Transluminal Treatment of Arteriosclerotic Obstruction

Description of a New Technic and a Preliminary Report of Its Application

By Charles T. Dotter, M.D., and Melvin P. Judkins, M.D.

Despite the frequency and importance of arteriosclerotic obstruction, current methods of therapy leave much to be desired. Nonsurgical measures, however helpful they may be, provide the patient little more than an opportunity to live with his disease. Consistent success in the use of surgical technics such as endarterectomy, angioplasty, and grafting has largely been confined to highly specialized vascular surgeons of whom there are far too few to cope realistically with literally millions of patients suffering the painful, disabling, or lethal consequences of the disease. Moreover, for practical purposes, surgical success is limited in the management of occlusions in smaller arteries.1-3 Thus, while aorto-ilio-iliac thromboendarterectomy has been generally successful, gangrene due to femoropopliteal occlusion frequently results in amputation. Expert vascular surgeons are reluctant to intervene in low femoral lesions if tolerable intermittent claudication is the only resulting disability.4 With these facts in mind, pursuit of a previously proposed approach5, 6 has led to the development of a safe, simple, and effective technic for directly overcoming arteriosclerotic narrowing and occlusion in the arteries of the leg. Impressive salvages already achieved in otherwise doomed legs amply justify this preliminary report even though long-term follow-up observations are not yet possible.

Method

Procedure

Prior angiographic survey of the abdominal aorta, its iliac branches, and the leg arteries, including those beyond the suspected primary block, is best done by retrograde catheterization of the opposite femoral artery, thus insuring a hematoma-free femoral region on the side to be treated. If an attempt appears indicated, the procedure, including its present experimental status, is fully discussed with the patient and specific permission is obtained. Oral anticoagulant agents are discontinued and barbiturate sedation is given at an appropriate time. Local anesthesia was used in all but two patients who received low spinal block.

The actual procedure is begun with downstream or antegrade femoral catheterization and control arteriography. A preliminary injection of 2,000 units of heparin is given into the artery, and under fluoroscopic control an ordinary coil-spring catheter guide of about 0.05 inch OD is passed down the lumen until its tip has traversed the stenosis to reach the lumen beyond. A tapered, radiopaque, Teflon dilating catheter * of approximately 0.1 inch OD is then slipped over the guide and advanced until it, too, has traversed the block, thereby enlarging the pre-existing or newly opened lumen. The guide is passed across the atheromatous block without going through the wall more by the application of judgment than of force; both are often needed to effect the subsequent dilatation. Where desirable and possible, a second dilating catheter of nearly 0.2 inch OD is passed over the first. Although secondary thrombotic luminal obliterations can be traversed and dilated with surprising ease, it may be difficult or impossible to pass the larger dilating catheter across primary, chronic, lengthy atheromatous occlusions. Fortunately, in patients with severe, longstanding ischemia striving improvement is likely to result from modest dilatations.

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* Cook Incorporated, 2305 East Second Street, Bloomington, Indiana.
TRANSLUMINAL TREATMENT OF OBSTRUCTION

During the course of dilatation, and especially with contrast injections, patients often experience increased pain in the foot, but there need be no other concern over the completely occluding catheter. Withdrawal of the guide permits confirmation that the desired lumen-to-lumen passage or dilatation has, in fact, been accomplished. To minimize the possibility of pain and arterial spasm associated with the periatheromatous and especially with the extramural injection of contrast agent, exploratory injections are delivered manually under direct fluoroscopic control with a minimum volume of dilute contrast agent. At present, we use Conray* diluted with an equal volume of heparin-saline irrigation solution; a suitable gaseous contrast medium may prove to have advantages in this application. In any case, pressure injection equipment and concentrated radiopaque agents have no place in this procedure.

After a successful transatheromatous dilatation, considerable traction is usually needed to withdraw the impacted catheter to a point above the treated segment. Often at this juncture, the patient will happily announce the return of adequate blood flow to the troubled extremity. Concentrated heparin is again injected and a final angiogram is made prior to removal of the remaining catheter. Hemostasis is manually obtained, and a nonconstricting bandage is applied over the site of the femoral puncture. We now use low-dose heparin following recanalization (40 mg. intramuscularly every 6 hours for 3 to 5 days).

