Prospective randomized trial of ACUSEAL (Gore-Tex) vs Finesse (Hemashield) patching during carotid endarterectomy: Long-term outcome

Ali F. AbuRahma, MD,[a] Patrick A. Stone, MD,[a] Michael Elmore, MD,[a] Sarah K. Flaherty, BS,[b] Lauren Armistead, MD,[a†] and **Zachary AbuRahma,[a]** *Charleston, WV*

Background: **Several studies have reported that carotid endarterectomy with patch angioplasty is superior to primary closure. Conventional polytetrafluoroethylene (Gore-Tex, W. L. Gore & Associates, Flagstaff, Ariz) patching has been shown to have results similar to autogenous saphenous vein patching; however, it requires a longer hemostasis time. This study examined the long-term clinical outcome and incidence of restenosis after carotid endarterectomy using the new ACUSEAL (Gore-Tex) patching vs Hemashield Finesse (Boston Scientific Corp, Natick, Mass) patching.**

Methods: **The study randomized 200 patients (1:1) undergoing carotid endarterectomy to 100 with ACUSEAL patching and 100 with Hemashield-Finesse patching. All patients underwent immediate and 1-month postoperative duplex ultrasound studies, which were repeated at 6-month intervals. Kaplan-Meier analysis was used to estimate the freedom from stroke, stroke-free survival, and the risk of restenosis for both groups.**

Results: **The demographic and clinical characteristics, the mean operative diameter of the internal carotid artery, and the length of the arteriotomy were similar in both groups. The mean hemostasis time was 5.1 for the ACUSEAL patching vs 3.7 minutes for Finesse patching ($P = .01$); however, the mean operative times were similar for both groups ($P = .61$). The incidence of ipsilateral stroke was 2% for ACUSEAL patching (both early perioperative strokes) vs 3% for Finesse patching (2 early and 1 late stroke) at a mean follow-up of 21 months. The respective cumulative stroke-free rates at 1, 2, and 3 years were 98%, 98%, and 98% for ACUSEAL patching vs 97%, 97%, and 97% for Finesse patching ($P = .7$). The respective cumulative stroke-free survival rates at 1, 2, and 3 years were 97%, 92%, and 88% for ACUSEAL patching vs 96%, 96%, and 91% for Finesse patching ($P = .6$). The respective freedom from ≥70% carotid restenosis at 1, 2, and 3 years was 98%, 96%, and 89% for ACUSEAL patching vs 92%, 85%, and 79% for Finesse patching ($P = .04$).**

Conclusions: **Carotid endarterectomy with ACUSEAL patching and Finesse patching had similar stroke-free rates and stroke-free survival rates. The mean hemostasis time for the ACUSEAL patch was 1.4 minutes longer than that for the Finesse patch; however, the Finesse patch had higher restenosis rates than the ACUSEAL patch. (J Vasc Surg 2008;48: 99-103.)**

Carotid endarterectomy (CEA) with patch angioplasty has been shown by multiple clinical trials to be more effective than CEA with primary closure in decreasing the incidence of perioperative stroke, perioperative carotid thrombosis, and late restenosis.[1-7] The ideal carotid patch has yet to be identified. Proponents of synthetic patches and of autogenous vein patches have yet to reach a consensus on the optimal patch material.[1-7]

Several studies have shown comparable results using autogenous vein patching and polytetrafluoroethylene (PTFE) patching,[2,3,5,8,9] and also between autogenous vein patching and Dacron patching.[2,10-12] Several advantages of synthetic patches compared with vein patches have been cited, including decreased operative times, decreased incidence of aneurysmal dilatation or patch rupture, availability, and avoiding harvest site complications. Few studies, however, have demonstrated a prolonged hemostasis time when using PTFE patches.[5,8,13,14] Because of this concern, W. L. Gore & Associates Inc (Flagstaff, AZ) introduced a new modified PTFE patch (ACUSEAL) in the last few years, which it claims has a better hemostasis time than conventional PTFE patching.

We previously reported results from a prospective study using the ACUSEAL patch, showing bleeding times similar to historic results (3 minutes) of the Dacron patch.[15] Meanwhile, within the last few years, a new collagen-impregnated Dacron patch was released, Finesse (Boston Scientific Corp, Natick, Mass), that was designed to limit its thrombogenicity. We reported previously on the early results from the prospective randomized trial that compared these two commercially available patches used during CEA.[16] The purpose of this study is to report on the late follow-up of both of these patches.

