To adjust for operator experience in the evaluation of complication differences between groups, logistic regression was used, giving odds ratios (ORs) as the measure of association. A Kaplan—Meier plot with log rank test was used to compare study groups for the time to the first access related complication and to reintervention. Hodges—Lehmann's method[19] was used for cost analysis (95% CI for median differences of total cost between study groups). A p value $<.05$ was considered statistically significant. SPSS version 17 (Chicago, IL, USA) and STATA release 11 (College Station, TX, USA) were used for analyses.

RESULTS

Study population

Between June 2006 and May 2009, 122 patients were screened for the trial. Before randomization, 22 patients were excluded, six due to exclusion criteria, two due to comorbidities, two rescheduled for open or hybrid repair. Four patients had died. Five patients could not be randomized because the endovascular operator had not fulfilled the minimum volume of procedures, and there were three protocol violations. One hundred patients were randomized (Örebro 54, Gothenburg 46); 99 patients were eligible for analysis. Fig. 1 shows the trial flow. The risk factors of

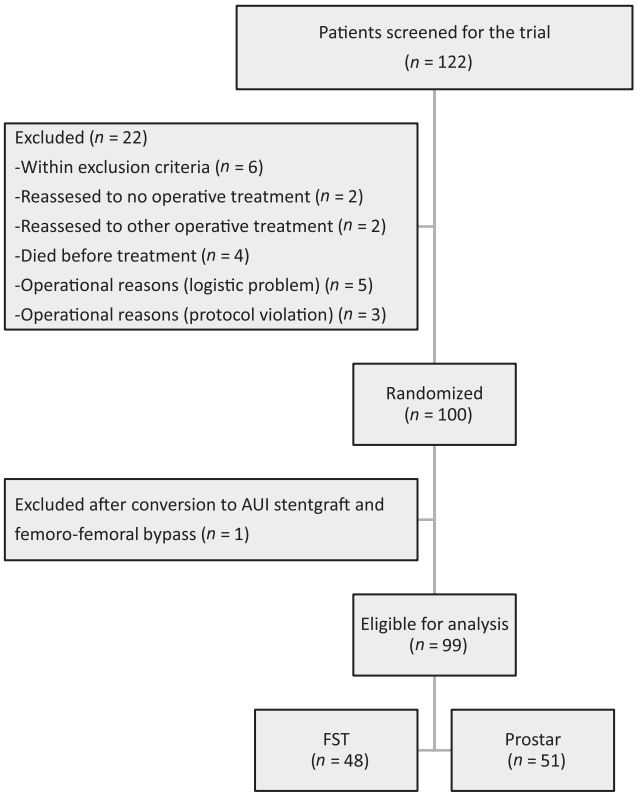

Figure 1. CONSORT diagram showing flow of patients through trial. FST = fascia suture technique.

patients were registered according to the Swedish Vascular Registry[20]; BMI and antiplatelet and anticoagulation treatment were noted (Table 1).

One patient randomized to the fascia suture group was converted to an AUI and femoro-femoral bypass procedure. Per-protocol analysis was therefore performed in 99 patients. The groups were well matched for baseline characteristics except for overweight and operator experience, which were more common in the FST group than in the Prostar group (Table 1).

Procedural details

Procedures were performed by endovascular surgeons (74%) or interventional radiologists (26%).

Commercially available devices were used for all endovascular repairs. The total surgical time was 184 minutes (SD 66) in the FST group compared with 194 minutes (SD 86) in the Prostar group ($p = .523$). There was no difference between introducer/stent graft outer diameter. One fascia suture was sufficient in 71% and maximum two sutures were used in 92% of the procedures. Two Prostar devices were used in 88% of the procedures (Table 2).

Access closure time

The median procedure time for closure was 12.4 minutes for FST and 19.9 minutes for Prostar, $p < .001$ (Fig 2). Prostar required 54% longer procedure time than FST (regression analysis, mean ratio 1.54 [95% CI 1.25—1.90,

Table 1. Demographics.

