Closure Devices:
Which Are The Best?

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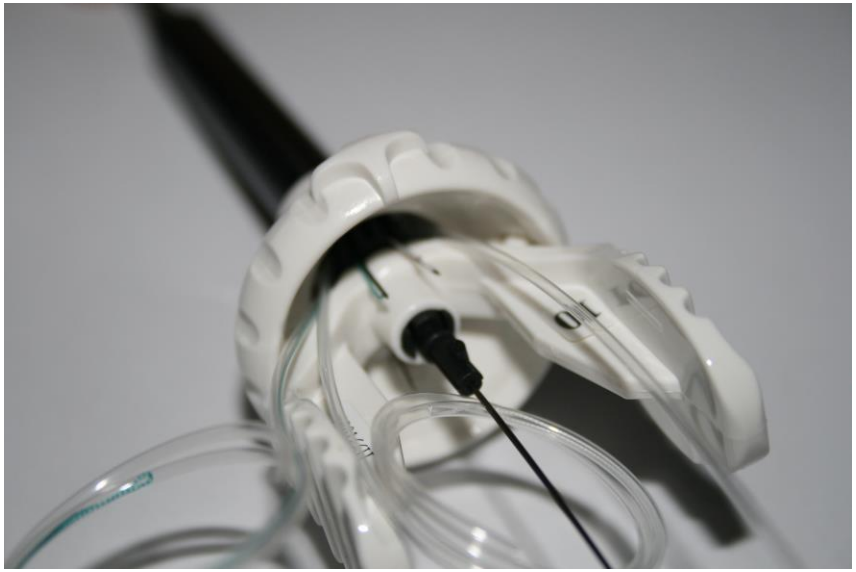


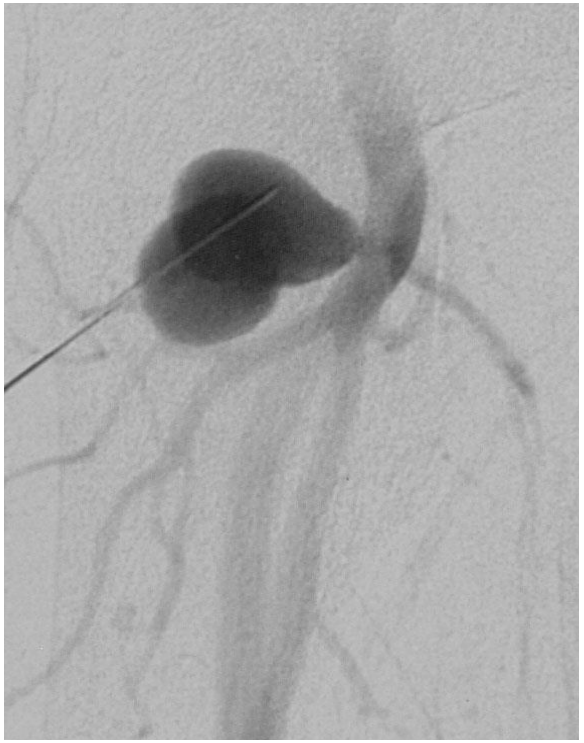
- **Disclosure**
- Speaker name:
- Ian Loftus
- I have the following potential conflicts of interest to report:
- Consulting/Speaker Fees/Proctor/Research Grants
  - Endologix
  - Medtronic
  - Abbott
  - Covidien
  - Cook Medical
- Shareholder in a healthcare company: Inotec

Percutaneous Solution

- *Advantages: procedural and post-operative*
  - *Smaller sheaths/more stable*
  - *Reduced bleeding*
  - Early mobilisation
  - Reduced length of stay
  - Reduced length of operation
  - Reduced wound complications
  - Overall cost reduction
  - Cosmesis and patient preference