It is convenient and informative to monitor the procedure and follow its results with a Parks mercury strain-gage plethysmograph.* In addition to providing an objective, permanent record of pulsations, this simple, economical instrument permits the determination of blood pressure in legs not possible by ordinary sphygmo-manometry.

* Conray, Mallinckrodt Pharmaceuticals, St. Louis, Missouri.

* Parks Electronics Laboratory, Route 2, Box 35, Beaverton, Oregon.

Figure 1

Case 1. Transluminal dilatation and segmental narrowing of the left superficial femoral artery. A. Control arteriogram showing threadlike lumen in region of adductor hiatus. B. Immediately after dilatation with catheter of 3.2 mm. OD. C. Three weeks after transluminal dilatation. Lumen remains open. Clinical and plethysmographic studies indicate continuing patency over 6 months later.

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Figure 2

Case 1. Objective improvement after transluminal treatment of subtotal superficial femoral obstruction. A. Blood pressures at indicated sites and times, before and after treatment; plethysmographic pulse waveforms. B. and C. Photographs of left foot 1 week and 5 months after the procedure.

Technical Problems and Complications

While the entire procedure can at times be successfully completed in 10 or 15 minutes, technical problems may prolong matters and lead to impaired results or failure. Passage of the guide and dilating catheters through the periatheromatous cleavage plane is not a desirable method of approaching or traversing the primary site of atheromatous block. Basic to the success of this technic is the transluminal traverse and dilatation of the primary atheromatous block with the formation of an inelastic conduit out of the patient’s own previously obstructing tissues. Neither total luminal closure at the site of primary obstruction (usually at the femoropopliteal junction in the adductor hiatus), nor more proximal obliteration by secondary thrombotic material is a critical deterrent to success, since a properly directed guide will pass harmlessly through both obstructions. What is important, we believe, is that the site of sclerotic primary obstruction be bridged by a lumen-to-lumen transatheromatous rather than periatheromatous route. In the latter event, there may be
considerable improvement in the patient’s ischemia, but the degree and permanence of benefit appears to be impaired.

Inadvertent entry into the peritheromatous cleavage plane is sometimes signaled by an increased sense of resistance and can be confirmed by the configuration and relative immobility of a small amount of contrast agent injected through the dilating catheter. Peritheromatous entry is somewhat more difficult to identify in the presence of pre-stenotic luminal thrombosis. Transmural passage, i.e., perforation of the artery, is usually easy to detect by the course of the guide. It does not require abandonment of the procedure, but rather indicates the need for withdrawal and redirection of the guide into the (patent or occluded) lumen. When avoidable, contrast agent should not be injected extraluminally, for pain and spasm of functioning regional arteries can ensue. A transluminal catheter path extending for several centimeters proximal to the site of occlusion aids the desired passage of the probe through the narrowed or obliterated lumen at the site of the primary atheromatous obstruction.

Figure 3
Case 2. Multiple short stenoses of superficial femoral artery before and after percutaneous transluminal dilatation. A. Control arteriogram showing two of the three segmental narrowings which were present. B. Improved luminal dimensions immediately after procedure.

Figure 4
Case 3. Atherosclerotic narrowing of deep femoral artery. Before (A) and after (B) transluminal dilatation. The outer diameter of the treated artery is approximately 1 to 1.2 mm. The dilatation required only a few seconds.

While both are occasionally frustrating, neither entry into the peritheromatous cleavage plane nor transmural penetration of the artery constitutes an alarming complication of the procedure. Should an undesired pathway be so situated as to be subsequently unavoidable, the attempted recanalization is best postponed for a few days. Due to the small caliber of the guide and length of its tract, “inside-out” puncture occurring during probe-traverse of an occluded lumen is less likely to cause bleeding than ordinary needle puncture. To date, we have observed no clinical or radiologic evidence that this technique has caused embolization downstream. If this occurred, its consequences have apparently been overshadowed by the benefits of the procedure.

Results

Case Reports
Case 1 (figs. 1 and 2)
L.S., an 82-year-old woman, was admitted with a cold, pulseless, continuously painful left lower extremity with an associated 2 by 4 cm. ischemic ulcer and progressing gangrene of three toes. Femoral angiography on January 6, 1964, disclosed a 0.5 cm. long atherosclerotic obstruction of the left superficial femoral artery at the level of the adductor hiatus. The lumen of the artery, though patent, was hardly discernible. The popliteal and tibial arteries filled slowly and contained numerous areas of irregular narrowing.