Patient population and methods. This study randomly assigned 200 patients undergoing CEA to arteriotomy closure with the ACUSEAL PTFE patch or with the Finesse collagen-impregnated Dacron patch. The Gore-Tex ACUSEAL cardiovascular patch uses advanced fluoropolymer technology enabling it to "seal" around pene-

From the Department of Surgery,[a] Robert C. Byrd Health Sciences Center, West Virginia University, and Charleston Area Medical Center.[b]
†Deceased.
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Reprint requests: Ali F. AbuRahma, MD, Department of Surgery, Robert C. Byrd Health Sciences Center, West Virginia University, 3110 MacCorkle Ave, SE, Charleston, WV 25304 (e-mail: ali.aburahma@camc.org).
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trating sutures and decrease suture line bleeding by as much as 88%. This, combined with improved suture retention and multidirectional strength, sets the patch apart from other PTFE patches. Increased sealing of suture holes to minimize bleeding is achieved by including a middle layer of a proprietary thermoplastic fluoropolymer with elastic properties. The addition of the dense middle layer actually increases the suture retention by approximately 10%. The Finesse patch is an ultrathin knitted polyester fabric that is impregnated with highly purified collagen, which is present on both sides of the patch, to minimize bleeding.

This study was conducted between August 2003 and October 2005 and was approved by the Institutional Review Board of Charleston Area Medical Center, Robert C. Byrd Health Sciences Center of West Virginia University. Patients undergoing CEA with concomitant coronary artery bypass grafting, re-do CEAs, and patients with high cervical lesions and severely elongated (kinked) arteries were excluded from this study.

All patients underwent color carotid duplex ultrasound (DUS) imaging or magnetic resonance angiography, or both, to determine preoperative stenosis. All demographic and clinical characteristics were recorded.

Randomization in a 1:1 ratio was accomplished by using sealed opaque envelopes, each containing a slip of paper with the patient's patch assignment. Details of the randomization and the operative techniques have been described previously.[16] In summary, all ACUSEAL PTFE patches and Finesse Hemashield patches were sutured using 6-0 Prolene suture (Ethicon, Summerville, NJ). Dextran-40 was given intravenously (25 mL/h) at the time of the CEA and continued for 24 hours.

After completion of patching and release of the carotid clamps, 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 intervals. Time required for repair stitches, such as for localized poor opposition of the arterial wall and patches, was excluded. All patients were started on an aspirin regimen (325 mg daily) ≤24 hours of their surgery, and this was continued indefinitely.

Surveillance protocol. Immediate postoperative DUS scans, done in the operating room, if scanning equipment and technician were available, otherwise ≤24 hours, were obtained using an ATL HDI-5000 system (Advanced Technology Laboratory, Phillips, Bellevue, Wash). All patients underwent clinical observation and an examination by another surgeon who was blinded to the type of patch. All patients underwent repeat carotid DUS studies at 30 days, which was repeated at 6 months and every 6 months thereafter. Carotid restenosis of >70% was defined by a peak systolic velocity of >150 cm/s on DUS examination with spectral broadening through systole and an end-diastolic velocity of >90 cm/s.[17]

Table. Overall morbidity and mortality by patch type

	ACUSEAL, No.	*Finesse, No.*	P[a]
CEA	100	100	...
Ipsilateral strokes (early and late)	2	3	>.99
Early stroke	2	2	
Late stroke	0	1	
All ipsilateral TIAs (early and late)	3	6	.498
Early TIA	0	2	
Late TIA	3	4	
All TIAs and strokes	5	9	.407
All-cause mortality	6	3	.498
Stroke mortality	1	0	
All TIA, stroke or death	10	12	.822
≥70% restenosis	4	12[b]	.07

CEA, Carotid endarterectomy; *TIA*, Transient ischemic attack.
[a]By Fisher exact test or χ^2, where appropriate.
[b]This includes 2 carotid occlusions.

Transient ischemic attack (TIA) was defined as a transient neurologic deficit lasting <24 hours. A stroke was defined as a neurologic deficit lasting >24 hours.

Statistical analysis. All statistical analyses were performed using SAS software (SAS Inc, Cary, NC). Continuous variables were compared using the two-tailed Student *t* test for independent measures and are represented as mean and standard deviation (SD). Morbidity rates and other categoric variables were analyzed with χ^2 or Fisher exact test. A value of $P < .05$ was considered statistically significant. A Kaplan-Meier analysis was used to estimate the freedom from stroke, stroke-free survival, and the risk of restenosis for both groups.