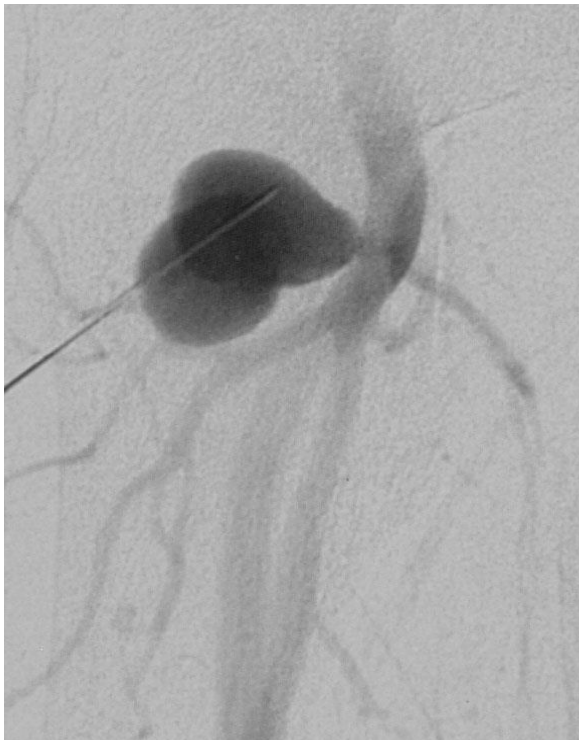
Percutaneous Solution

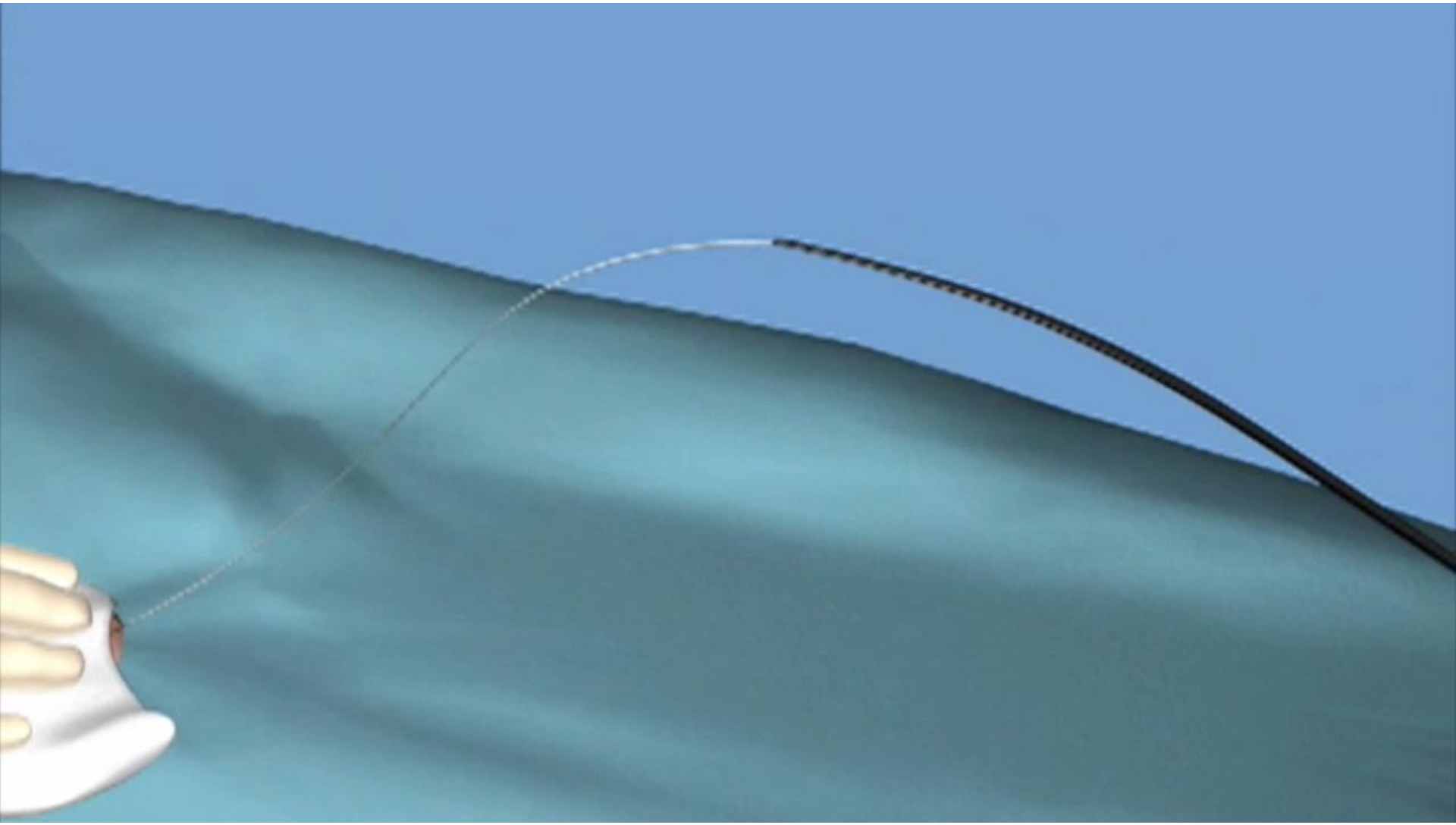
- *Disadvantages*
  - Loss of access disasterous
  - Technical failure
  - Device specific complications

