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A Randomized Trial of Transcutaneous Extraction Atherectomy in Femoral Arteries: Intravascular Ultrasound Observations

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Abstract: *Objectives.* The purpose of this study was to test the hypothesis that in occlusions of the superficial femoral artery, removal of atherosclerotic plaque would result in a higher long-term patency rate compared to balloon dilatation alone. A secondary hypothesis was that long term patency would be proportional to the amount of plaque removed.

Methods. A randomized controlled study of patients with occluded superficial femoral arteries was performed comparing balloon dilatation alone versus a 2.7 mm or a larger (4.0 mm or 4.7 mm) transcutaneous extraction catheter (TEC) atherectomy device followed by balloon dilatation. The effect of these devices on plaque area was assessed directly by intravascular ultrasound imaging.

Results. The mean occlusion length was 19.4 cm \pm 11.7 cm. The mean lumen area increased from 4.7 mm² to 15.1 mm², primarily due to balloon dilatation, but the mean atheroma area of 19.8 mm² did not change with either size of TEC device. Although the initial procedure success rate was high (79%), the 6 month patency was only 45%. There was no difference in 6 month patency between the 3 groups.

Conclusions. The data indicate that the TEC atherectomy devices do not remove a significant amount of atherosclerotic plaque in occluded superficial femoral arteries. The 6 month patency is no different with these atherectomy devices than with balloon dilatation alone. The larger (4.0 mm or 4.7 mm) TEC device does not remove any more tissue than the smaller (2.7 mm) device. The use of intravascular ultrasound to quantitate the effects of this atherectomy device provides important insights into the mechanism of action and lack of efficacy of the TEC atherectomy catheter. © 1995 John Wiley & Sons, Inc.

Indexing Words: Atherectomy · Intravascular ultrasound · Peripheral vascular disease · Vascular disease

Although balloon angioplasty is an established method for the treatment of peripheral vascular disease with a high initial success rate of 86% to 95%,¹⁻⁴ the 1-year patency rate is variable (18% to 67%) if the vessels are initially occluded in-

stead of stenotic.⁵⁻¹¹ The transcutaneous extraction catheter (TEC) is one of several atherectomy devices which has been developed to remove atheroma with the expectation that the restenosis rate may be decreased compared to standard balloon angioplasty. The TEC device has two cutting blades at the end of a catheter that rotates at 700 rpm. There is a vacuum suction bottle at the proximal end of the catheter.^{12,13} Unlike the directional atherectomy device that requires multiple passes to remove a significant amount of material, the TEC atherectomy device cuts continu-

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ously as it is advanced over a guide wire. The device is designed to cut in a forward direction to facilitate treatment of long occlusions typically present in peripheral artery disease.

The hypothesis of this study was that removal of plaque by a TEC device prior to balloon dilatation would improve patency in patients with an occluded superficial femoral artery (SFA). A second hypothesis was that removal of more tissue with a larger cutting device would provide additional benefit. To test these hypotheses, a randomized trial was performed comparing (1) balloon angioplasty alone, (2) TEC atherectomy with a 2.7 mm diameter cutter followed by balloon angioplasty, and (3) TEC atherectomy with a larger cutter (4.0 mm or 4.7 mm) followed by balloon angioplasty. The effectiveness of the atherectomy was assessed by intravascular ultrasound (IVUS) imaging.

METHODS

Patient Selection

To ensure a relatively homogeneous population, only patients with an occluded superficial femoral artery (SFA) were chosen for this study. Patients were referred for the study if there were symptoms of claudication with one to two blocks of walking. All patients had evidence of peripheral vascular disease by the presence of diminished pulses and decreased ankle/brachial pressure index (ABI). Patients underwent diagnostic angiography, and only patients who had evidence of complete occlusion of an SFA were referred for the study protocol. Patients were excluded if there was a previous peripheral bypass operation in the target vessel or if there were insufficient distal run-off vessels. All patients signed the informed consent which was approved by the institutional human subjects review committee.

The patients were randomly distributed into three groups using a random number table. The ipsilateral common femoral artery was recanalized using a mechanical approach with a guide wire and introducing catheter. If the mechanical recanalization was successful, further treatment was provided as follows: group 1 patients were treated with balloon dilatation alone; group 2 patients were treated with a 2.7 mm diameter TEC atherectomy device plus balloon angioplasty; and group 3 patients were treated sequentially with a 2.7 mm and a 4.0 mm or 4.7 mm TEC atherectomy device plus balloon angioplasty.

Procedure

The common femoral artery was punctured in an antegrade direction with an 18 gauge needle, and a 7.5 French introducing sheath was placed. A 0.038 inch guide wire (Coons Wire, Cook, Inc.) was inserted through a 7 French pull-down Torcon catheter with a 5 French distal tip and advanced over the wire into the area of obstruction. The guide wire was used to probe the obstructed area under fluoroscopic control. The catheter was advanced over the guide wire as the guide wire progressed distally through the arterial occlusion.

If the patent distal vessel could not be reentered, the patient was placed on his stomach and a puncture of the popliteal artery was performed in a retrograde fashion using external ultrasound guidance and/or a Doppler flow needle. A guide wire was advanced under fluoroscopic control up the artery and used to probe the distal segment of the occlusion to attempt to enter into the proximal dissection plane created from the antegrade approach.