RESULTS

As indicated in our previous study,[16] the differences in demographic and clinical characteristics in both groups were not statistically significant. The mean operative diameter of the internal carotid artery and the length of the arteriotomy were also similar in both groups.[16] The mean (SD) hemostasis time for the ACUSEAL patch was 5.17 (5.2) minutes, with a median of 4 minutes (range, 0-35 minutes) vs a mean of 3.7 (2.7) minutes for the Finesse patch (range, 0-15 minutes; $P = .01$). The mean operative times were similar for both groups ($P = .61$). The mean follow-up of 21 months was also similar in both groups. The perioperative morbidity and mortality were comparable and have been reported previously.[16]

The incidence of ipsilateral stroke was 2% for the ACUSEAL patch (both early perioperative strokes) vs 3% for the Finesse patch (2 early perioperative strokes, 1 late stroke associated with ≥70% restenosis) at a mean follow-up of 21 months. The combined (early and late) TIA and stroke and asymptomatic ≥70% restenosis rate was 7% for ACUSEAL patching vs 17% for the Finesse patching ($P = .048$).

Table I summarizes the overall TIA, ipsilateral stroke, morbidity, and mortality rate according to the type of patch. Two patients with ACUSEAL patching sustained perioperative ipsilateral strokes. One patient had a normal

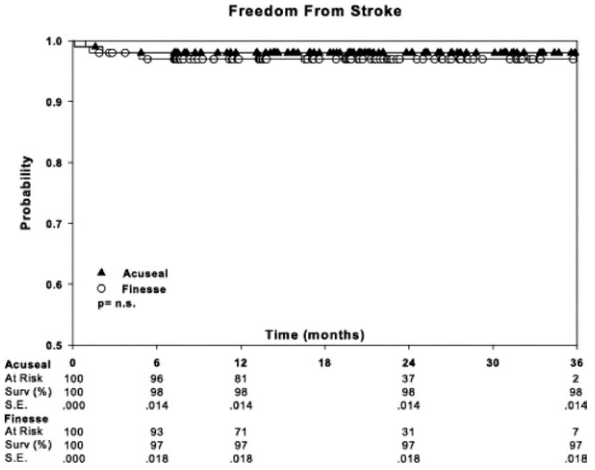

Fig 1. Kaplan-Meier analysis for freedom from stroke using ACUSEAL (*triangles*) and Finesse patching (*circles*).

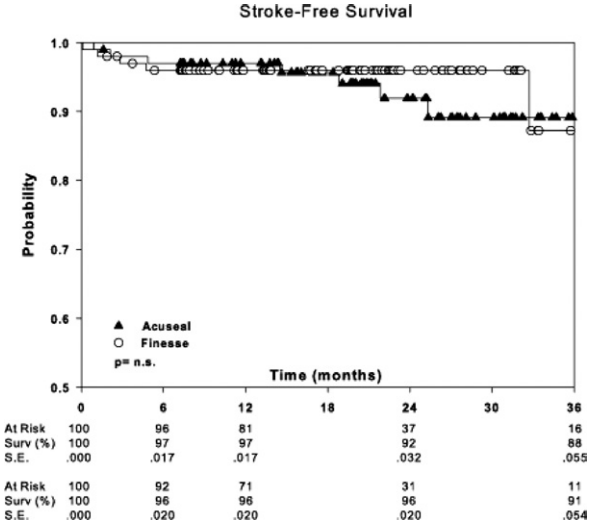

Fig 2. Kaplan-Meier analysis for stroke-free survival using ACUSEAL (*triangles*) and Finesse patching (*circles*).

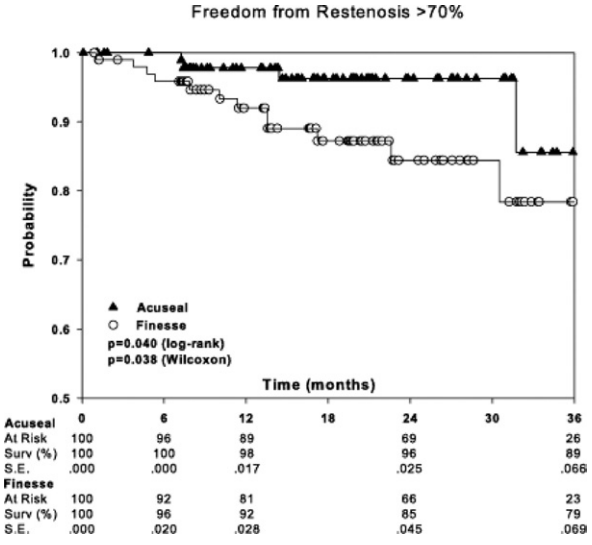

Fig 3. Kaplan-Meier analysis for freedom from >70% restenosis using ACUSEAL (*triangles*) and Finesse patching (*circles*).