Because of advancing gangrene, amputation
Case 2 (fig. 3)
J. R., a 58-year-old man, complained of increasing coldness and claudication in his left leg. Femoral arteriography revealed three short subtotal narrowings of the superficial femoral artery. On February 14, 1964, a transfemoral dilatation was performed as seen in the second angiogram (fig. 3B). During the procedure, the catheter entered the periatheromatous cleavage plane several times and one or more transmural perforations occurred. It was not then realized that the patient was taking an oral anticoagulant drug because of previous coronary occlusion. During the week following the procedure, a large hematoma developed in the left inguinal area. Surgical drainage and infection obscured any immediate benefit from the procedure. The patient has not permitted further angiograms.

Case 3 (fig. 4)
H. H., a 64-year-old man had been on anticoagulant therapy following a stroke in 1959. His present complaint related to claudication in a

was strongly advised but the patient refused. On January 16, 1964, percutaneous transfemoral catheter dilatation of the segmental femoral obstruction was carried out in a matter of minutes and without difficulty. Coincident with the removal of the catheter from the site of the previous stenosis, good pulses were palpable for the first time in the lower leg and foot. Angiography showed that the stenosis was no longer present. Plethysmography demonstrated marked improvement in pulse and blood pressure, previously unobtainable on the left.

Pain, discoloration, and coldness of the foot, present on admission, diminished immediately following relief of the obstruction. During the following week, there was rapid healing of the ischemic skin changes, including ulceration of the lower leg.

Follow-up angiography on February 6, 1964, 3 weeks after dilatation, showed continuing patency of the lumen. At present, over 8 months after the procedure, the patient is ambulatory; the ulceration is gone; her gangrenous toes have separated and the sites are healed.

Case 5. Complete midpopliteal occlusion; recanalization via periatheromatous route. A. Before procedure. The distal fibular artery is patent. B. Composite angiogram shows direct communication between popliteal and fibular arteries, catheter extending down an adjacent vascular bundle. The appearance of the contrast material in the popliteal artery is characteristic of a periatheromatous pathway.
cold, pulseless left foot and leg with gangrene in one of the toes. Angiography, with a distally directed catheter located in the profunda femoral artery, demonstrated by reflux a 3 to 4 cm. complete obstruction of the superficial femoral artery at the adductor hiatus. In addition, there was severe stenosis of the lower profunda femoral artery, clearly hampering flow through important collateral channels. A coaxial dilating catheter was passed downward until the inner catheter (OD 2 mm.) had traversed this stenosis. Subsequent angiography indicated that the luminal caliber had been increased several-fold with resultant improvement of collateral blood flow. An effort to relieve the complete obstruction was not desired by referring physicians, and this was subsequently treated by endarterectomy and vein patch angioplasty.

Case 4 (fig. 5)
M. D., a 78-year-old diabetic Negro woman gave a 2-year history of claudication with multiple ulcerations leading to gangrene of the right leg and foot. Right femoral arteriography showed a complete popliteal block at the level of the trifurcation. Neither the anterior nor posterior tibial arteries filled, and extensive small artery disease was shown. A 5-cm. block of the fibular artery was noted, and it was decided to attempt to bridge it. This was accomplished with the extravasation of contrast material into distal vascular bundles. The procedure appeared to be of no immediate clinical benefit, presumably because of endarteritis. Continuing rest pain led the patient to demand amputation, which was done 2 days later.