After successful passage of the guide wire and the Torcon pull-down catheter through the occlusion, the patients were given 100 U/kg heparin. The activated clotting time was monitored, and additional heparin was given to maintain the activated clotting time greater than 250 seconds. An 8 French introducing sheath with a hemostatic seal was inserted into the common femoral artery from the antegrade puncture. A peripheral angiogram was obtained at the end of the intervention in each of the three groups. In group 1, a balloon angioplasty was performed using a 6 mm or 7 mm diameter by 10 cm long balloon catheter, depending on the reference vessel size. Overlapping inflations were performed along the length of the occluded segment as well as inflations in the proximal or distal vessel to enlarge any stenotic segments.

For the patients in groups 2 and 3, after successful recanalization of the occluded segment, a 0.012 inch by 300 cm long guide wire with a 0.020 inch ball at the distal tip (to prevent the TEC device from passing beyond the guide wire) was inserted antegrade into the femoral artery through the Torcon pull-down catheter. A 2.7 mm TEC atherectomy cutter was inserted through the 8 French introducing sheath over the guide wire. This was placed under fluoroscopic control in the previously occluded segment of the artery. The rotating cutter was slowly advanced under fluoroscopic control. Continuous aspiration was per-

formed through the central lumen. In most patients, only one passage was attempted. When there was resistance, two or more passes were made until smooth passage of the device was achieved. The patients in group 2 then had balloon dilatation performed with a 6 mm or 7 mm diameter catheter.

For the patients in group 3, TEC atherectomy was performed with a 2.7 mm and then with a 4.0 mm or 4.7 mm diameter cutter from the proximal to the distal segment under fluoroscopic guidance and continuous suction. For these patients, a 12 or 14 French sheath was used to accommodate the larger TEC device. Depending on the angiographic reference size of the vessel, balloon angioplasty was performed with a 6.0 mm or 7.0 mm diameter balloon.

Using a monorail ultrasound system, intravascular ultrasound (IVUS) imaging was recorded as follows: (1) after recanalization but before balloon dilatation or TEC atherectomy, (2) after the TEC atherectomy, and (3) after balloon angioplasty.

The procedure was considered to be successful if (1) the final angiogram showed <50% residual diameter stenosis with evidence of rapid flow between the proximal and distal lumen; (2) there was a decrease in clinical symptoms; and, (3) the peripheral pulse improved with an increase in the ankle-brachial index (ABI) of greater than 0.15.^{4,7-9,14,15}

IVUS Analysis

The IVUS catheter used for this study was a 20 MHz 4.3 French or a 25 MHz 3.9 French catheter (InterTherapy/CVIS, Inc., Sunnyvale, CA). A ra-

diopaque ruler was placed under the patient's leg to correlate the position of the ultrasound images with the angiogram along the length of the artery. The ultrasound images were obtained at 30 frames/second and were recorded on super VHS tape during pull-back from the distal to proximal segment of the artery. After the procedure was completed, the tapes were replayed and images were analyzed at the same level of the artery before and after the interventions.

Measurements were made on the ultrasound images as demonstrated schematically in Figure 1. The lumen cross sectional area (CSA) was identified as the echolucent central portion of the image. The potential lumen CSA was defined as the area bounded by the hypochoic medium. This area encompassed the atherosclerotic plaque as well as the actual lumen. The atheroma CSA was then calculated as the potential lumen CSA minus the lumen CSA. The percent area atheroma was defined as the plaque CSA divided by the potential lumen CSA. This is similar to a histologic definition of CSA stenosis.¹⁶ Cross sectional measurements were made at 1 cm intervals along the length of the prior occlusion. The most severe residual stenosis was chosen for comparison. Plaque calcification was scored as none to severe using the following scale: no calcification = 0; calcium in one quadrant = +1; calcium in two quadrants = +2; and three or more quadrants = +3.

The angiograms were measured for the length of the occluded segment and the major and minimal diameters of the reopened segment following the procedure. Patients received noninvasive assessment by Doppler pressures to determine the ABI before the procedure and at follow-up. Subsequent patency was defined as improvement in

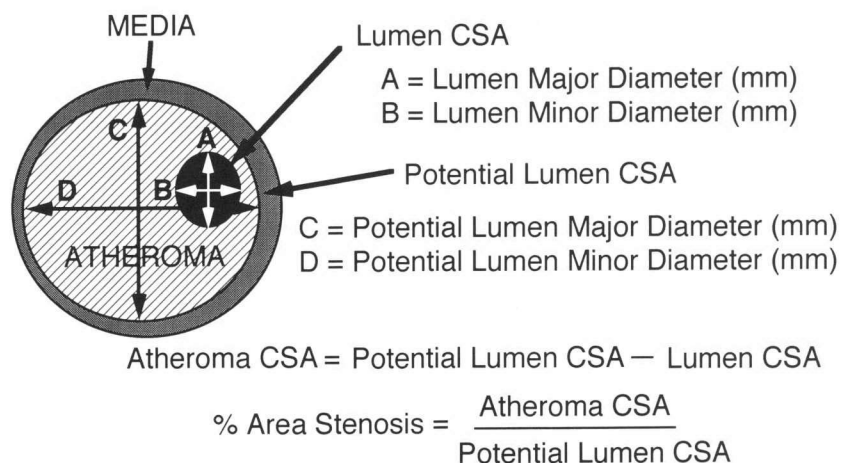


FIGURE 1. Intravascular ultrasound measurements of the lumen and vessel were made in the IVUS images. The inner boundary of the echolucent media was used to define the extent of the atherosclerotic plaque.

clinical symptoms as well as sustained improvement in the ABI.

Statistical Analysis

The data were expressed as mean \pm 1 standard deviation. Comparisons of the measurements among the three groups of patients were assessed by analysis of variance. Comparison of the lumen, potential lumen, and plaque CSA as well as percent stenosis before and after TEC atherectomy were performed by paired Student's *t*-test. The incidence of clinical variables among the three groups was assessed by χ^2 analysis. Differences in mean values between groups were considered to be statistically significant at $p < 0.05$.