result on carotid DUS but died perioperatively. The other patient had a neurologic deficit in the operating room and underwent an immediate intraoperative angiogram, followed by exploration with thrombectomy to remove what was thought to be white clots (with no carotid occlusion), and was re-patched. The patient recovered from her stroke ≤1 week and had a normal DUS study result at 30 days.

Two patients with Finesse patching had minor perioperative ipsilateral strokes with normal postoperative carotid DUS studies, and one patient had a late stroke, which was associated with ≥70% restenosis. Three patients with ACUSEAL patching had late TIAs; two were associated with ≥70% restenosis and were treated with carotid artery stenting, and the third patient had no restenosis. In contrast, six patients with Finesse patching had TIAs; two were early perioperative TIAs with normal carotid DUS scans, and four were late TIAs, three of which were associated with ≥70% restenosis, which were treated with carotid artery stenting, and one patient had no restenosis.

As noted in Fig 1, the rates of freedom from stroke (ipsilateral) at 1, 2, and 3 years were, respectively, 98%, 98%, and 98% for ACUSEAL vs 97%, 97%, and 97% for Finesse (the log-rank, $P = .65$). Fig 2 summarizes the stroke-free survival rates for both patches. The ipsilateral stroke-free survival rates at 1, 2, and 3 years were, respectively, 97%, 92%, and 88% for ACUSEAL vs 96%, 96%, and 91% for Finesse (log-rank $P = .60$). Fig 3 summarizes the rate of freedom from ≥70% restenosis at 1, 2, and 3 years, which was, respectively, 98%, 96%, and 89% for ACUSEAL vs 92%, 85%, and 79% for Finesse (log-rank $P = .04$).

Overall, four patients with ACUSEAL patching had ≥70% restenosis, two of whom were symptomatic (TIA) vs 12 patients with Finesse patching, four of whom were symptomatic (3 late TIAs and 1 late stroke). Overall, four patients with ACUSEAL patching had ≥70% to 99% restenosis and three underwent carotid artery stenting, compared with 10 patients with Finesse patching who had ≥70% to 99% restenosis, of whom four underwent carotid artery stenting and six were observed.

DISCUSSION

Several studies, including a recent systematic review of randomized controlled trials, have confirmed that CEA with patch angioplasty decreases perioperative stroke rates, perioperative carotid thrombosis, and recurrent carotid stenosis compared with primary repair.[1-7,18] However, no specific patch material has been shown to be superior.[4,9] The prevention of early thrombosis with patch closure occurs by changing flow characteristics and by widening the artery. Patching reduces the incidence of intimal hyperpla-

sia.[19,20] Bond et al[7] and Counsell et al[9] performed a systematic review of randomized carotid trials and concluded that the results of synthetic and autogenous vein patching were similar.[9] Many authorities, however, prefer a synthetic patch because it is readily available, eliminates wound complications from vein harvest sites, reduces potential patch ruptures or aneurysmal changes, and preserves the autogenous vein for future coronary or peripheral revascularizations.

One of the main criticisms of the conventional PTFE patch is the hemostasis time.[5,8,13,14] We previously demonstrated a mean hemostasis time of 14 minutes for the conventional PTFE patch and only 3 minutes for the new ACUSEAL patch.[15] Although the difference between the 5-minute hemostasis time for the ACUSEAL patch and the 3.7-minute hemostasis time for the Finesse patch was statistically significant, its clinical significance is debatable in this present study.

The overall comparison of perioperative (30-day) ipsilateral stroke or TIA events between the two patches did not demonstrate any statistically significant differences. The ACUSEAL patch had an overall neurologic event rate of 2% (2 ipsilateral strokes), and the Finesse patch had a rate of 4% (2 ipsilateral strokes; 2 TIAs).[16]

In contrast, the late results, with a mean follow-up time of 21 months, showed some statistically significant outcomes, particularly in restenosis rates. Similar results were found between the patches for overall neurologic events (TIA/ipsilateral strokes), but the combination of all neurologic events with asymptomatic ≥70% restenosis rates was statistically significantly better for the ACUSEAL patch ($P = .048$).

