Prospective randomized trial of ACUSEAL (Gore-Tex) versus Hemashield-Finesse patching during carotid endarterectomy: Early results

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Background/Purpose: **Several studies have reported that carotid endarterectomy (CEA) with patch angioplasty produces superior results compared with primary closure. Conventional polytetrafluoroethylene (PTFE) patching has been shown to have results comparable to autogenous vein patching; however, it requires a prolonged hemostasis time. Therefore, many surgeons use collagen-impregnated Dacron patching (Hemashield [HP]). Recently, we reported a satisfactory hemostasis time using the new hemostatic PTFE patch (ACUSEAL by Gore). This study is the first prospective randomized trial comparing the ACUSEAL patch with the HP Finesse patch.**

Methods: **200 CEAs were 1:1 randomized into two patch closure groups (ACUSEAL or Finesse). All patients underwent immediate and 1 month postoperative duplex ultrasound studies. Demographic and clinical characteristics were similar in both groups, including the mean operative diameter of the internal carotid artery and length of arteriotomy.**

Results: **The overall perioperative ipsilateral stroke rate was 2% (2% ACUSEAL, 2% Finesse; $P = 1.0$). The perioperative ipsilateral TIA rates were 0% for the ACUSEAL and 2% for the Finesse patch ($P = .5$). The combined perioperative neurological event (TIA + stroke) rates were 2% for ACUSEAL and 4% for the Finesse ($P = .68$). The early ≥50% restenosis rate was 0% for ACUSEAL vs 4% for Finesse patching. Two perioperative carotid thromboses were noted with Finesse patching vs none with ACUSEAL patching ($P = .50$). The combined early morbidity rate (TIA, stroke, and ≥50% restenosis or thrombosis) was 2% for the ACUSEAL patch vs 8% for the Finesse patch ($P = .10$). The mean hemostasis time for the ACUSEAL and Finesse patches was 5.1 vs 3.7 minutes ($P = .01$), however, the mean operative times were similar for both groups ($P = .61$).**

Conclusion: **The perioperative neurological events and overall short-term morbidity associated with CEA when using ACUSEAL or Finesse patches were similar. Both patches have short hemostasis times. (J Vasc Surg 2007;45:881-4.)**

Over the past several years, we have published several prospective studies concerning closure methods for carotid endarterectomy (CEA). Results from these studies revealed the benefits of patching compared with primary closure and superior results with PTFE compared with collagen-impregnated Dacron Hemashield synthetic patches (fewer neurologic events, less early and late restenosis).[1-3] Our work raised concerns about the thrombogenic nature of the conventional collagen-impregnated Hemashield patches, with a significant risk of carotid thrombosis following repair, however, significantly prolonged bleeding was seen with the conventional PTFE patch.[2,3]

Hence, when a new patch was made available by W.L Gore (ACUSEAL), with an improved design that reduced needle hole bleeding time, we changed our preference to this patch. We have reported the only prospective work using the ACUSEAL patch, showing bleeding times similar to historic results of the Dacron patch at 3 minutes.[4] At the same time that the ACUSEAL became available, a new collagen-impregnated Dacron patch was also released (Finesse) that had been designed to limit its thrombogenicity. We report the early results from a prospective, randomized trial comparing these two commercially available patches used during carotid endarterectomy.

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Competition of interest: none.

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PATIENT POPULATION AND METHODS

Between August, 2003 and October, 2005, 200 carotid endarterectomies (200 patients) were randomized into two groups using either the ACUSEAL polytetrafluoroethylene (PTFE) patching (W. L. Gore & Associates, Flagstaff, Ariz) or the Finesse collagen-impregnated Dacron patching (Boston Scientific Corp, Natick, Mass). Using sealed opaque envelopes, each containing a slip of paper with the patch assignment, patients were randomized in a 1:1 ratio. The randomization envelopes were generated in blocks of 10 and placed in closed containers. After induction of anesthesia, but prior to skin incision, an envelope was pulled from the container by the study controller and opened, and the surgeon was notified of the patch selection. This study was approved by the Institutional Review Board of Charleston Area Medical Center, Robert C. Byrd Health Sciences Center of West Virginia University. Patients excluded from this study included those undergoing CEA with concomitant coronary artery bypass grafting (three patients), and redo CEA (two patients).