Case 5 (fig. 6)
V. S., a 62-year-old diabetic woman, was admitted because of bilateral ischemic rest pain, right lower leg ulceration, and gangrene of the right first toe. Physical examination disclosed primary carcinoma of the epiglottis with involvement of the cervical lymph nodes. Her right leg exhibited reduced capillary filling, markedly reduced or absent distal pulses, and infected ischemic ulceration of the lower leg. Arteriography demonstrated subtotal obstruction of the right popliteal artery with obliterated anterior and posterior tibial arteries and a partially blocked fibular artery. There was extensive endarteritis. Despite these multiple obstructions, creation of an intravascular channel between the femoral and fibular arteries was thought to be possible and

**Figure 7**

*Case 6. Transluminal recanalization of complete obstructions of the superficial femoral artery.*  
A. Before procedure. B. Tapered dilating catheter traversing the block. C. Luminal continuity and minor extravasation immediately after removal of catheter. D. One week later. Residual luminal narrowing did not prevent reversal of gangrenous changes and complete relief of symptoms. See also figure 8A.
Figure 8

Plethysmographically determined blood pressures and pulse waveforms in three patients before and after percutaneous transluminal recanalization of complete obstructions of superficial femoral artery. A., B., and C: Cases 6, 7, and 8. Systolic pressures determined with Parks plethysmograph. Circled values are after the procedure.
worth while. On April 9, 1964, a guide and the smaller dilating catheter traversed the obstruction. Unfortunately, continuity was achieved via the periatheromatous route and, as was expected, her clinical improvement was limited to temporary progress in healing of the ulceration and diminution in rest pain on the treated side. Attention has centered on the treatment of the carcinoma and the appearance of severe ischemia has recently led to amputation.

**Case 6 (figs. 7 and 8A)**

F. S., a 65-year-old man, was hospitalized a year earlier because of increasing bilateral claudication, rest pain, and coldness of the feet and legs, most severe on the right. Distal pulses were absent on the right and questionably present on the left. Right external iliac and common femoral endarterectomy and vein-patch angioplasty were done. His present admission on April 7, 1964, was occasioned by a cold, cyanotic, and atrophic right lower leg and foot; an ulceration 3 by 5 cm. in diameter was present on the lateral aspect of the lower leg. The left lower leg showed ischemic skin changes, markedly reduced popliteal pulsation, and no distal pulsations. Pulsation in the toes could not be detected by plethysmography.

On April 14, 1964, a percutaneously introduced antegrade guide spring and graduated dilating catheters quickly traversed the previously demonstrated 2-cm. area of completely ob-

![Figure 9](https://example.com/figure9.png)

**Figure 9**

*Case 7. Percutaneous transluminal recanalization of 6-cm. complete occlusion of superficial femoral artery in a diabetic man of 68. A. Control arteriogram. B. Immediately after recanalization (which was extended only to level of arrow). C. Six weeks later. Recanalized lumen appears even larger and now unnecessary collateral channels, though patent, are only faintly opacified. Excellent symptomatic result persists. See figure 8B.*

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vessels. His legs were thin, atrophic, hairless, and cool below the knee.

Survey retrograde transfemoral aortography on February 27, 1964, revealed complete obstruction of the right superficial femoral artery 4 cm. distal to the femoral bifurcation. The partially stenosed profunda femoral provided meager collateral circulation to the popliteal artery. On the left, a 6 cm. complete segmental block of the superficial femoral artery was present within the adductor canal.

On April 29, 1964, a distally directed spring guide readily passed the obstruction in the left leg. Over the spring, a radiopaque Teflon catheter was passed to the popliteal area. A second dilating catheter of nonopaque polyethylene (P. E. 300) was passed through but not beyond this area of complete occlusion. Prior to the procedure, strain-gage plethysmography had failed to show a pulsation in the left first digit. When the dilating catheter was removed, the prompt appearance of the lower leg pulsations and an ankle blood pressure of 105 mm. Hg provided immediate objective evidence consistent with the patient’s reported relief of ischemic pain. The improvement persists.

Case 8 (figs. 8C and 10)

O. W., a 55-year-old man, had experienced intermittent claudication for 2 years. He had, nevertheless, been able to walk one or two blocks without pain until 7 weeks before admission, when he rapidly developed numbness, tingling, coldness, and pain in his left lower leg and was admitted to the University Hospital. Physical examination showed that popliteal and distal pulses were absent in the left lower leg, which was cold and continuously painful. There were small ulcerations on the lateral aspect of the foot. A diagnosis of arterial occlusion with “impending gangrene” was made.