	FST	Prostar
Patients		
Patients (number of patients)	48	51
Age, mean (SD)	76.3 (6.7)	74.6 (8.2)
Gender, female (%)	8 (17%)	9 (18%)
Anatomical location/pathology		
Abdominal aortic aneurysm	42 (88%)	38 (74%)
Thoracic aortic aneurysm	3 (6%)	7 (14%)
Iliac aneurysm	2 (4%)	6 (12%)
Thoracic aortic dissection	1 (2%)	0 (0%)
Indication		
Primary elective	44 (92%)	45 (88%)
Secondary elective[a]	4 (8%)	5 (10%)
Acute	0 (0%)	1 (2%)
Risk factors[b]		
Cerebrovascular	6 (13%)	7 (14%)
Diabetes	6 (13%)	8 (16%)
Hyperlipidemia	16 (33%)	20 (39%)
Hypertensive disease[c]	37 (77%)	38 (75%)
Cardiac	26 (54%)	27 (53%)
Previous vascular surgery or amputation	7 (15%)	10 (20%)
Pulmonary	8 (17%)	11 (22%)
Renal	3 (6%)	6 (12%)
Smoking	13 (27%)	16 (31%)
BMI[d]		
Normal range (18.5—24.9)	13 (27%)	24 (47%)
Overweight (25.0—29.9)	25 (52%)	19 (37%)
Obese class I—III (≥30.0)	10 (21%)	8 (16%)
Drug therapy		
Platelet inhibition	28 (58%)	32 (63%)
Anticoagulation	8 (17%)	7 (14%)
Operators		
Proficiency level	26 (54%)	14 (27%)
Basic level	22 (46%)	37 (73%)

Data are presented as mean (SD) or number of patients and percentage.

[a] Previous endovascular treatment of aorta has been performed.

[b] Risk factors according to guidelines in the Swedish Vascular Registry.

[c] Antihypertensive medication or diastolic blood pressure >110 mmHg.

[d] Body mass index (BMI) with definition according to the World Health Organization.

Table 2. Access related (index site) procedural details.

	FST $n = 48$	Prostar $n = 51$
Introducer/stentgraft		
Maximum OD	21.0 (1.8)	21.0 (1.9)
Fascia suture		
1 suture	34 (71%)	
2 sutures	10 (21%)	
3 sutures	3 (6%)	
4 sutures	1 (2%)	
Prostar		
2 devices		45 (88%)
3 devices		5 (10%)
4 devices		1 (2%)

Abbreviations: OD = outer diameter.Data are presented as mean (SD) or number of patients and percentage.

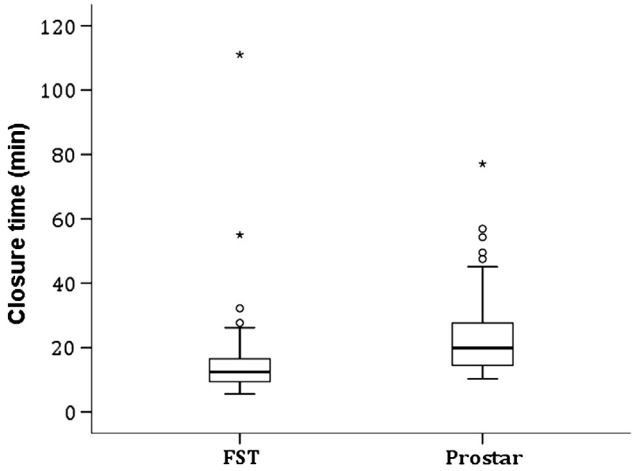

Figure 2. Box plot of access closure time by fascia suture technique (FST) and Prostar. *Note*. The boxes represent the 75th and 25th percentiles; the horizontal bar within a box is the median; the whiskers are max and min if no outliers are present, otherwise open circles (○) represent outliers: values >1.5 box lengths from the 25th or 75th percentile. The asterisk (*) represents extremes: values >3 box lengths from the 25th or 75th percentile.

