

# Carotid endarterectomy with a polyurethane patch versus primary closure: A prospective randomized study

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**Introduction:** The use of synthetic patch angioplasty during carotid endarterectomy (CEA) has been advocated to reduce restenosis, stroke, and death, but the type of material used is still being debated. This study compared rate of restenosis, neurologic events, and perioperative death in patients undergoing CEA with primary closure versus polyester urethane patch closure.

**Patients and Methods:** In a prospective randomized study, we compared patch angioplasty with polyester urethane (Vascular-patch, B. Braun Medical AG, Tuttlingen, Germany) to primary closure between February 1999 and March 2002 in 404 operations. Early (30-day) stroke and mortality rate, long-term restenosis, and neurologic events were compared in the two groups during 2.5 to 5 years of follow-up (median follow-up, 2 years).

**Results:** Primary closure was used in 216 operations, and patch angioplasty was used in 206. Clamping time was significantly shorter in the primary closure group ( $P < .001$ ). Perioperative mortality and neurologic events were similar in both groups (1.9% vs 3.9%,  $P = .21$ , odds ratio [OR], 2.1; 95% confidence interval [CI], 0.56 to 9.85). The rate of residual stenosis ( $\geq 50\%$ ) at 0 or 3-month follow-up was significantly lower in the patch group (2 operations, 1.1%) compared with the primary closure group (17 operations, 8.9%) ( $P = .001$ , OR, 0.114; 95% CI, 0.026 to 0.5). Multivariable logistic regression showed that only primary closure was found to influence residual stenosis. Restenosis of 70% was significantly less in the patch angioplasty group (2.2% vs 8.6%) ( $P = .01$ , hazard ratio, 0.246; 95% CI, 0.08 to 0.75). No correlation was found between restenosis and gender, preoperative symptoms, or risk factors.

**Conclusions:** Patch angioplasty with polyester urethane significantly reduced the restenosis rate ( $P = .01$ ) compared with primary closure. Even though clamping time was longer, patching was not associated with more perioperative complications. (J Vasc Surg 2005;41:403-8.)

Carotid endarterectomy is the treatment of choice for patients with symptomatic and asymptomatic high-grade carotid stenosis.<sup>1-3</sup> The form of arteriotomy closure has been examined in recent reviews of the Cochrane Library,<sup>4-5</sup> and seven trials comprising 1300 operations were evaluated to assess the effect of routine or selective carotid patch angioplasty compared with primary closure. In these reviews, carotid patch angioplasty showed a reduction in the risk of stroke and death during the perioperative period and in long-term follow-up. It also demonstrated a reduction in perioperative arterial occlusion and decreased restenosis in long-term follow-up. No difference was found in the incidence of hemorrhage, infection, cranial nerve palsies, or pseudo-aneurysm formation.

There is controversy about which patch material is optimal for use. Currently used materials include autologous vein, polytetrafluoroethylene (PTFE), polyester, and bovine pericardium. A recent review of the Cochrane Library compared different patch materials.<sup>6</sup> The differences found were very small, although one trial found PTFE patches to be superior to collagen-impregnated Dacron

grafts in terms of perioperative stroke and restenosis. Pseudoaneurysms were more common after a vein patch than with a synthetic patch.

Prosthetic patches are readily available, technically easy to use, and may reduce the risk for rupture and aneurysmal dilatation previously reported in saphenous vein patch graft after carotid endarterectomy.<sup>7-9</sup> Infection is a serious possible complication of synthetic patch angioplasty but can be treated with reasonable success.<sup>10-12</sup>

In our review of the literature, we did not find studies that the evaluated restenosis rate and postoperative complications after polyester urethane patch angioplasty. To study these questions, we conducted a prospective randomized study of polyester urethane patch angioplasty versus primary closure after CEA.

## METHODS

Between February 1999 and March 2002, all patients undergoing CEA in the Carmel Medical Center vascular department who consented to participate in this study were prospectively randomized into two groups (404 patients, 422 operations). Group 1 had primary closure of the arteriotomy (216 operations), and group 2 had polyester urethane patch angioplasty (206 operations) (Vascular-patch, B. Braun Medical AG, Tuttlingen, Germany).