On April 30, 1964, a femoral arteriogram was performed with a distally directed catheter. This revealed a complete obstruction of the midsuperficial femoral artery. During its introduction into the femoral artery, the guide spring was inadvertently passed across the block admitting sufficient blood to the distal superficial femoral artery to elevate the popliteal blood pressure from a control level of 40 mm. Hg to 70 mm. Hg. Small inner and larger outer catheters were used to dilate the reopened lumen to an inner diameter of 3.2 mm. Distal femoral blood pressure immediately rose to 140 mm. Hg; all distal pulses became palpable and the patient said that his leg felt “normal for the first time in several years.”

Follow-up arteriograms, although done, were unnecessary to demonstrate patency, since the
Case 9 (fig. 11)

G. G., a man of 75 with diabetes, developed severe pain in his left foot and ankle while working on March 1, 1964. He was hospitalized elsewhere and left lumbar sympathectomy was carried out within 24 hours. He continued to have rest pain, which markedly increased with exercise. His leg below the knee was cold. On April 2, 1964, he was admitted to the hospital because of severe, unremitting pain and early gangrene of left toes. Pigmentation, patchy redness, and decreased skin temperature were present below the left knee. Right retrograde transfemoral aortoarteriography a week later showed patent iliac and common femoral arteries, but demonstrated complete obstruction of the distal left superficial femoral and popliteal arteries. After a 20-second delay, the junction of two patent tibial arteries filled faintly by way of devious collateral channels. Above-the-knee amputation was planned and accepted by the patient.

Told of the present technic, the patient gladly consented to experimental recanalization, which was undertaken on May 1, 1964. Qualified success resulted when a 35-cm.-long segment of completely occluded femoropopliteal artery was traversed by the spring guide and a 2-mm. dilating catheter of radiopaque Teflon. Extensive vascular calcification and the use of television fluoroscopy permitted several needed corrections of the course. These were achieved through appropriate bending of the tip of the removable central piano-wire stiffener of the spring guide. Resistance to the guide varied widely and unpredictably at various points within the occluded vessels. On two occasions, steady forward pressure on the guide led to transmural perforation of the artery. Redirection into a transatheromatous or periatheromatous route proved possible after the guide had been pulled back into the artery. When lumen-to-lumen passage had been accomplished, the small tapered Teflon catheter was advanced over the guide with considerable difficulty. Passage of a larger, outer polyethylene catheter appeared to be out of the question. After withdrawal of the Teflon catheter to the upper femoral artery, arteriography established beyond a doubt that lumen-to-lumen bridging had been achieved.

The patient noted a pronounced diminution in ischemic pain. This improvement led to cancellation of planned amputation and discharge of the patient. It was expected that the long (35 cm.), narrow (2.0 mm.) channel would soon thrombose. It was our plan to attempt a more adequate dilatation as soon as an expandable guide could be devised. About 3 weeks later, at 7 p.m. on May 20, 1964, the patient suddenly developed recurrent rest pain. The following noon, emergency recanalization was performed. Again, there was immediate relief of his rest pain. Previously unobtainable plethysmographic pulses were recorded. The re-opened 2.0 mm. by 35 cm. channel has remained patent to the present (4 months). He anxiously awaits the development of a dilating catheter-probe.

Case 10

V. H. is the same patient reported as Case 7.

Right Leg: On May 5, 1964, an attempt to traverse a long segmental block of the superficial femoral artery failed presumably because of our inability to start the recanalization with the spring in a proximal, unoccluded segment of the superficial artery above the region of block. Repeated extravascular passage resulted. This effort is not regarded as a total failure, since dilatation of a stenosed profunda femoral artery at the level of the second perforating branch was easily accomplished and appeared to improve collateral flow. Digital plethysmographic pulsation was absent before and after this procedure.

On June 5, 1964, a second attempted recanalization resulted in a lumen-to-lumen channel, portions of which were subatheromatous. There was subjective improvement and plethysmographically measurable blood pressure.

A third attempt 5 days later failed to develop a completely transatheromatous channel. In view of subsequent subjective improvement, a new approach has not been attempted.

Case 11

F. S. is the same patient reported as case 6.

Right Leg: On April 21, 1964, a spring guide was passed through a 30 cm., completely occluded segment of superficial femoral artery to connect with a patent distal popliteal artery. Continuity was observed fluoroscopically. A small dilating catheter traversed the obstruction to the knee joint space. Severe arterial spasm prevented further advance of this catheter or passage of a larger dilator. To this spasm and to insufficient irrigation during the procedure is attributed the prompt thrombosis which followed and then extended to include a short segment of stenosed, but previously patent lumen of the superficial femoral artery. There were no clinically evident untoward effects.