$p < .001$] unadjusted). When adjusted for operator experience, the mean ratio was 1.30 (95% CI 1.09—1.55, $p = .005$). When stratified by operator experience, the mean ratio for operators at proficiency level was 1.25 (95% CI 1.05—1.49, $p = .014$) and for operators at the basic level it was 1.33 (95% CI 1.01—1.75, $p = .044$). The operators at the basic level ($n = 59$) took a median of 22.2 minutes closure time and those at the proficiency level ($n = 40$) a median of 11.1 minutes. Adjusted for BMI (normal weight, overweight and obesity) the regression analysis showed mean ratio of 1.59 (95% CI 1.28—1.96, $p < .001$). Stratified on BMI, normal weight showed a mean ratio of 1.83 (95% CI 1.36—2.46, $p < .001$), overweight 1.41 (95% CI 0.99—2.02, $p = .058$) and obesity 1.61 (95% CI 0.92—2.82, $p = .087$). Adjusted for BMI and operator experience the mean ratio was 1.31 (95% CI 1.09—1.57, $p = .005$).

Complications

There were no significant difference in complications, $p = .18$ (log rank test) (Fig. 3 and Table 3) or reinterventions, $p = .14$ (log rank test) (Fig. 4) between the two groups. Two patients with persistent bleeding in the FST group had a primary closure of the femoral artery entry site and one of them had excessive blood loss and peri-operative cardiac arrest and was resuscitated. Nine patients in the Prostar group had bleeding complications that were treated with an arteriorraphy ($n = 5$), a fascia suture ($n = 3$), or with Vasoseal (Datascope Corp., Montvale, NJ, USA) devices ($n = 1$). Technical problems with the Prostar device occurred with needle entrapment in one case, and in another the sutures were deployed outside the vessel. They were solved by an open repair and a fascia suture respectively.

Post-operative complications relating to the main access site were recognized in five patients after FST. One patient

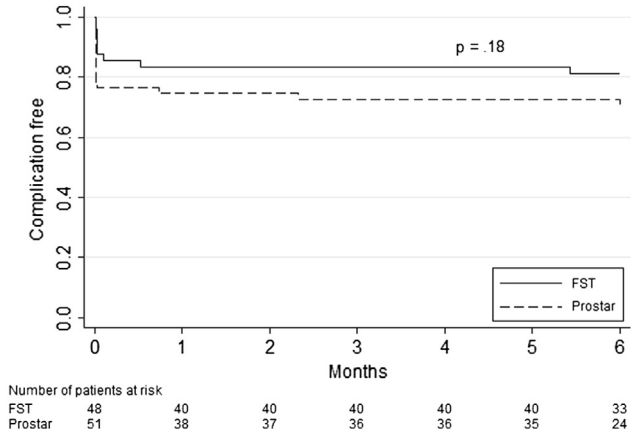

Figure 3. Kaplan—Meier plot of time to first access related complication (index site) in fascia suture technique (FST) and Prostar. $p = .18$ (log rank test).

had bleeding requiring arterioraphy. Thrombectomy was performed in two patients: one combined with patch and iliac stent, and one suffering local neuralgia had the fascia suture removed successfully. One local hematoma was treated conservatively. In the Prostar group one patient suffered acute ischemia on the first postoperative day. A plaque dissection was confirmed, requiring a thromboendarterectomy. The total peri-operative and immediate post-operative complication rate (technical failure) was 15% (7/48) for FST and 24% (12/51) for Prostar (Table 3). The technical failure rate for operators at the proficiency level was 5% (2/40) compared with 29% (17/59) for those at the basic level, ($p = .003$). The proficiency level group had a technical failure rate of 4% (1/26) for FST and 7% (1/14) for Prostar ($p = 1.00$), while corresponding rates for the basic level group were 27% (6/22) for FST and 30% (11/37) for Prostar ($p = .84$).

Clinical follow up was performed at 1 and 6 months. At 1 month a hematoma in the FST group had resolved; in the Prostar group one pseudoaneurysm had resolved, while another patient had a wound infection successfully treated. There were no complications at 6 months. One patient in the Prostar group died at home from unknown reason before the 6 month follow up (Table 3).