The scrub nurse, using sealed envelopes, did the randomization in the operating room. Twenty-four patients were excluded because intraoperative findings such as small diameter internal carotid artery (ICA) or the need for an

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Competition of interest: none.

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interposition graft precluded using the original patient assignment to the two treatment groups.

Preoperative data were age, gender, hypertension, nicotine use, ischemic heart disease, diabetes mellitus, hypercholesterolemia/hyperlipidemia, previous vascular surgery, and a history of carotid symptoms, including stroke, transient ischemic attack (TIA), silent brain ischemia on computed tomography (CT) scan, and asymptomatic. Results of preoperative imaging (duplex scanning, CT angiography [CTA], angiography) were also noted. Intraoperative data, including systemic and stump pressures, clamping time, and type of carotid closure were recorded.

All operations were performed under cervical block unless the patient could not tolerate local anesthesia due to low compliance (nine patients). An intraluminal shunt was used in cases of change in neurologic status during carotid clamping or in patients undergoing general anesthesia with a stump pressure <40 mm Hg. Intravenous heparin (5000 U) was administered to all patients before carotid clamping.

After the operation, all patients were monitored for 6 hours in the recovery room and received intravenous heparin (500 U/24 h). All patients received aspirin (100 mg once daily) pre- and postoperatively and were usually discharged on the second postoperative day.

Postoperative evaluation included a duplex scan at 1, 3, 6, and 12 months, and annually thereafter up to 5 years. All patients were contacted by telephone to ensure regular follow-up.

The primary endpoint of this study was the postoperative incidence of residual disease = 3 months and restenosis >3 months. Secondary endpoints were perioperative morbidity and mortality, and stroke-free and overall survival.

Duplex ultrasound scanning was used as the primary imaging tool for the determination of residual and recurrent carotid stenosis. The duplex study was performed by an HDI 3500 and HDI 3000 (Philips) using a 4-7 Mhz transducer. The patients, ultrasound technicians, and doctors were blinded to the type of arteriotomy closure. In our noninvasive vascular laboratory, the degree of carotid stenosis is reported as grades 1 to 5:

- Grade 1: 0% to 25%, peak systolic velocity (PSV) of 125 to 130 cm/s, end diastolic velocity (EDV) <40 cm/s.
- Grade 2: 26% to 50%, PSV, 131 to 150 cm/s; EDV <40 cm/s.
- Grade 3: 51% to 70%, PSV, 151 to 170 cm/s, EDV <110 cm/s, PSV in the ICA and PSV in the common carotid artery (CCA) ( $PSV_{ICA}/PSV_{CCA}$ ) > 3.2 to 4.
- Grade 4: 71% to 90%, PSV >171cm/s, EDV 110 to 140 cm/s,  $PSV_{ICA}/PSV_{CCA}$  >4.
- Grade 5: 91% to 99%, EDV >140cm/s,  $PSV_{ICA}/PSV_{CCA}$  >4 or string sign.
- Grade 6: occluded. Cases of suspected occlusion were validated by high-resolution CTA

Recurrent stenosis for this study was defined as luminal diameter stenosis >70% as diagnosed by follow-up duplex ultrasound examination. We also reported the recurrent

stenosis of >50% because some of the previous studies in this area have defined restenosis as >50%. No intraoperative before or after CEA imaging was used. The hospital board of ethics and the ministry of health (HTA 920) approved this clinical trial.

**Statistical analysis.** We constructed this study to address the main question of residual and recurrent stenosis. With a recurrent stenosis of about 10% in large controlled trials,<sup>4-6</sup> we calculated that a sample size of 200 in each group was needed to detect a reduction in restenosis from 10% to 3%.

Binary demographics (gender), baseline risk factors, and outcome variables (shunt, complications and residual stenosis) were compared between treatment groups using the  $\chi^2$  test, the Fisher exact test when appropriate, and odds ratios (OR) along with 95% confidence interval (CI). Continuous demographics (age) and outcome variables (clamp time, stump pressure) were summarized using mean  $\pm$  standard deviation and were compared between groups by using the *t* test.

Survival and restenosis-free proportions were calculated and presented using Kaplan-Meier survival curves. The log-rank test was used to test differences between groups in event-free curves. The multivariate Cox proportional hazard model was used to adjust treatment comparisons to demographics and baseline risk factors and to test interactions.