RESULTS

The patient profile and clinical data are shown in Table 1. There was no significant difference between the characteristics of the patients among the three groups except that the mean age was slightly older in group 3. Guide wire recanalization of the occluded SFA was successful in 32 of 39 (82%) lesions. Perforation of the artery by the guide wire during attempted recanalization occurred in three patients. Recanalization could not be completed because the catheter continued to follow the tract outside of the artery.

Ten of the patients in group 1 had successful balloon dilatation. In group 2, all 13 patients had successful recanalization with a guide wire and subsequently had TEC atherectomy with a 2.7 mm catheter. In group 3, the occluded artery was reopened with a guide wire in 9 of the 13 (69%) patients. Lesion length, baseline ABI, mechanical recanalization success rate, and selected balloon size of the three groups are shown in Table 2. The overall angiographic success rate was 79% (31/39). The mean length of occlusion was 19.4 ± 11.7 cm (range 2 to 44). The mean minimum lumen

diameter after the final procedure in the successfully recanalized segments was 4.2 ± 1.3 mm. The contents of the vacuum bottles did not reveal any significant amount of macroscopic particles of atheroma.

Complications

In group 1, there were three perforations due to guide wire manipulation during the attempt at recanalizing the occluded SFA. There was no hematoma formation and these patients were treated conservatively. In group 3, a 4.7 mm diameter TEC device was used in the first three patients to maximize plaque removal; however, there were 1 perforation and 2 cases of distal embolization. The use of the 4.7 mm device was abandoned, and the 4.0 mm catheter was used instead in the other 10 patients. There were 2 other instances of small distal embolization during use of the 4.0 mm TEC atherectomy device.

One of the patients who had an unsuccessful initial recanalization with the guide wire suffered an acute myocardial infarction while he was on the procedure table. There was no significant blood loss or hemodynamic instability to account for precipitating the myocardial infarction.

Two TEC devices broke while rotating inside the artery. The separated distal section of the catheter shaft was retrieved by pulling back the TEC guide wire which has a small metallic ball at its distal end. In two cases, the cutter became entwined in fibrous atheroma which prevented further cutting. The catheter was removed and cleaned and the procedure was successfully completed.

Clinical Follow-Up

The 6 month patency and ABI data are provided in Table 3. The vessel patency at 6 months was 45% (14/31). There was no significant difference

TABLE 1
Patient Profile and Lesion Characteristics

	Balloon alone	2.7 mm TEC + balloon	4.0 mm TEC + balloon	<i>p</i> Value
Number of patients	13	13	13	
Age (yrs)	61 ± 4.1	64 ± 6	70 ± 6	0.003
Male	13	12	13	0.98
Diabetes	3	4	4	0.89
Hypertension	8	5	7	0.88
Hypercholesterolemia	4	3	1	0.96
History of smoking	11	11	13	0.98
Calcium detected by film	4	11	4	0.52

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TABLE 2
Lesion Length, Baseline Ankle Arm-Index, Success Rate, and Balloon Size

	Balloon alone	2.7 mm TEC + balloon	4.0 mm TEC + balloon	p Value
Lesion length (cm)	14.8 ± 12.1	20.0 ± 10.0	23.4 ± 11.7	0.35
Ankle-brachial index	0.43 ± 0.18	0.61 ± 0.13	0.54 ± 0.29	0.08
Success of guide wire recanalization	10/13	13/13	9/13	0.16
Balloon size (6 mm/7 mm)	7/3	8/5	8/0	0.13

in patency among the three treatment groups. Of the 13 patients assigned to balloon dilatation alone, 10 had a primary success; at 6 months, 5 (50%) were still patent. In group 2, all 13 patients had a primary success, and at 6 months 6 (46%) were patent. In group 3, 8 had a primary success, but at 6 months only 3 (38%) were patent. In the patients with patent vessels at 6 months, the mean ankle-brachial index was 0.84 ± 0.16 .

IVUS Observations

Adequate ultrasound images were obtained in 23 of the 31 patients who had successful recanalization procedures. IVUS could not be achieved in 8 patients due to lack of machine availability or difficulty in passing the catheter. There were 8 patients in group 1, 7 patients in group 2, and 8 patients in group 3 who had complete IVUS studies. Most of the plaque consisted of a mixture of fibro-fatty or fibro-calcific tissue. The amount of calcification is shown in Table 4. Three patients appeared to have intraluminal thrombus as defined by IVUS. The presence of thrombus was defined in the ultrasound image as a bright speckled echogenic structure that pulsed with blood flow. There were no differences in the quality or quantity of the various tissue components among the three groups.

The IVUS measurements before and after the various interventions in the three groups are shown in Table 4. In Group 1, 31 lesion sites were compared at the same section before and after the

procedures. The lumen CSA improved from $5.0 \pm 2.4 \text{ mm}^2$ to $13.6 \pm 3.8 \text{ mm}^2$ following balloon dilatation alone. The potential lumen CSA stretched from $24.5 \pm 6.1 \text{ mm}^2$ to $31.8 \pm 4.7 \text{ mm}^2$ while the atheroma CSA did not change significantly. The calcium score was 0.9 ± 0.6 .

In Group 2 (2.7 mm TEC device plus balloon dilatation), 28 lesion sites were compared at the same sections. The lumen CSA improved from $4.4 \pm 2.7 \text{ mm}^2$ to $16.6 \pm 4.6 \text{ mm}^2$ after the interventions. The atheroma CSA decreased only 1.6 mm^2 , which was not statistically significant. The calcium score was 0.8 ± 0.7 .