Measurements

Nine patients had asymptomatic stenoses on pre-operative ultrasound and/or at the 6 month examination (Table 4). One patient (2%) in the FST group had a pseudoaneurysm (11 mm), as did three patients (6%) in the Prostar group (12—41 mm) (Table 3). None of these pseudoaneurysms resulted in active treatment. There was no venous thrombosis.

Table 3. Number of access related (index site) complications.

	FST $n = 48$	Prostar $n = 51$	Unadjusted[a] OR (p-value)	Adjusted[b] OR (p-value)
Peri- and post-operative complications				
Peri-operative complications				
Bleeding	2 (4%)	9 (18%)		
Technical error with device	0 (0%)	2 (4%)		
Total	2 (4%)	11 (22%)	6.3 (.01)	4.6 (.06)
Post-operative complications				
Bleeding	2 (4%)	0 (0%)		
Thrombosis	2 (4%)	0 (0%)		
Stenoses	0 (0%)	1 (2%)		
Neuralgia	1 (2%)	0 (0%)		
Total	5 (10%)	1 (2%)		
Total complications before discharge	7 (15%)	12 (24%)	1.8 (.26)	1.2 (.72)
Complications after discharge				
Complications from discharge to 1 month				
Hematoma	1 (2%)	0 (0%)		
Wound infection	0 (0%)	1 (2%)		
Pseudoaneurysm	0 (0%)	1 (2%)		
Total	1 (2%)	2 (4%)		
Complications from 1 month to 6 months[c]				
Pseudoaneurysm	1 (2%)	3 (6%)		
Total	1 (2%)	3 (6%)		
Total complications from discharge to 6 months[c]				
	2 (4%)	4 (8%)[d]		

Data are presented as number of patients and percentage.

[a] Evaluated by chi-square test or Fischer exact test when appropriate.

[b] Adjusted for operator level (proficiency/basic) by logistic regression, odds ratio (OR) above 1 indicate more complications in Prostar group.

[c] One patient in FST and three patients Prostar lost to follow up at 6 month.

[d] One patient had same type of complication twice after discharge.

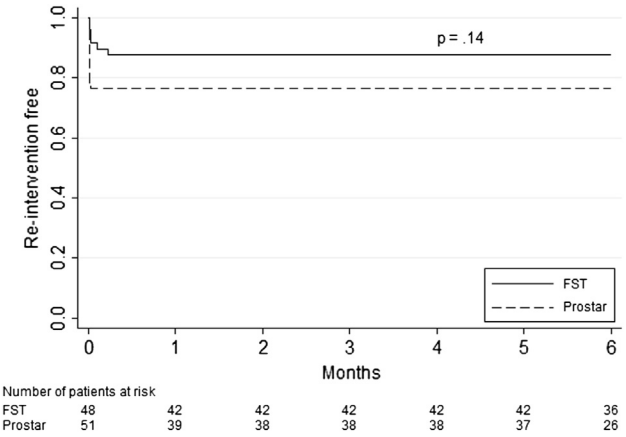

Figure 4. Kaplan—Meier plot of time to first reintervention in fascia suture technique (FST) and Prostar. $p = .14$ (log rank test).

Pre-operative, post-operative, 1 and 6 month follow up ABI measurements were completed in 89 patients (90%). Five patients had incompressible arteries due to Monckeberg's sclerosis. Four patients did not complete the measurement and one patient died before the 6 month follow up. ABI values did not change significantly from the pre-operative values for any group (Fig. 5).

Access closure cost

There was a significant cost difference in favor of FST, with a median difference of €800 (95% CI 710—927, $p < .001$) with a negligible cost for the fascia suture material. The procedure time for FST was shorter, resulting in a lower procedural cost; however, more re-operations after FST ($n = 4$) than Prostar ($n = 1$) reduced this difference. In the Prostar group, 50% of the total cost was attributable to the materials (Table 5).

DISCUSSION

The data are in favor of FST as the faster method to achieve closure of the access site for operators at both the basic and the proficiency level. The complication rate seems favorable even though this trial was not powered to address any difference in complication rates. The shorter closure time had a positive economic effect, but the main reason why the fascia suture was significantly cheaper was the reduction of material costs while the complication rate was kept at an equal level. In this study it has also been shown that fascia suture can work as a bailout procedure for a failed Prostar suture.