The unit of observation for the analyses was the operated artery, except for the demographics and time-to-death analyses where patients with bilateral operations were considered at their first procedure. All statistical tests were two-sided, with a 5% significance level.

Analyses were performed with the Statistical Package for the Social Sciences (SPSS) (version 11) (SPSS, Inc.) and Statistical Analysis System (SAS) SAS (version 9.1) (SAS Institute, Inc.) software.

## RESULTS

Four hundred four patients (265 men, 157 women) underwent 422 procedures. Thirteen (3%) were lost to follow-up, which ranged from 1 month to 5 years (median, 2 years). Primary closure was used in 216 operations and patch angioplasty in 206. There was no difference between the study groups with regard to patients lost to follow-up, gender, baseline risk factors, or preoperative symptoms. The mean age was  $71 \pm 8.5$  years in the primary closure group and  $68 \pm 9.4$  years in the patch angioplasty group ( $P = .002$ ). Preoperative demographics are listed in Table I.

A shunt was used in 80 operations (51 in the patch group, 29 in the primary closure group) ( $P = .003$ , OR, 2.12; 95% CI, 1.28 to 3.51). The clamping time was significantly longer ( $P < .001$ ) for the patch group ( $35 \pm 11$  minutes) versus the primary closure group ( $23 \pm 8$  minutes).

**Early mortality and morbidity rates.** One patient (0.2%) died during the first postoperative month from a myocardial infarction. Eleven patients experienced an im-

**Table I.** Preoperative patient demographic data

	Primary closure n (%)	Patch n (%)	P
Gender*			.26
Male	131 (63)	134 (68)	
Female	77 (37)	62 (32)	
Age (mean ± SD)	71 ± 8.5	68 ± 9.4	.002
Smoker	34 (16)	48 (23)	.05
Hypertension	155 (72)	146 (71)	.84
Diabetes mellitus	74 (34)	76 (37)	.57
Dyslipidemia	96 (44)	99 (48)	.46
Ischemic heart disease	108 (50)	95 (46)	.45
Previous vascular surgery (CABG, CEA, peripheral bypass)	72 (33)	71 (34)	.8
Preoperative symptoms			0.6
Asymptomatic	109 (51)	108 (52)	
Transient ischemic attack	69 (32)	57 (28)	
Stroke	38 (18)	41 (20)	

CABG, coronary artery bypass graft; CEA, carotid endarterectomy.  
\*At first surgery for patients with bilateral surgery.

**Table II.** Immediate postoperative complications (30-day)

	Primary closure	Patch closure
Neurologic events		
TIA	2	5
Stroke	1	3
Bleeding	3	5
Infection	6	1
Coronary event*	3	0
Cranial nerve damage	7	5

TIA, Transient ischemic attack.

Any complications:  $P = .86$  (odds ratio, 0.94; 95% confidence interval, 0.47 to 1.9).

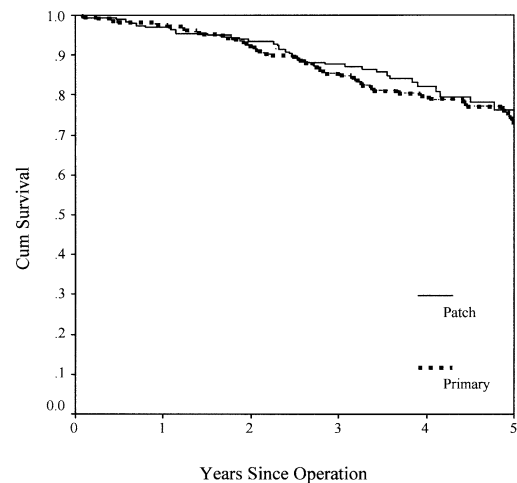
Any neurologic events:  $P = .21$  (odds ratio, 2.14; 95% confidence interval, 0.56 to 9.85).

\*All coronary events were myocardial infarctions with elevated troponin levels.

mediately nonfatal postoperative neurologic event, 3 patients after primary closure (1 cerebrovascular accident [CVA], 2 TIA) and 8 patients after patch angioplasty (3 CVA, 5 TIA) (Table II). There was no statistical difference in the rate of neurologic events between the two groups ( $P = .21$ , OR, 2.14; 95% CI, 0.56 to 9.85). The combined postoperative mortality and stroke rate was 1.2%.