In Group 3 (4.0 mm TEC device plus balloon dilatation), 25 lesion sites were compared at the same sections before and after the procedures. The lumen increased from $4.9 \pm 2.1 \text{ mm}^2$ to $13.6 \pm 5.5 \text{ mm}^2$. This was associated with stretching of the potential lumen CSA from $24.5 \pm 6.0 \text{ mm}^2$ to $32.4 \pm 7.8 \text{ mm}^2$ and a decrease in the atheroma CSA from $19.6 \pm 5.5 \text{ mm}^2$ to $19.4 \pm 6.5 \text{ mm}^2$, a decrease of 1%. The calcium score was 0.5 ± 0.4 . These data are presented graphically in Figure 2.

The analysis of variance among the three groups demonstrated no statistically significant difference in baseline values; however, the lumen CSA was significantly greater in the 2.7 mm TEC device plus balloon treated patients. This was associated with larger stretching of the potential lumen CSA but was not due to greater removal of atheroma. The atheroma CSA was not statistically different among the three groups at baseline, after balloon dilatation alone, or after ex-

TABLE 3
Six Month Patency Follow-Up

	Balloon alone	2.7 mm TEC + balloon	4.0 mm TEC + balloon	ANOVA p value
Procedural success	10/13	13/13	8/13	0.16
Ankle-brachial Index (pre)	0.53 ± 0.16	0.64 ± 0.14	0.62 ± 0.15	0.33
Ankle-brachial Index (F/U)	0.79 ± 0.14*	0.86 ± 0.22†	0.89 ± 0.13†	0.83
Patency %	50% (5/10)	46% (6/13)	38% (3/8)	0.16

* $p < 0.05$, † $p < 0.01$ (comparing ABI in patients with an initial successful recanalization to the ABI in the patients who were still patent at 6 months).

TABLE 4
IVUS Measurements Pre- and Post-Balloon Dilatation or Atherectomy

	Balloon alone (n = 31)	2.7 mm TEC + balloon (n = 28)	4.0 mm TEC + balloon (n = 25)	ANOVA p value
Pre-intervention*				
Lumen CSA (mm ²)	5.0 ± 2.4	4.4 ± 2.5	4.9 ± 2.1	0.56
Vessel CSA (mm ²)	24.5 ± 6.1	24.8 ± 9.6	24.5 ± 6.0	0.98
Atheroma CSA (mm ²)	19.5 ± 5.9	20.4 ± 9.5	19.6 ± 6.7	0.88
Calcium score	0.9 ± 0.6	0.8 ± 0.7	0.5 ± 0.4	0.08
Post-intervention				
Lumen CSA (mm ²)	13.6 ± 3.8†	16.6 ± 4.6†	13.6 ± 5.5†	0.03
Vessel CSA (mm ²)	31.8 ± 4.7†	35.4 ± 7.2†	32.4 ± 7.8†	0.11
Atheroma CSA (mm ²)	18.1 ± 5.0	18.8 ± 9.0	19.4 ± 6.5	0.81

*Post mechanical recanalization.

†Pre- vs. post-intervention; $p < 0.0001$.

traction atherectomy plus balloon dilatation with either the 2.7 mm or 4.0 mm devices. An example of ultrasound images following successful mechanical recanalization, after treatment with a 2.7 mm extraction catheter, and after subsequent balloon dilatation, is demonstrated in Figure 3. In most cases there was mild improvement in the size of the lumen following passage of the 2.7 mm TEC device. An occasional patient had evidence of more mechanical disruption, such as a tear in the plaque after passage of the 2.7 mm TEC device, as demonstrated in Figure 4. An example of the effect of the 4.0 mm TEC atherectomy device is demonstrated in Figure 5.

All 31 successfully treated patients had angiographic evidence of dissection following balloon angioplasty. The ultrasound examinations also demonstrated the presence of large plaque fractures with torn flaps separated from the media. Although balloon dilatation induced significant stretching of the external artery wall, the CSA of atheroma was not affected by balloon dilatation, suggesting that there was no evidence for compression of plaque following balloon dilatation.¹⁷

DISCUSSION

The primary hypothesis of this study was that, in occlusions of the SFA, removal of atherosclerotic plaque by a TEC device would result in a higher long term patency rate compared with balloon dilatation alone. To accomplish this goal, two different-sized TEC atherectomy devices were used and compared with standard balloon dilatation. A secondary hypothesis was that the larger size TEC device would remove a greater amount of plaque and result in the best long-term patency rate. The results of this study do not support either hypothesis. Instead, the data indicate that

the TEC atherectomy devices do not remove a significant amount of atherosclerotic plaque in occluded SFAs. Because the desired result of removal of a sufficient amount of plaque was not achieved, the first hypothesis was proven to be incorrect. The use of IVUS to analyze the quantitative effects of these interventions provided insight into the mechanism of action and lack of efficacy of the 2 sizes of TEC devices.