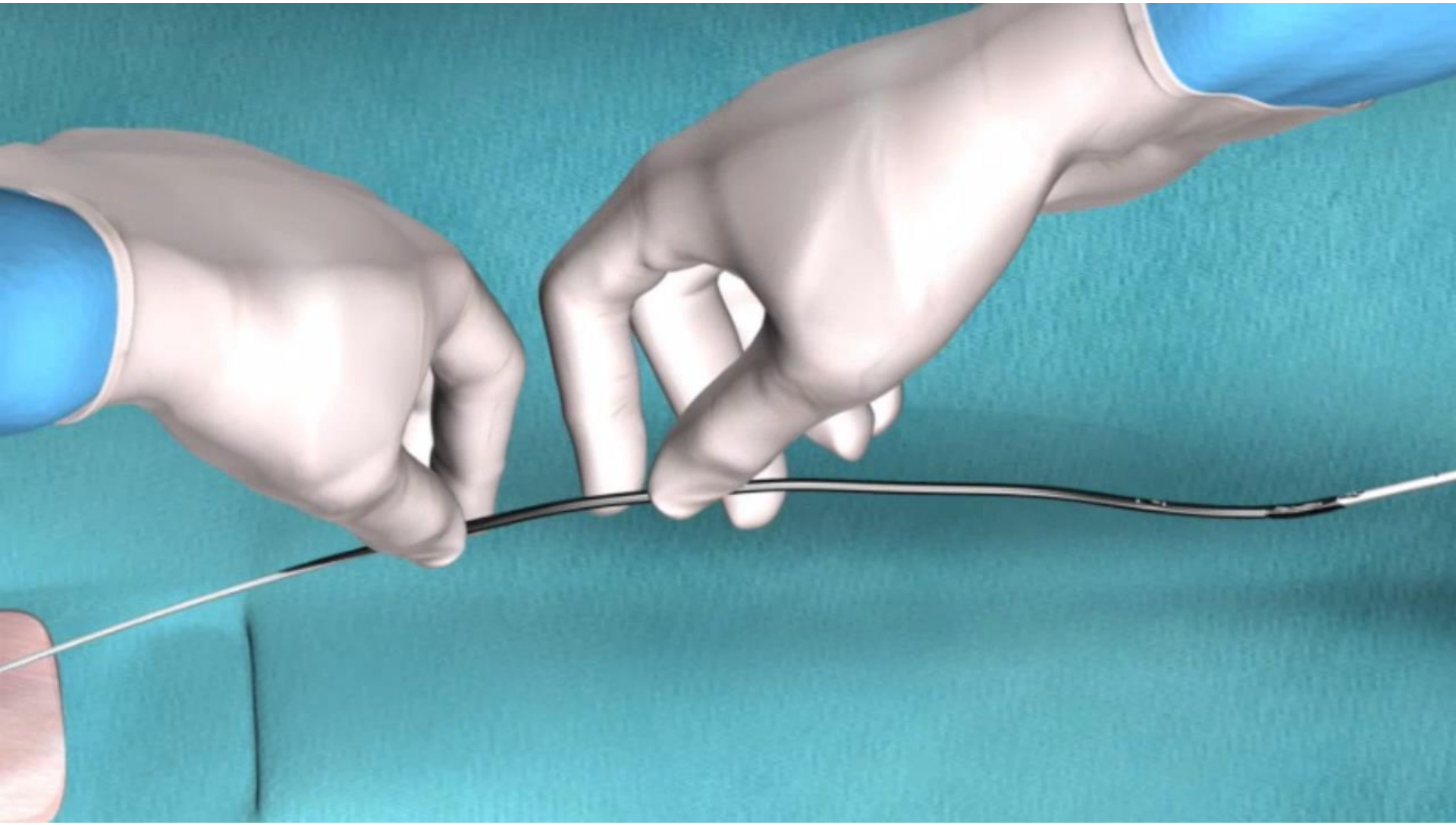


Complications of P/C Closure

- Case related factors:
  - Obesity
  - Scar tissue
  - Vessel disease
- Expertise related factors
  - Learning curve







Closure Devices: *Features*

	Proglide	Prostar
Diameter	6Fr	10Fr
Length	Short	Long
Suture type	Monofilament	Braided
Evidence base	++	+++
Ease of Use	+++	++
Number of devices/vessel	2	1
Indication	5-21Fr	8.5-10Fr

Clinical Results: Prostar

Prospective Evaluation in 500 patients (n=903)

- Primary success 868/903 (96.1%)
- All 35 secondary procedures <1 week
  - Bleeding 28
  - Pseudo-aneurysm 4
  - Vessel thrombosis 3
- Predictors of technical failure
  - Sheath size
  - Scarring

Elsenack et al, J Endo Ther 2009;16:708-13

Results: *St Georges Experience*

- Consecutive series Prostar (n=186) vs or FE (n=208)
- Technical success 95.2%
- Reduced operation time reduced by 20 minutes
- Reduced length of stay by 1 day
- Reduced groin complication rate (3 vs 8%)
- Overall cost saving
- Predictors of success: obesity, CFA disease, operator experience