In the primary closure group, two patients underwent re-exploration. In one patient, a dissection was found at the arteriotomy site and treated with a vein graft repair. The other patient had a white clot removed and the artery was closed with an interposition Gortex graft (WL Gore & Associates).

Three patients with patch closure underwent re-exploration. In two, a thrombus was found at the arteriotomy site and was removed. One was treated with an interposition 6-mm Gortex graft, the other with a Dacron patch. In the third patient, the thrombus was found distal



Numbers at risk:

Primary	208	203	192	152	104	49
Patch	196	190	183	142	74	22

**Fig 1.** Kaplan-Meier analysis shows cumulative survival rate for primary closure and patch angioplasty. Numbers at risk are shown at 1-year intervals. (Age-adjusted hazard ratio, 0.87; 95% confidence interval, 0.58 to 1.36;  $P = .55$ )

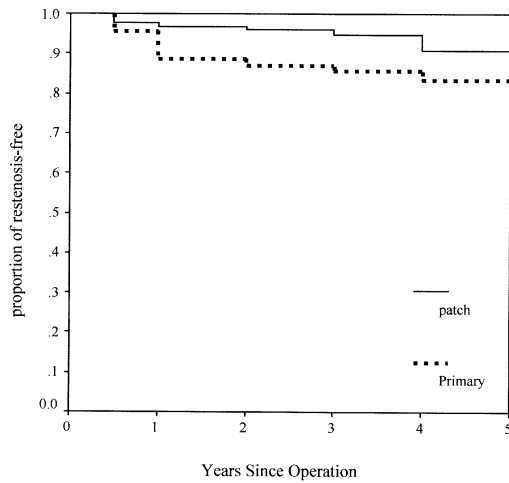
to the patch. The patient was treated by intracarotid urokinase with a subsequent patch angioplasty. The rest of the symptomatic patients that were not explored had normal duplex or CT examinations.

One patient with a patch angioplasty had an infected hematoma and was treated by removal of the synthetic patch and replacement by a vein patch, with no subsequent clinical symptoms or restenosis. There was no significant difference between the two groups in the combined complication rate (9.7% vs 9.2%).

The rate of residual stenosis ( $\geq 50\%$ ) at 0 or 3-month follow-up was significantly lower in the patch group (2 operations, 1.1%) compared with the primary closure group (17 operations, 8.9%) ( $P = .001$ , OR, 0.114; 95% CI, 0.026 to 0.5). When only multivariable logistic regression was used, primary closure was found to influence residual stenosis.

**Long-term outcome.** Seventy-nine additional patients (19.6%) died during the 5-year follow-up. The 1-year overall survival rate, calculated according to the Kaplan-Meier method, was  $97.6 \pm 1.1$  in the primary closure group and  $97 \pm 1.2$  in the patch group (Fig 1). There was no statistical difference between the groups in the crude or age-adjusted overall survival (age-adjusted hazard ratio, 0.87; 95% CI, 0.56 to 1.36;  $P = .55$ ).

Recurrent stenosis  $\geq 70\%$  was found in 18 postoperative arteries (5.2%): 14 (8.6%) after primary closure and 4 (2.2%) after patch. According to Kaplan-Meier curves (Fig 2), restenosis-free rates were higher in the patch group ( $P = .01$ , hazard ratio = 0.246; 95% CI 0.08 to 0.75). Looking at the 2-year restenosis-free rate only, it can be seen that the



Numbers at risk:

Primary	162	141	100	66	38
Patch	185	173	119	78	25

**Fig 2.** Kaplan-Meier analysis shows significant recurrent stenosis ( $\geq 50\%$ ) free rate for primary closure and patch angioplasty. Numbers at risk are shown at 1-year intervals. (Hazard ratio, 0.36, 95% confidence interval, 0.16 to 0.78;  $P = .01$ )