There have been several reported series on the efficacy and safety of TEC atherectomy devices in peripheral arteries. Wholey and Jarmolowski reported 126 lesions with peripheral obstructive disease that were treated with 2.3 mm or 3.0 mm TEC atherectomy.¹⁹ The technical success rate was 92%, and there was no incidence of distal embolism. The mean ABI improved from 0.6 to 0.8 at the 6-month follow-up period. However, occluded lesions longer than 8 cm showed a high restenosis rate. Lincolf, et al, showed a 60% restenosis rate for occluded lesions.²⁰ Stack, et al, reported that TEC atherectomy for peripheral vascular disease had a high success rate (98%) without distal embolization.²¹ Graor, et al, performed 6 TEC cases but had 2 distal embolizations.²² Hong, et al, reported a distal embolization incidence of 30% after TEC atherectomy in saphenous vein grafts. It was unclear whether distal embolism was due to the TEC device or adjunctive balloon dilatation.²³

From the angiographic and clinical results obtained in our study, the primary success rate was 79% with an initial increase in the mean ABI from 0.58 to 0.93 in successful cases. The average lesion length of occlusion was 19.4 ± 11.7 cm (range 2 to 44), consistent with the presence of diffuse disease. This subset of patients carries a poor prognosis for standard balloon dilatation. The group of patients with occluded SFAs was

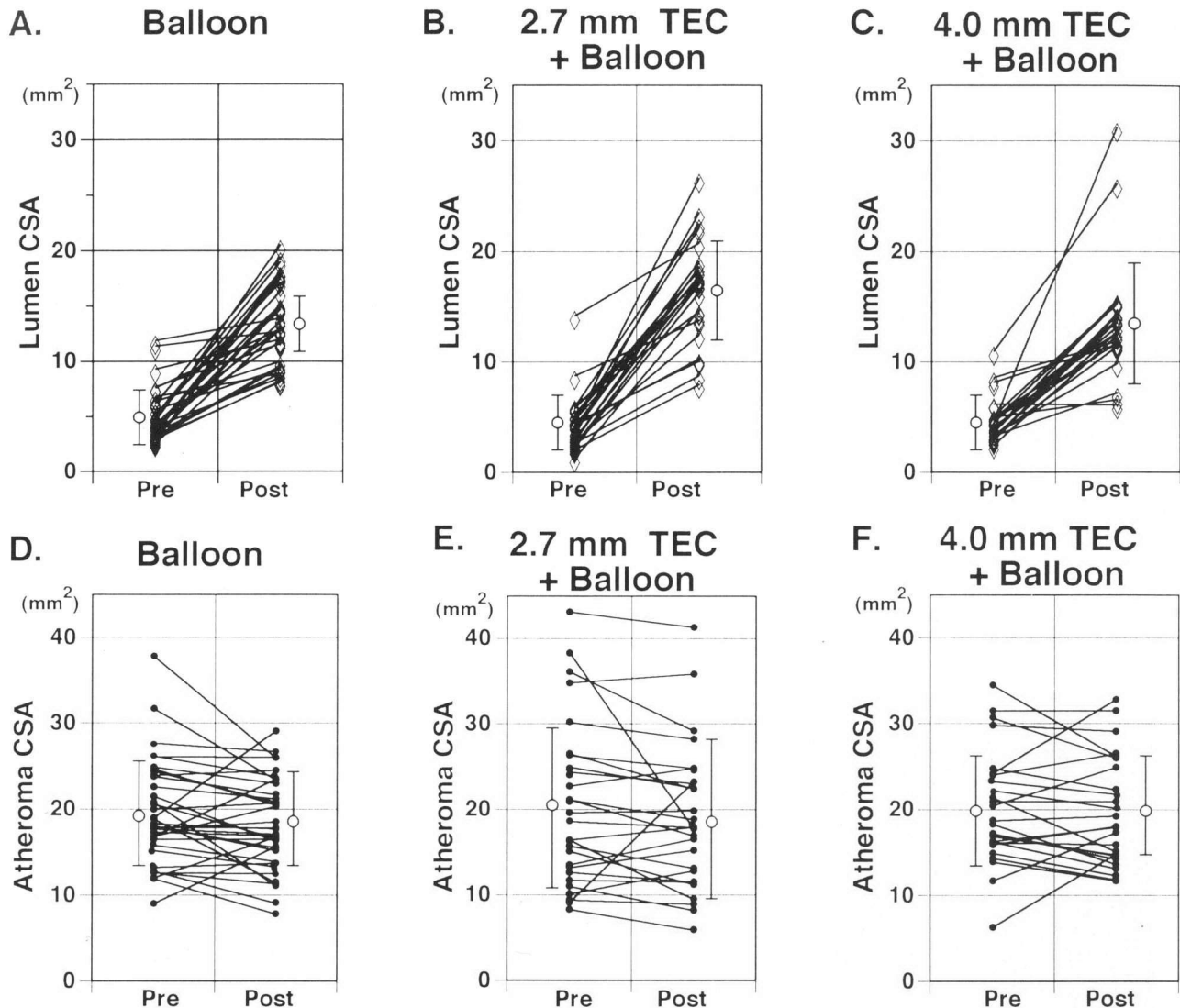


FIGURE 2. Effect of interventions on lumen and atheroma cross-sectional area (CSA). The major increase in potential lumen CSA was due to enlargement of the lumen subsequent to balloon dilatation for each group (A,B,C). The atheroma area was not reduced significantly by either of the TEC atherectomy devices compared with balloon dilatation alone (D,E,F).

specifically chosen for this study because of our ongoing attempt to achieve a more successful percutaneous treatment for this subset of patients with peripheral vascular disease. The high initial success rate in recanalizing these occluded femoral arteries, associated with angiographic evidence of a patent lumen with antegrade flow, ordinarily would be interpreted as demonstrating the beneficial effect of the TEC device. However, IVUS examination demonstrated that neither the 2.7 mm nor the 4.0 mm TEC device removed a significant amount of atherosclerotic plaque. In a subset analysis that excluded the effect of predilatation, the mean percentage area atheroma was reduced only 9% by the 2.7 mm device and was not significantly reduced by the 4.0 mm TEC device.