Prior to CEA, all patients underwent carotid color duplex ultrasound imaging and/or magnetic resonance angiography as a means of determining preoperative steno-

sis levels. Baseline blood cholesterol and triglyceride levels were also tested. Preoperative risk factors including hypertension, tobacco use status, diabetes mellitus, coronary artery disease, and any preoperative use of antiplatelet therapy were recorded. Indications for surgery were categorized into hemispheric transient ischemic attacks (TIA), amaurosis fugax, hemispheric strokes, nonhemispheric TIAs, and asymptomatic carotid stenoses of ≥70%.

Operative technique. All CEAs were done using general anesthesia with systemic heparin and routine shunting with a carotid Argyle shunt (C. R. Bard, Billerica, Mass). No protamine was given at the end of the procedure. At the time of the operation, the normal internal carotid artery distal to the lesion was measured in millimeters using calipers. The CEA was extended proximally and distally beyond grossly diseased intima. All ACUSEAL PTFE patches (8 mm wide, 0.5 mm thick) used were sutured using 6-0 Prolene sutures (Prolene, Ethicon, Summerville, NJ).[5] The Finesse Hemashield patches (8 mm wide, 0.4 mm thick) were sutured with 6-0 Prolene sutures. Dextran-40 was given intravenously (25cc/hour) beginning at the time of endarterectomy and continuing for 24 hours. After completion of patching and release of the carotid clamps, and if no suture bleeding points were noted, the hemostasis time was recorded as zero. If bleeding points were noted, thrombin-soaked oxidized cellulose and digital pressure were applied to stop any bleeding points before closure. Hemostasis was checked after 3 minutes, and, if necessary, in 2 minute increments. Operative and hemostasis times were recorded. All procedures were drained for 24 hours and all patients were started on an aspirin regimen (325 mg daily) within 24 hours of their surgery.

Postoperative surveillance protocol. All patients underwent immediate postoperative color duplex ultrasound scanning (CDUS) (in the operating room if machine was available, otherwise within 24 hours) using an ATL HDI 5000 system (Advanced Technology Laboratory, Phillips, Bellevue, Wash), clinical observation, and examination by a physician who was blinded to the type of patch. CDUS was then repeated at 30 days. Duplex scanning was performed to assess the presence of any residual and/or early restenosis. Peak systolic velocities >140 cm/sec with spectral broadening throughout systole and an increased diastolic frequency were considered consistent with ≥50% stenosis.[5]

Statistical methods. All statistical analyses were performed using SAS version 8.02 (SAS Inc, Cary, NC). Data were analyzed based on the intent to treat. Continuous variables (such as operative time, hemostasis time, and vessel diameter) were compared using two-tailed Student *t*-tests for independent measures and are represented as mean ± standard deviation. Morbidity rates and other categorical variables were analyzed with either the χ^2 or Fisher exact test, as appropriate. A *P* value less than .05 was considered to represent statistical significance.

RESULTS

Indications for surgery, demographic, and clinical characteristics were comparable between the patch groups (Table I). Table II summarizes the perioperative data for both patches. As shown, the mean internal carotid artery diameter and the length of arteriotomy were comparable for both groups. The hemostasis time was significantly longer for the ACUSEAL patch (5.17 vs 3.73 minutes, $P = .01$), however, the operative time from skin to skin was comparable for the two patches (97 vs 96 minutes, $P = .61$). No patients in either group suffered postoperative hematoma requiring exploration.