The freedom from ≥70% restenosis events at 1, 2, and 3 years was, respectively, 98%, 96%, and 89% for ACUSEAL patching vs 92%, 85%, and 79% for Finesse patching ($P = .04$). Of the 12 patients in this category for the Finesse patch, two had perioperative carotid occlusions in contrast to no carotid occlusions with the ACUSEAL patch. It should be noted that our criteria for defining >70% stenosis has been published previously,[17] with a sensitivity of 85%, specificity of 95%, positive-predictive value of 91%, negative-predictive value of 92%, and an overall accuracy of 92%. All patients with >70% restenosis according to our criteria were also verified using the consensus criteria for carotid stenosis that were published previously (a peak systolic velocity of ≥230 cm/s).[21]

Overall, two of four ACUSEAL patients and four of 12 Finesse patients with >70% restenosis became symptomatic. The ACUSEAL group included two TIAs, whereas the Finesse group included three TIAs and one ipsilateral stroke. All six symptomatic patients underwent successful carotid artery stenting, as did one asymptomatic ACUSEAL patient.

The late results of the ACUSEAL PTFE patching in the present study were similar to what we published previously using the same patch.[15] To our knowledge, no other studies have been reported using the ACUSEAL patch after CEA. Meanwhile, the early and late results of the Finesse Dacron patch in the present study were superior to our past experience using the conventional Dacron Hemashield patch, which had a higher perioperative carotid thrombosis rate of 5% vs 2% in the present series.[20] In a previously published prospective randomized trial of CEA with primary closure vs patching using saphenous vein, jugular vein, and PTFE patching, a multiple linear regression analysis showed that the incidence of >50% restenosis was associated more strongly with primary closure and female sex. However, no statistically significant differences in female sex was noted in our present study between ACUSEAL patching and Finesse patching.[5]

To our knowledge, no data have been published using Finesse Dacron patches after CEA. However, Ricco et al[22] analyzed the use of collagen-impregnated knitted polyester patches (Hemacarotid patch, Ultrathin, Intervascular, W.L. Gore & Associates, Flagstaff, Ariz) in 221 CEAs and reported a 1.8% ipsilateral occlusion rate with a 1.4% ipsilateral stroke rate and a 1.4% ipsilateral TIA rate. They also reported that the percentage of women free from a >50% restenosis was 82% at 3 years, compared with 90% for men for the same period ($P = .035$). Because of these results, they concluded that the use of these patches should be restricted to men.

The data presented in this study raise the question of whether this Hemashield patch is thrombogenic in the carotid location. Collagen-impregnated Dacron has gained wide acceptance as a conduit in aortic aneurysm repair and in aortoiliac reconstruction since the mid-1980s. Implantation of various grafts in dogs showed medium-porosity knitted Dacron to have better endothelial coverage, perigraft attachment, and thrombus-free surface than collagen-impregnated knitted Dacron.[23] It is possible that the bovine collagen found in collagen-impregnated knitted Dacron grafts does not experience the "washout" of collagen in the carotid artery as fast as it does in a large-diameter high-flow conduit such as an aortic graft. Several authors have shown in animal experimental models that Dacron prostheses have different characteristics when placed in the thoracic and abdominal aorta[24] and in the carotid and femoral sites.[25] The environment of the endarterectomized carotid artery is very different from that of the aorta, mainly because of the presence of denuded adventitia with its exposed collagen along the carotid bifurcation. Studies have shown increased platelet deposition on both PTFE and knitted Dacron, with a greater deposition on knitted Dacron.[26]

CONCLUSION

Carotid endarterectomy with ACUSEAL patching and Finesse patching had similar ipsilateral stroke and stroke survival rates. The mean hemostasis time for the ACCUSEAL patch was 1.4 minutes longer than that for the Finesse patch; however, the Finesse patch had higher restenosis rates than the ACCUSEAL patch.

AUTHOR CONTRIBUTIONS

Conception and design: AA, PS
Analysis and interpretation: AA, SF
Data collection: ME, LA, ZA
Writing the article: AA, PS, ME
Critical revision of the article: AA, SF
FINAL approval of the article: AA, PS, ME, SF, ZA
Statistical analysis: AA, SF
Obtained funding: Not applicable
Overall responsibility: AA

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