In comparison with other studies using the TEC atherectomy device, our differences in interpretation stem from the direct cross-sectional measurements of lumen and plaque by IVUS. These measurements before and after use of the devices determined the amount of atheroma removed. Studies that are based only on angiographic analysis cannot distinguish between the stretching effect of the catheter versus its ability to cut and remove atheroma. An angiogram only demonstrates the luminal diameter that is eventually achieved; it does not indicate the mechanism by which the lumen size is produced.

These observations are consistent with the conclusion of Pizzulli, et al, that the mechanism of TEC atherectomy was a combination of stretching and Dotter effect.²⁴ Our data suggest that

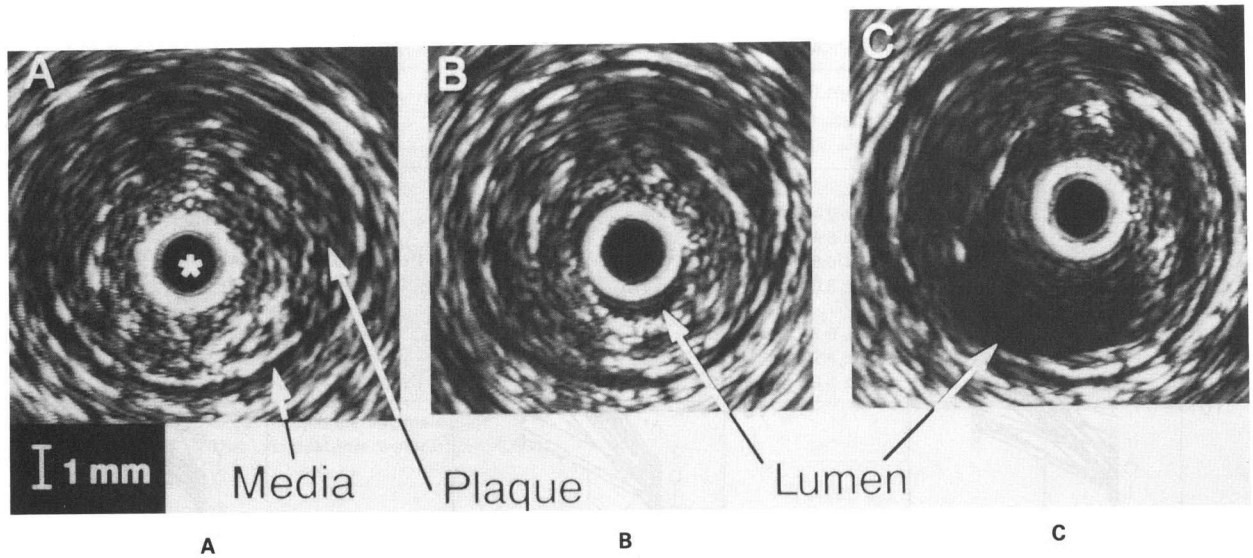


FIGURE 3. TEC atherectomy was performed in this occluded SFA with a 2.7 mm diameter device. **(A)** Pre TEC: the ultrasound image following mechanical recanalization but before TEC atherectomy. The plastic sheath of the catheter is represented by the intense echogenic white circle in the center of the image. A large atheroma is present around the catheter without evidence of calcification. The catheter is wedged in a central position in the total occlusion. **(B)** Post TEC: the effect of the 2.7 mm TEC device at the same level in the artery. The lumen is slightly enlarged with a small amount of atheroma cut around the catheter. **(C)** Post balloon: the results after dilatation with a 6 mm diameter balloon. The lumen CSA was significantly enlarged and the plaque was dislocated eccentrically.