Table I. Demographic and preoperative data by patch

	ACCUSEAL	*Finesse*	P-*Value*
Number of CEA (N)	100	100	
Female	53	48	
Male	47	52	0.48
Age (years)	67.7 ± 11.1	68.1 ± 10.1	0.80
Hypertension	91	86	0.27
Coronary artery disease	46	43	0.67
Diabetes mellitus	31	26	0.43
Peripheral vascular disease	12	14	0.67
Hyperlipidemia	68	61	0.30
Current tobacco use	30	35	0.45
Past tobacco use	40	35	0.47
Any preop antiplatelet Rx	80	79	0.86
Preoperative aspirin	66	72	0.36
Preoperative clopidogrel	37	35	0.77
Preoperative total cholesterol	179.9 ± 40.5	187.8 ± 37.7	0.15
Preoperative triglycerides	223.2 ± 153.8	223.0 ± 169.7	0.99
Indications for CEA			0.78
Asymptomatic	45 (45.0)	45 (45.0)	1.0
Amaurosis fugax and/or hemispheric TIA	41 (41.0)	36 (36.0)	0.56
Stroke	8 (8.0)	11 (11.0)	0.63
Nonhemispheric TIA	6 (6.0)	8 (8.0)	0.78

Significance testing by either χ^2, Fisher exact, or two-tailed t-tests (with F-tests for variance).

Table II. Perioperative data by patch

	ACCUSEAL	*Finesse*	P-*Value*
Number of CEA (N)	100	100	
Left side CEA	54	53	
Right side CEA	46	47	0.89
Stenosis of operated vessel			0.30
50%-59%	6	3	0.50
60%-69%	16	24	0.22
70%-99%	78	73	0.51
ICA diameter (mm)	5.3 ± 0.8	5.5 ± 1.0	0.35
Arteriotomy length (cm)	4.4 ± 0.8	4.5 ± 0.8	0.35
Skin to skin operative time (mins)	97.4 ± 23.7	95.9 ± 18.7	0.61
Hemostasis time (mins)	5.17 ± 5.2	3.73 ± 2.7	0.01

Significance testing by either χ^2, Fisher exact, or two-tailed t-tests (with F-tests for variance).

Table III. Morbidity and mortality data by patch

	ACCUSEAL	*Finesse*	P-*Value*
Number of CEA (N)	100	100	
Any perioperative neurological event	2	4	0.68
Stroke (ipsilateral)	2	2	1.0
TIA (ipsilateral)	0	2	0.5
Perioperative mortality	1*	0	1.00
Restenosis (≥50%) at 30-day U/S	0	4	0.12
50%-59%	0	1	1.0
60%-69%	0	0	1.0
70%-99%	0	1	1.0
Thrombosis	0	2	0.5
Combined perioperative neurological events (TIA/stroke, ≥50% restenosis, or carotid thrombosis)†	2	8	0.1

*Patient is 1 of 2 with perioperative stroke. Significance testing by either χ^2, Fisher exact or two-tailed t-tests (with F-tests for variance).
†Number of patients.

Table III summarizes perioperative morbidity and mortality for both patches. As noted, the perioperative ipsilateral stroke rate was 2% in both patches. The overall perioperative neurologic event (TIA/stroke) rate was 2% for the ACUSEAL patches vs 4% for Finesse patches, however, this difference was not significant ($P = .68$). There was one perioperative death in the ACUSEAL patch group, which was the same patient who suffered a stroke, whereas the Finesse patch had 0% perioperative mortality. In the two patients with ACUSEAL patching who suffered perioperative strokes, one was discovered in the operating room, and the other occurred on postoperative day three. The patient who had a neurologic deficit in the operating room underwent immediate intraoperative angiogram, followed by exploration with thrombectomy to remove what was felt to be white clots and was repatched. The patient recovered from her stroke in less than 1 week and had a normal duplex exam at 30 days. The other patient had a normal postoperative duplex ultrasound exam without residual stenosis, but suffered an embolic stroke that was treated with heparin therapy, which led to a cerebral hemorrhage and death, 3 days postoperatively.

Two patients with Finesse patching had perioperative minor strokes, one was noted in the recovery room and one in the operating room. Both patients had normal postoperative carotid duplex ultrasounds and were treated with antiplatelet therapy. Two other patients with Finesse patching had perioperative TIAs, one was noted in the recovery room and had a normal carotid duplex ultrasound and was treated with antiplatelet therapy; the other patient had a TIA 2 weeks postoperatively with a normal carotid duplex ultrasound and was also treated with antiplatelet therapy.