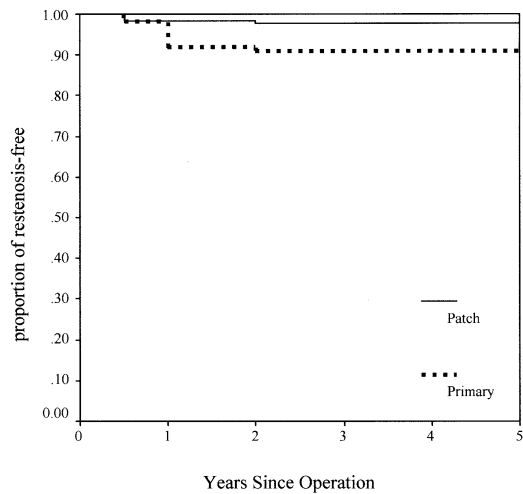
patch group had a  $97.6 \pm 1.2\%$  restenosis-free rate as compared with  $90.9 \pm 2.3\%$  in the primary closure group versus the primary closure group ( $90.9 \pm 2.3$ ) ( $P = .01$ , hazard ratio, 0.246; 95% CI, 0.08 to 0.75). In multivariate analysis that included baseline risk factors and demographics, only patch angioplasty was found to influence restenosis rate. Restenosis  $\geq 50\%$  was found in 31 arteries (8.9%): 22 (13.6%) after primary closure versus 9 (4.9%) arteries with patch closure. According to Kaplan-Meier curves (Fig 3), restenosis-free rates were higher in the patch group ( $P = .01$ , hazard ratio = 0.36; 95% CI 0.16 to 0.78). Looking at the 2-year restenosis-free rate only, it can be seen that the patch group had a  $95.9 \pm 1.5\%$  restenosis-free rate as compared with  $86.9 \pm 2.8\%$  in the primary closure group.

In the univariate analysis, aside from the patch, only female gender ( $P = .09$ , hazard ratio, 1.8; 95% CI, 0.9 to 3.8) and hypertension ( $P = .05$ , hazard ratio, 3.4; 95% CI, 1 to 11.3) had borderline significance; however, in multivariate analysis, only patch closure retained its significance. In subgroup analysis, the hazard ratio among men with patch closure was 0.21 (95% CI, 0.06 to 0.75), whereas in women, the hazard ratio was 0.71 (95% CI, 0.24 to 2.1); however, the interaction was not statistically significant ( $P = .12$ ). When men and women in the patch group were compared, women had a higher rate of restenosis ( $P = .04$ , hazard ratio, 4.2; 95% CI, 1.06 to 16.51).

Only one patient with restenosis was symptomatic (recurrent TIAs).

**DISCUSSION**

Controversy continues on the benefit of carotid patch angioplasty and the optimal material used.<sup>4-6</sup> The rate of



Numbers at risk:

Primary	162	155	104	69	40	14
Patch	185	174	121	79	25	7

**Fig 3.** Kaplan-Meier analysis shows significant recurrent stenosis ( $\geq 70\%$ ) free rate for primary closure and patch angioplasty. Numbers at risk are shown at 1-year intervals. (Hazard ratio, 0.246, 95% confidence interval, 0.08 to 0.75;  $P = .01$ )

perioperative stroke and TIA in this study was statistically similar in both primary closure and polyester urethane patch angioplasty. This differs from previous reports that suggest a higher rate of perioperative strokes, carotid thrombosis, and early restenosis with polyester patch (collagen-impregnated Dacron-Hemashield) compared with PTFE,<sup>15-16</sup> which might be explained by a continued platelet adhesion up to 9 months after surgery.<sup>17</sup>

Because postoperative events are relatively rare to achieve statistic significance, a large randomized trial is needed. For such a study, 3000 patients will have to be randomized to have an 80% chance of detecting a 50% reduction of combined death and stroke rate from 5% to 2.5% between the two groups.<sup>13-14</sup>

Patch angioplasty tends to take longer and concerns about postoperative complications after a longer clamping time have been raised. Although the clamping time was longer in the patch group, this did not increase the postoperative complication rate in this study.

The rate of residual stenosis  $\geq 50\%$  was significantly lower after patch angioplasty (1.1 % vs. 8.9%,  $P = .001$ ). Intraoperative imaging was not preformed, so we cannot exclude a technical problem in the closure of the arteriotomy. Intraoperative imaging should be considered, especially in primary closure, to diagnose and correct such problems.