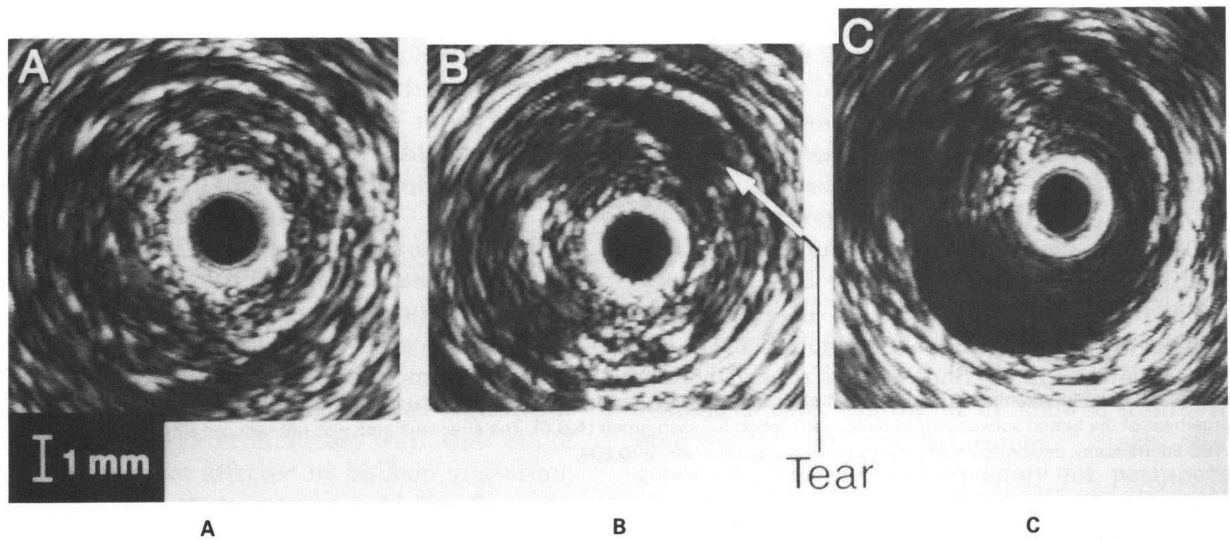


FIGURE 4. Evidence for plaque fracture following a 2.7 mm TEC atherectomy. **(A)** Pre TEC: following recanalization with a 0.035 inch guide wire, the ultrasound image demonstrates a centrally located catheter with a large fibrous plaque. **(B)** Post TEC: after passage of the 2.7 mm TEC device, there is a fracture in the plaque extending from the 2 o'clock position next to the catheter to 12 o'clock at the edge of the internal elastic membrane immediately adjacent to the thin echolucent zone of medium (arrow). This type of plaque fracture was uncommon following passage of the atherectomy device but provided significant improvement in the available lumen CSA. **(C)** Post balloon: Following balloon dilatation, the lumen is further enlarged and the external wall of the vessel is significantly stretched.

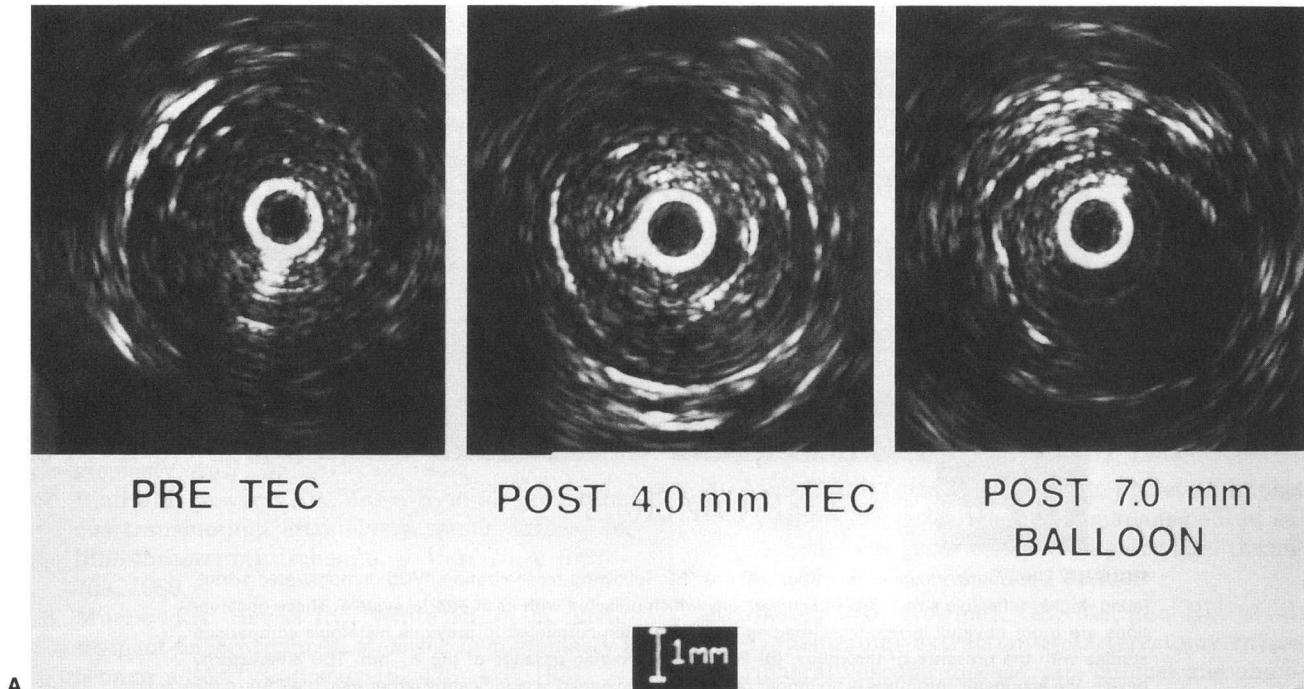
there is some removal of atherosclerotic plaque, although it is a small amount and does not produce a lumen that is even equal to the catheter itself. It could be argued that even this small reduction in atheroma could be beneficial for the subsequent effect of balloon dilatation. However, the high restenosis rate in all three groups suggests that the TEC atherectomy device does not alter the clinical results compared to balloon di-

latation alone in patients who have complete occlusion of the SFA.