There were two patients in each group (n = 4 total) with residual stenosis of <50%, all of whom were asymptomatic. The incidence of ≥50% restenosis at 30 days was 0% for the ACUSEAL patch vs 4% for the Finesse patch (this included one patient with asymptomatic 50% to less than 60% stenosis, one patient with asymptomatic 70% to less than 99% stenosis, and two with asymptomatic perioperative carotid thrombosis, $P = .5$, and both were noted at 30 days postoperatively).

The combined incidence of perioperative neurological events (TIA/stroke) and ≥50% restenosis or carotid thrombosis was 2% for the ACUSEAL patch vs 8% for the Finesse patch ($P = .10$).

DISCUSSION

Recently, a systematic review of randomized controlled trials comparing primary closure vs patching,[6] concluded that patch angioplasty decreases the risk of perioperative death or stroke as well as long-term risk of ipsilateral ischemic events. Despite this conclusion that routine patching should be recommended based on literature support, the use of autologous vs prosthetic patching was unsettled. Autologous tissue either by jugular vein or saphenous vein, has shown good results.[1,7] However, most institutions use a synthetic patch for multiple reasons such as: eliminating wound-related complications secondary to autologous vein harvesting, leaving vein conduits intact and readily available for potential future coronary or peripheral revascularizations, and reduced incidence of patch rupture and aneurysmal changes.[8,9] Although infection of a carotid patch is a feared complication, we did not see any patch infections in this series.

Bleeding has been the Achilles heel of the PTFE patch. In our previous comparison of conventional PTFE with Hemashield, bleeding was significantly longer with a mean hemostasis time of 14 minutes for PTFE compared with 3 minutes with the Hemashield patch.[2] Hemostasis time in the current series with the improved PTFE ACUSEAL patch was 5 minutes, which was similar to the 3 minute time reported in our recent report with this patch.[4] Despite this improved hemostasis time compared with the traditional PTFE patch, the Finesse patch had a shorter hemostasis time with a mean of three minutes, although most would consider such a time difference clinically insignificant.

A criticism of our previous randomized study comparing the conventional PTFE to the Hemashield was that we used a PTFE suture (TT-9 needle, CV-6 suture) in the PTFE group only.[2] Hence, in the current series we used 6-0 Prolene sutures in both groups. The use of the PTFE suture has been shown to reduce needle hole bleeding in modified PTFE patch with a design of needle/suture diameter ratio of 1:1.[10,11]

Overall comparison of perioperative neurological events between the two patches did not demonstrate any statistically significant differences. The overall neurological event rate of the new modified PTFE patch was similar to that found with conventional PTFE reported in our previous randomized trial. (2% vs 3%, respectively). However, the Finesse patch produced better results than those previously achieved with the conventional Hemashield patch (4% vs 12% respectively). Additionally, the number of patients with >50% stenosis at 30-day duplex exam was reduced from 12% in the previous series to 4% using the Finesse patch. The ACUSEAL PTFE patch was comparable

to the conventional PTFE for restenosis, with no patients with duplex findings of >50% stenosis at 30 days in the current series compared with our previous report of 2%.[12]

One concern with the use of the conventional Dacron-Hemashield patches was the thrombogenic nature of this patch, as five perioperative carotid thromboses occurred in our previous experience. The Finesse patch was associated with two perioperative carotid thromboses, compared with none in the ACUSEAL patch group. However, this difference was not statistically significant. Long-term follow-up will be needed to evaluate any potential differences in the rate of late restenosis and thrombosis between the two patches.

Overall, the results of this study show equally good outcomes from both patches. There was no statistically significant difference in deaths, stroke rates, TIA rates, or in early restenosis. Although a significant difference did appear in the hemostatic time, it is probably a finding of limited clinical significance.

AUTHOR CONTRIBUTIONS

Conception and design: AA, PS
Analysis and interpretation: AA, SF
Data collection: PA, ZA
Writing the article: AA, PS
Critical revision of the article: AA, PS
Final approval of the article: AA, PS, SF, ZA
Statistical analysis: AA, SF
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