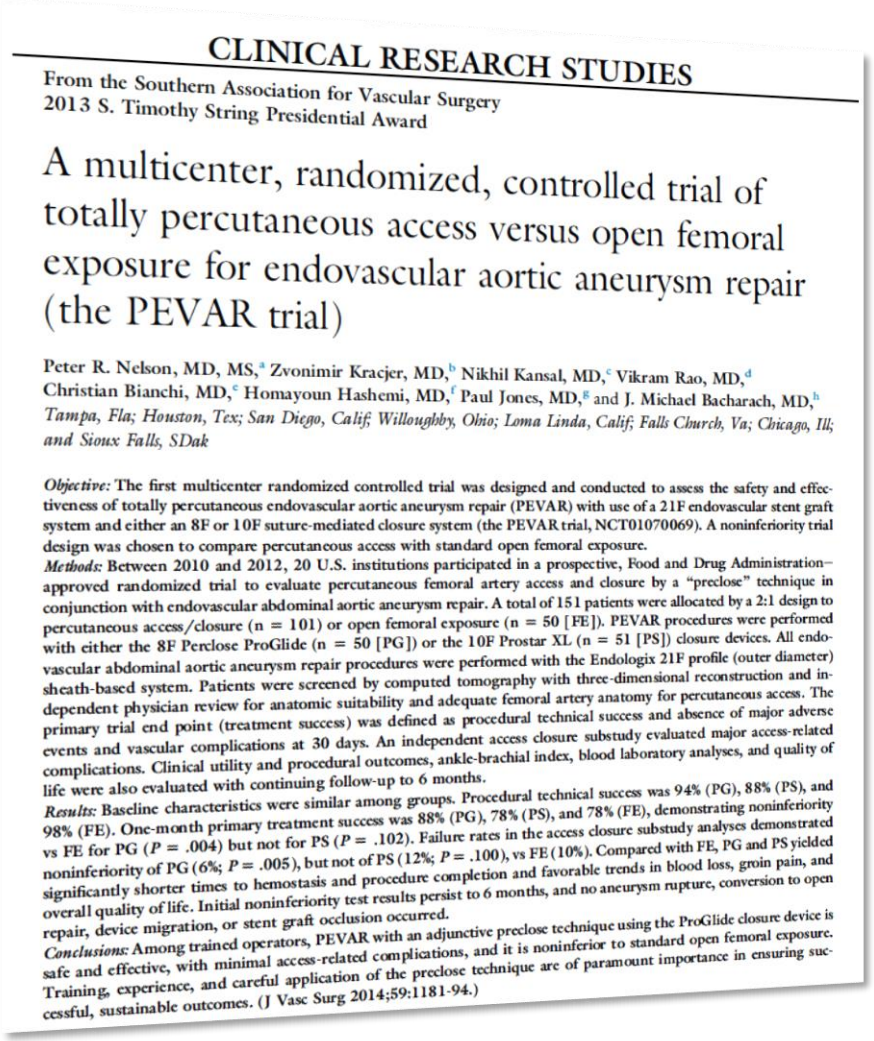
Metcalfe et al, EJVES 2012;43:378-81

Clinical Results:

Meta-analysis of 21 Studies

- Absolute success 624/692 (92%)
- Procedural time (n=193) 66 mins less than open
- Reduced time to discharge and time to ambulation
- Risk ratio of complication vs open 0.94 (0.51-1.72)
- Reduced procedural time and hospitalisation lead to cost savings

Haulon et al, EJVES 2011;41:201-213



CLINICAL RESEARCH STUDIES

From the Southern Association for Vascular Surgery
2013 S. Timothy String Presidential Award

A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial)

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Objective: The first multicenter randomized controlled trial was designed and conducted to assess the safety and effectiveness of totally percutaneous endovascular aortic aneurysm repair (PEVAR) with use of a 21F endovascular stent graft system and either an 8F or 10F suture-mediated closure system (the PEVAR trial, NCT01070069). A noninferiority trial design was chosen to compare percutaneous access with standard open femoral exposure.

Methods: Between 2010 and 2012, 20 U.S. institutions participated in a prospective, Food and Drug Administration–approved randomized trial to evaluate percutaneous femoral artery access and closure by a "preclose" technique in conjunction with endovascular abdominal aortic aneurysm repair. A total of 151 patients were allocated by a 2:1 design to percutaneous access/closure (n = 101) or open femoral exposure (n = 50 [FE]). PEVAR procedures were performed with either the 8F Perclose ProGlide (n = 50 [PG]) or the 10F Prostar XL (n = 51 [PS]) closure devices. All endovascular abdominal aortic aneurysm repair procedures were performed with the Endologix 21F profile (outer diameter) sheath-based system. Patients