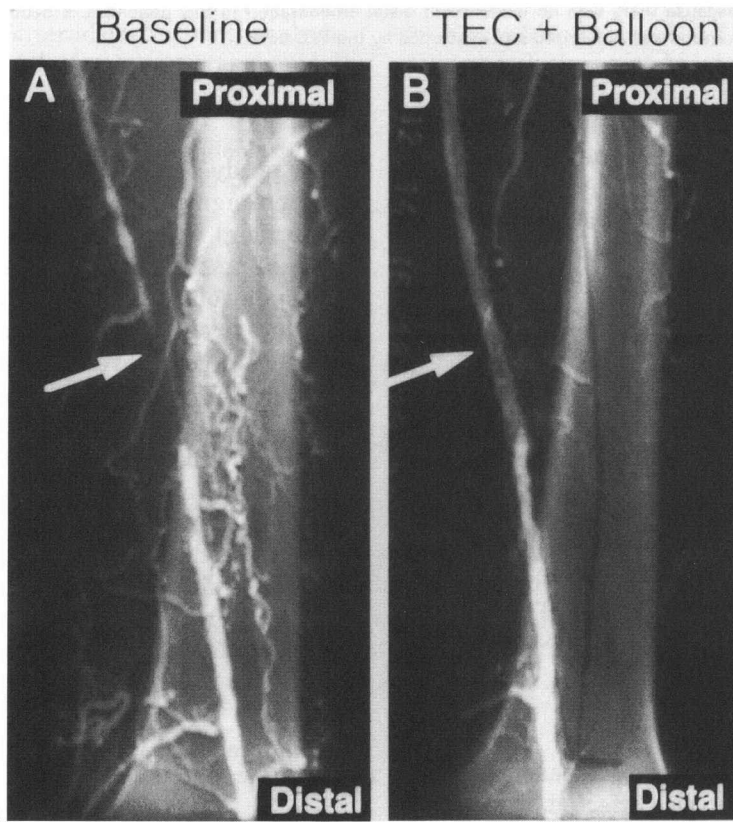
Effect on Thrombus

Dorros, et al, demonstrated by histologic analysis that thrombus was present in 41% of occluded peripheral arteries treated by directional atherectomy.²⁵ TEC atherectomy has some theoretical

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A



B

FIGURE 5. (A) Ultrasound images before (left) and after (middle) passage of a 4.0 mm diameter TEC atherectomy device. There is minimal improvement in the lumen CSA after use of the TEC device. The lumen is enlarged significantly following dilatation with a 7.0 mm diameter balloon (right). **(B)** Baseline angiogram of a 5.0 cm long occlusion of the distal SFA at the level of the adductor canal. There is an extensive collateral blood supply filling the distal vessel. Following treatment with a 4.0 mm TEC device and balloon dilatation, there is satisfactory antegrade blood flow with a marked decrease in presence of collateral blood vessels. The lumen diameter appears satisfactory with the presence of multiple dissections. The angiographic result overestimates the effect of the TEC atherectomy device compared with IVUS imaging.

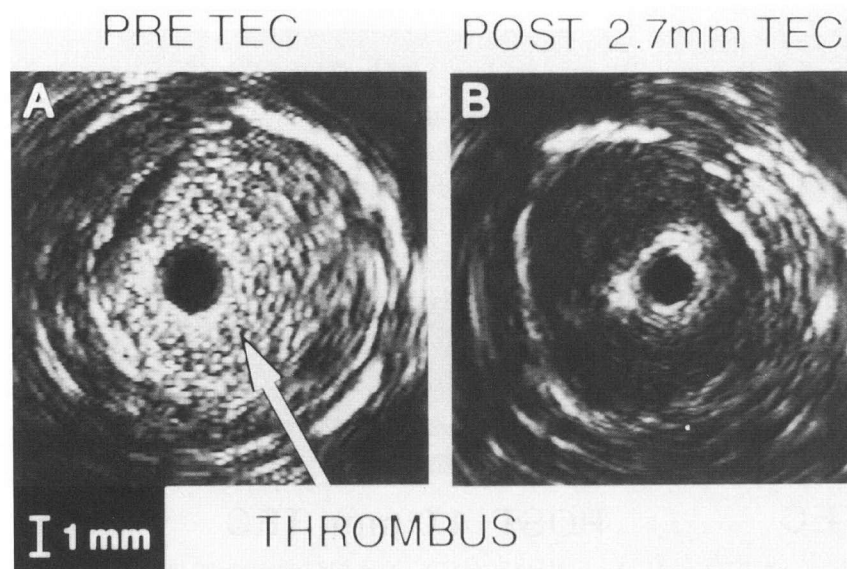


FIGURE 6. Ultrasound image of thrombus. **(A)** Pre TEC: following recanalization, IVUS demonstrated scintillating, highly reflective small dots of echogenicity which pulsed with each arterial systole. These observations are more obvious in real-time imaging and have been correlated in previous histologic comparison studies with the presence of thrombus. **(B)** Post TEC: following passage of the 2.7 mm TEC atherectomy device, the echogenic thrombus is no longer present and the lumen is significantly larger than the CSA of the TEC device. Because there was no evidence of distal embolization in this patient, it is deduced that the echogenic thrombus was pulverized and evacuated by the TEC device.

advantage in treating lesions with active thrombus because the device cuts and suctions material within its pathway. A study by Larkin, et al, found that TEC atherectomy was effective in thrombotic lesions during an acute myocardial infarction.²⁶ In our study, 3 patients had ultrasonic evidence of soft thrombus, and 1 of these patients had dramatic improvement in the lumen with disappearance of the thrombus following passage of the 2.7 mm TEC device, consistent with the mechanism of removal of thrombus through the suctioning component of the extraction catheter (Figure 6). However, the two other lesions did not change after passage of the TEC catheter. This ability to pulverize and evacuate thrombus may partially explain the reported success rate of TEC atherectomy in saphenous vein bypass grafts.²⁷

Limitations

It is possible that the ultrasound measurements underestimate the lumen size affected by atherectomy. The introducing sheath that was placed through the common femoral artery into the SFA could limit or obstruct antegrade flow into the vessel, therefore diminishing the distention pressure at the visualized segments. Although this would affect our measurements of lumen size and potential lumen CSA, the measured atheroma CSA would not be affected.

CONCLUSION

This study demonstrates that TEC atherectomy has no significant beneficial effect for occluded superficial femoral arteries. IVUS is an effective method to describe and quantitate the results of interventional devices on lumen morphology and plaque area. Although angiography demonstrated successful results following the use of two sizes of TEC atherectomy devices, IVUS revealed only a limited cutting effect (9% of plaque CSA) with this procedure. Patients with occluded SFAs have a poor prognosis following any percutaneous intervention. This lack of efficacy in removing plaque as documented by IVUS was consistent with the similar clinical outcome at 6 months compared with balloon dilatation alone.

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