Table 4. Descriptive data of patients with ultrasound verified stenosis pre-operatively and at 6 months follow up (index site).

Access closure method	Pre-operative US stenosis	ABI	6 months US stenosis	ABI
Prostar	No	0.50	Yes	0.75
Prostar	Yes	0.46	Yes	0.66
Prostar	No	0.94	Yes	1.07
FST	Yes	0.78	No	0.86
Prostar	Yes	0.73	Yes	0.68
FST	Yes	1.06	No	1.17
Prostar	Yes	1.15	Yes	1.07
FST	No	1.33	Yes	1.33
Prostar	No	1.08	Yes	1.04

Note. Data presented only on patients with pre-operative and/or 6 months US stenosis. US = ultrasound; ABI = ankle—brachial pressure index; FST = fascia suture technique.

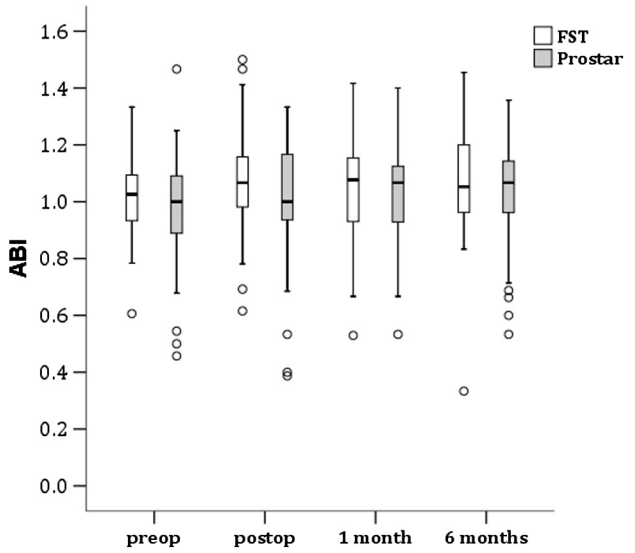

Figure 5. Box-plot of ankle—brachial pressure index (ABI) before and after access closure by fascia suture technique (FST) and Prostar. *Note*. The boxes represent the 75th and 25th percentiles; the horizontal bar within a box is the median; the whiskers are max and min if no outliers are present, otherwise open circles (○) represent outliers: values >1.5 box lengths from the 25th or 75th percentile.

Comparison with other studies

In many publications presenting percutaneous access for EVAR common reasons not to apply SMCD have been obesity and calcification,[5,7—9,11,12,21] although successful outcomes have been reported for this group of patients.[22] Mousa et al.[23] reported severely calcified arteries as predictive of conversion but BMI was a non-significant predictor. Calcification and BMI were not exclusion criteria in the study. FST has a potential advantage in calcified arteries, as the stitches do not involve the vessel wall. Previous groin surgery has also been a reason to exclude patients from percutaneous EVAR.[11] It was not possible to evaluate the effect of a scarred groin (present in just four patients), but in the authors' experience scarred tissue works as well as normal fascia for FST.

There was a strong relationship between reduced technical failure and high level operator experience in line with previous reports for Prostar, which indicates an important learning process.[24,25] Metcalfe et al.[25] used a cutoff of 20 supervised deployments of Prostar to define a proficiency level, and 15 cases constituted the request for "license." In the hands of experienced operators, the complication rate was 4—7%, close to earlier reports for either technique.[4,15—18,22] The closure time was, however, shorter for FST regardless of experience level.

Table 5. Cost analysis for access closure and access related complications (index site).

	FST ($n = 48$)	Prostar ($n = 51$)	Median difference (95% CI)
Total cost			
Per patient in Euro, median (range)	349 (160–4318)	1,181 (920–2866)	800 (710–927)
Cost subgroups			
Primary procedure,[a] sum cost in Euro (%)	21,631 (71%)	33,112 (46%)	
Material, sum cost in Euro (%)	506 (2%)	35,548 (50%)	
Secondary procedure,[b] sum cost in Euro (%)	8,235 (27%)	1,674 (2%)	
In-hospital care,[c] sum cost in Euro (%)	0 (0%)	1,286 (2%)	
Total, sum cost in Euro (%)	30,372 (100%)	71,620 (100%)	

Note. Data are presented in Euro (1 Euro = 8.50 Swedish krona). FST = fascia suture technique.
[a] Calculated as Euro 27/minute.
[b] Calculated as Euro 22/minute.
[c] Calculated as Euro 643/day.