were screened by computed tomography with three-dimensional reconstruction and independent physician review for anatomic suitability and adequate femoral artery anatomy for percutaneous access. The primary trial end point (treatment success) was defined as procedural technical success and absence of major adverse events and vascular complications at 30 days. An independent access closure substudy evaluated major access-related complications. Clinical utility and procedural outcomes, ankle-brachial index, blood laboratory analyses, and quality of life were also evaluated with continuing follow-up to 6 months.

Results: Baseline characteristics were similar among groups. Procedural technical success was 94% (PG), 88% (PS), and 98% (FE). One-month primary treatment success was 88% (PG), 78% (PS), and 78% (FE), demonstrating noninferiority vs FE for PG ($P = .004$) but not for PS ($P = .102$). Failure rates in the access closure substudy analyses demonstrated noninferiority of PG (6%; $P = .005$), but not of PS (12%; $P = .100$), vs FE (10%). Compared with FE, PG and PS yielded significantly shorter times to hemostasis and procedure completion and favorable trends in blood loss, groin pain, and overall quality of life. Initial noninferiority test results persist to 6 months, and no aneurysm rupture, conversion to open repair, device migration, or stent graft occlusion occurred.

Conclusions: Among trained operators, PEVAR with an adjunctive preclose technique using the ProGlide closure device is safe and effective, with minimal access-related complications, and it is noninferior to standard open femoral exposure. Training, experience, and careful application of the preclose technique are of paramount importance in ensuring successful, sustainable outcomes. (J Vasc Surg 2014;59:1181-94.)