Restenosis  $\geq 70\%$  was observed in 18 arteries with a significant advantage to patch over primary closure (2-year restenosis-free rate was 97.6% vs 90.9%,  $P = 0.01$ ). The incidence of 13.6% significant ( $\geq 50\%$ ) restenosis in the primary closure in this study is comparable with the review by the Cochrane library.<sup>4</sup> We did not find comparable

prospective randomized trials that used a polyester urethane patch. Using multivariate Cox regression analysis, we found that restenosis of  $\geq 50\%$  was associated with primary closure ( $P = 0.01$ ).

Previous studies have suggested that recurrent stenosis might be connected to gender, with a higher rate of restenosis in women.<sup>15,19, 22-24</sup> In a study by Ricco et al,<sup>18</sup> women with patch closure (knitted polyester patch impregnated with collagen) had a higher rate of restenosis than did men. This result is similar to the results in this study where women in the polyester urethane patch group had a higher rate of restenosis ( $\geq 50\%$ ) ( $P = .04$ , hazard ratio, 4.2; 95% CI (1.06 to 16.51)). A larger sample size might aid in further evaluating the interaction between patch and gender, especially in this synthetic patch.

One patient (4.2%) with restenosis was symptomatic. This finding is similar to the literature<sup>19-21</sup> and may be explained by the gradual development of the restenosis, usually due to intimal hyperplasia, without macroulcerations that may be responsible for neurologic symptoms in carotid stenosis caused by arteriosclerosis. The decision on how to treat patients with recurrent carotid artery stenosis must be influenced by this and by the high complication rate of a reoperation. We prefer to treat these patients with a carotid stent and only when there is a contralateral occlusion or the patients are symptomatic.

In conclusion, this randomized prospective study has shown that carotid patch angioplasty with a polyester urethane patch has good postoperative results with a low rate of immediate postoperative complications and, compared with primary closure, has a much lower rate of restenosis.

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## INVITED COMMENTARY

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In this prospective randomized trial, the outcomes of 216 primarily closed carotid endarterectomies (CEAs) and 206

polyurethane-patched CEAs were compared. The perioperative mortality and neurologic event rates were low and similar in both

groups. When these results are added to the Cochrane Review of similar trials, the meta-analysis will probably continue to show that patching gives statistically significant lower rates of perioperative stroke and death than does primary closure.

The authors chose residual stenosis and recurrent stenosis as their major end-points because the occurrence rates of these two outcomes are high enough with a study size of  $\approx 400$  to obtain adequate statistical power. The  $>50\%$  residual stenosis rate was 1.1% in the patched group and 8.9% with primary closure ( $P < .001$ ). This illustrates one of the recognized problems with frequent or obligatory primary closure, namely a high residual stenosis or occlusion rate. The 8.9% rate of residual stenosis in the primary closure group was obtained despite the exclusion of 24 patients from the study because of operative findings of a small internal carotid or the necessity for an interposition bypass.

Excluding the residual stenotic CEAs, the 2-year Kaplan-Meier rate for  $>70\%$  recurrent stenosis for the polyurethane-patched CEAs was 2.2% versus 8.6% for primary closure ( $P = .01$ ) and for  $>50\%$  was 4.9% versus 13.6% for primary closure ( $P = .01$ ). Other studies and a Cochrane Review have similar statistically

significant results for patching versus primary closure, with the clinical implication that obligatory or frequent primary closure is not advisable. The relatively low recurrent stenosis rate for polyurethane-patched CEAs may be important. In other studies, collagen-impregnated Dacron, a commonly used patch, had considerably higher restenosis rates. Further, the relatively low recurrent stenosis rates for polyurethane-patched CEAs approach those that others have obtained with greater saphenous vein patching.

Identifying the optimal CEA patch material continues to be an ongoing topic of investigation. Because the probability of a recurrent stenosis becoming symptomatic is low, some surgeons do not consider this a major problem. I disagree, particularly for patients operated on for asymptomatic stenosis, which is now by far the most frequently used indication for performing CEA, as recurrent stenosis defeats the primary reason for operation. Even though a recent Cochrane Review meta-analysis demonstrated little difference in restenosis rates between various patch materials, the challenge to identify the best material continues, and polyurethane could be a serious contender in the synthetic category.