Technical failures were usually detected and managed pre-operatively, and the few post-operative complications could be solved before discharge. Three patients had minor complications detected at clinical follow up. Small pseudoaneurysms after FST have been described in up to 14% at the 1 month follow up,[18] but they usually seal spontaneously and reinterventions are rarely required. The same observations have been made after Prostar.[26] In this study pseudoaneurysms were rare, 2% after FST and 6% after Prostar, at 6 month follow up. A more aggressive surveillance protocol, as suggested,[27] seems unjustified.

Strengths and limitations

The strength of this trial is that no anatomical exclusion criteria were accepted except the presence of an aneurysm at the access site. The two participating centers had different protocols; in one, FST was the routine technique and in the other Prostar. The two techniques were applied and harmonized with a strict protocol for both centers. Ahead of the study the teams trained each other in order to get "closure license" for both techniques. Fifteen procedures were recognized as a minimum request for a "license" and 60 procedures were used as an arbitrary measure of proficiency. The "license" was achieved by carrying out a few procedures during supervision followed by a self reported statement by the participating doctors. It may be a limitation that no formal examination was performed. Technical failure was initially discussed as a primary endpoint. Significantly more patients had to be included, which was not realistic due to problems with patient recruitment, based on the limited use of FST when the study was designed. The primary endpoint was access closure time and a limitation is that the procedure time could be influenced in an open study, a risk reduced by detailed stopwatch timekeeping. Another limitation is that the outcome of the randomization was skewed with regard to operator experience and BMI, and is the reason why statistical adjustments were made.

The study protocol did not require strict guidelines for post-operative management and the period of supine rest was not defined. Whether early mobilization increases the risk of bleeding or pseudoaneurysm formation cannot be concluded. A strength of the study is that no external compression was allowed, whereas it was in another report.[17]

Vascular surgeons performed the majority of the procedures, which may have been beneficial for FST as it utilizes standard surgical materials and technique. The Prostar technique has the advantage of maintaining EVAR as a strictly percutaneous procedure while the FST requires a limited groin dissection to the femoral fascia, which is an uncommon procedure for interventional radiologists. It might be a limitation that a procedures log and a protocol with standardized questions were not established during the training phase.

Future work

Logistically it was not possible to include ruptured aortic aneurysms in this trial. However, FST was routinely implemented in the repair of these cases. The FST did not reach the 10-minute threshold for a clinically relevant difference, but with the advantage of no need for pre-suturing, FST is probably of greater benefit in emergency situations than in elective operations.

With increased FST experience, as gained in this study, it has been possible to identify some risk factors for failure. Puncture above the inguinal ligament should be avoided, as there is no femoral fascia to cover the access hole at this location. A careful evaluation of the computed tomography image to determine the relationship between the femoral bifurcation and skeletal reference points is useful to ensure an optimal puncture site. Ultrasound guided puncture is valuable, as is angiography, to confirm an appropriate puncture site before exchange to a large bore sheath takes place.

The stitches of the suture must be sufficiently deep in order to achieve tissue for the "fascia plug." On the other hand, stitches that are too deep may cause obstruction. The study showed that post-operative complications (bleeding, thrombosis) were slightly more common in the FST group. By using a duplex Doppler device, the blood flow velocity can be evaluated peri-operatively to prevent arterial constriction.

In conclusion, the fascia suture technique is a faster and cheaper technique than the suture-mediated closure device, Prostar XL. The trial was not powered to show possible

differences in complication rates between the two techniques. A significant independent risk factor was shown to be operator experience, independent of which closure technique was used. To get an optimal outcome, a proper training program should be implemented.

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CONFLICT OF INTEREST

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