- Randomised Trial
- 2:1 percutaneous access vs. femoral exposure (FE)
- Prostar (PS)/ProGlide (PG)
- Endologix AFX 21F

Clinical Results: RCT 2014

	PG (50)	PS (51)	FE (50)
Major access related complications (%)	6	12	10
Vascular injury (%)	2	10	2
Lower extremity ischaemia (%)	4	2	4
Nerve injury (%)	0	0	2

Clinical Results: RCT 2014

	PG (50)	PS (51)	FE (50)
Blood loss (ml)	**213 (205)**	**193 (148)**	**280 (290)**
Procedural time (min)	**107 (45)**	**95 (35)**	**141 (73)**
Time to discharge (d)	**1.3 (0.7)**	**1.4 (0.4)**	**1.8 (2.4)**

Operator Experience

From the Society for Clinical Vascular Surgery

Predicting the learning curve and failures of total percutaneous endovascular aortic aneurysm repair

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Introduction: Percutaneous endovascular aneurysm repair (PEVAR) has been shown to be feasible; however, technical success is variable, reported to be between 46.2% and 100%. The objective of this study was to quantify the learning curve of the PEVAR closure technique and identify predictors of closure failure.

Methods: We reviewed patient- and procedure-related characteristics in 99 consecutive patients who underwent PEVAR over a 30-month period in a single academic institution. A suture-mediated closure device (Proglide or Prostar XL) was used. Forward stepwise logistic regression was used to investigate associations between the failure of the closure technique and a number of patient and operative characteristics. To ensure objective assessment of the learning curve, a time-dependent covariate measuring time in calendar quarters was introduced in the model. Poisson regression was used to model the trend of observed failure events of the percutaneous technique over time.

Results: Overall PEVAR technical success was 82%. Type of closure device ($P < .35$), patient's body mass index ($P < .86$), type of anesthesia ($P < .95$), femoral artery diameter ($P < .09$), femoral artery calcification ($P < .56$), and sheath size as measured in Fr ($P < .17$) did not correlate with closure failure rates. There was a strong trend for a decreasing number of failure events over time ($P < .007$). The average decrease in the odds of technical failure was 24% per calendar quarter. The predicted probability of closure failure decreased from 45% per patient at the time of the initiation of our PEVAR program to 5% per patient at the end of the 30-month period. There were two postoperative access-related complications that required surgical repair. Need for surgical cutdown in the event of closure failure prolonged the operative time by a mean of 45 minutes ($P < .001$). No groin infections were seen in the percutaneous group or the failed group.

Conclusions: Technical failure can be reduced as the surgeon gains experience with the suture-mediated closure device utilized during PEVAR. Previous experience with the Proglide device does not seem to influence the learning curve. (J Vasc Surg 2013;57:72-6.)

Advances in technology combined with smaller sheath sizes to deliver large stent grafts have transformed abdominal aortic surgery over the last decade. Endovascular exclusion (EVAR) has become the first-line therapy in treating abdominal aortic aneurysms (AAAs), and now percutaneous EVAR (PEVAR) is increasingly becoming more popular than surgical femoral cutdown (FC-EVAR) for stent graft delivery. Multiple prospective studies[1-8] and one randomized study[9] have shown the feasibility of PEVAR since its introduction in 1999.[10] PEVAR has been shown to reduce groin wound infections and lymphoceles as well as hematomas. On the other hand, PEVAR technical success has been reported to be between 46% and 100%[2-10] in the literature. Large sheath size,[2-4,6] obesity,[2-4,6] and femoral calcifications[1-2,6] have been reported as predictors of PEVAR technical failure. Operator's inexperience has been alluded to as a contributing factor for decreasing technical success.[5] Only one study reports the impact of surgeon experience on PEVAR outcomes; this study demonstrated an odds ratio of 43.2 ($P < .001$) for early conversion to FC-EVAR in the hands of inexperienced operators (<30 interventions).[1]

The purpose of our study was to examine the learning curve over time as well as identify predictors of failure since the initiation of our PEVAR program in March of 2009.

METHODS

Patient- and procedure-related characteristics were reviewed in the first 99 consecutive patients who underwent PEVAR (abdominal and thoracic) over a 30-month period in a single academic institution since March of 2009. Retrospective review of the data was performed at the Michael E. DeBakey Veterans Affairs Hospital in Houston, TX. Institutional Review Board approval from both Baylor College of Medicine and the Michael E. DeBakey Veterans Affairs hospital was obtained. All the cases were performed in the operating room under either general, regional, or local anesthesia with moderate sedation. All patients received preoperative intravenous antibiotics and a sterile

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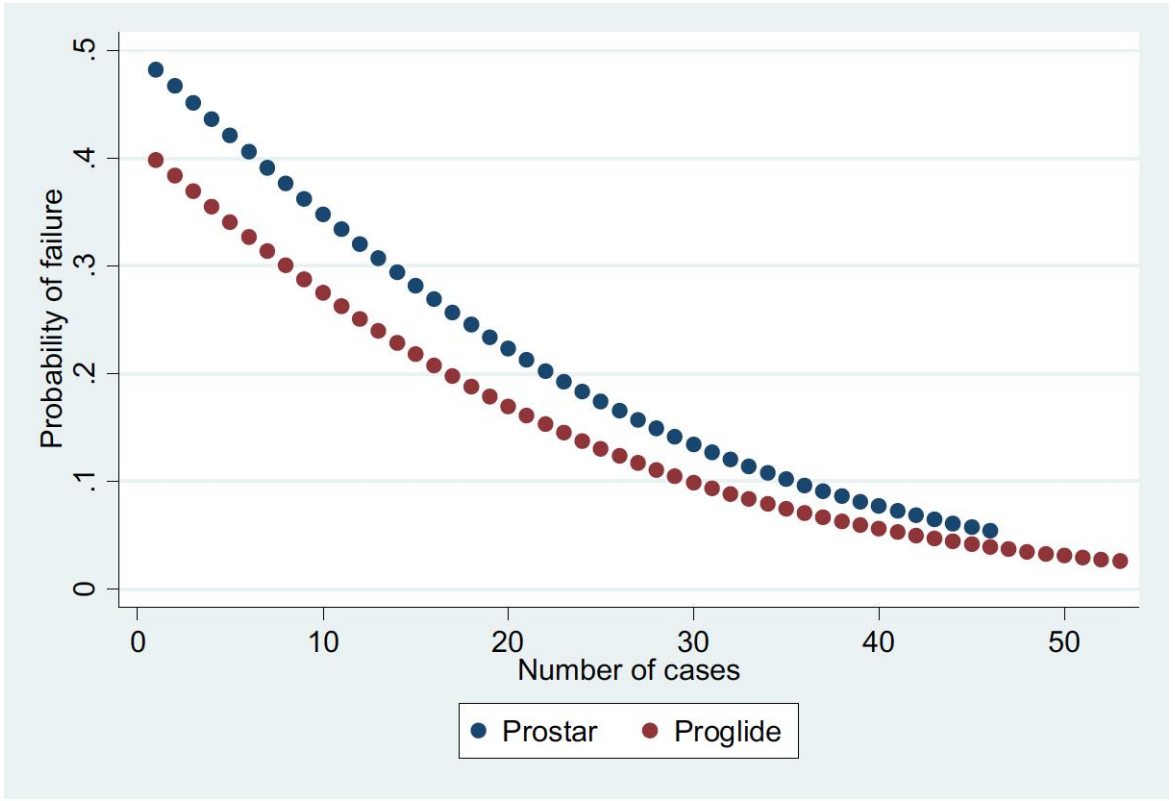

Personal Observations

- Proglide preferable and default option
  - More useable and teachable
  - Consistent
  - Lower diameter/atraumatic
  - But: cost implications
- Prostar better in some difficult iliac access
  - Longer shaft
  - Single pass
- Achieve complication/failure <2% with experience

Personal Observations

- Absolute contraindications for both:
  - Connective tissue disease
  - Acute dissection of CFA
  - Aneurysmal CFA
  - Severe circumferential calcification of CFA

Summary

- Complete p/c treatment is technically feasible in most cases, is safe and leads to early mobilisation and reduced length of stay, therefore cost savings
- Proglide is technically simple and reliable
- Complication profile is different to open approach
- Complications can be minimised by prudent case selection, training and careful device deployment