On May 5, 1964, this man was taken to surgery and the right popliteal artery was exposed. He was immediately transported to the Radiology Department where a catheter was passed through the exposed popliteal artery; the distal popliteal artery was likewise catheterized and a patent,
Figure 11

but partly peritheromatous channel from the iliac to the distal popliteal artery was established. At the time of wound-closure, there was pulsatile flow in the popliteal artery and capillary flow in the previously cyanotic foot. Thrombosis occurred on the sixth day and the leg was amputated. This cold leg with gangrenous changes and ischemic ulcerations had been scheduled for amputation prior to the performance of these procedures.

**Evaluation of Results**

Fifteen procedures have been performed on 11 lower extremities in nine patients (table 1). Seven of the 11 extremities were those of diabetic subjects with moderate-to-severe microangiopathy. Most of these patients had been rejected for definitive surgery and were scheduled for amputation; of the 11 extremities treated, six were for gangrene, four for rest pain, and one for claudication. Six extremities improved markedly (four amputations averted). Clinical improvement quickly followed increases in blood pressure and circulation. Three are unchanged; two scheduled amputations were not averted; a third was delayed for 3 months. Results have been objectively gauged on the basis of healed ischemic or gangrenous changes and the return of measurable peripheral blood pressure. Symptoms were relieved in extremities that did not receive maximum benefit by these criteria.

Failures were unassociated with harm to the patient and did not appear to reflect on the method of approach as much as they did our early inexperience, the particular disease present in a given patient, and the inadequacy of our present instruments when used in long segment blocks.

**Rationale of Method**

Surgery is the treatment of choice for obstructive lesions of the aorta and other large arteries, but its effectiveness bears a direct relation to arterial size. The failure of surgical measures applied to smaller arteries reflects an increase in the importance of limiting factors such as technical difficulty, operative trauma, postoperative perivascular swelling, mural fibrin deposition, and fibrocytic incisional repair. Particularly important

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*Figure 12*

Endarterectomy, superficial femoral artery. A. Before surgery. B. Removal of atheroma leaves dilated segment of artery with abrupt change in lumen caliber. A good result but the inevitable disturbance in flow pattern could prejudice its durability. Compare to luminal caliber shown in figures 1 and 10. (Films through courtesy of Drs. Rogoff and DeWeese, Strong Memorial Hospital, Rochester, New York.)

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*End of block (arrow) shown by Conray injected directly into blocked superficial femoral artery at outset of procedure. Collateral vessel near knee. C. Appearance of recanalized distal superficial femoral artery. Note partially visualized unsuspected aneurysmal cavity (arrow). D. Same, later phase to show branch filling. E. Tibial view corresponding to B., showing two patent tibial arteries at lower end of 35-cm. total block. F. During passage of spring guide. Tip of spring has been bent to follow lumen. Flexing knee aided in establishing luminal continuity. G. Dilating catheter of Teflon, 2 mm. OD, is across the occlusion and injecting into the fibular artery. H. Corresponds to C and D. However irregular the lumen, it is filling two of the three popliteal branches. This stayed patent 3 weeks whereas recurrence of leg pain indicated re-thrombosis. Opened a second time, it has now remained patent for 6 weeks. Scheduled amputation is not necessary at present.*

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### Summary of Cases

<table>
<thead>
<tr>
<th>Case no.</th>
<th>Pt.</th>
<th>Hosp. no.</th>
<th>Age, sex</th>
<th>Side</th>
<th>Before procedure, clinical</th>
<th>Diabetic</th>
<th>Before procedure, radiographic</th>
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<tbody>
<tr>
<td>A. Partial Obstructions</td>
<td></td>
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<tr>
<td>1</td>
<td>L.S.</td>
<td>32-79-70</td>
<td>82 F L</td>
<td>Cold, pulseless, painful foot with ulceration and gangrene of the toes</td>
<td>0</td>
<td>Near complete obstruction of superficial femoral artery at adductor hiatus. Moderate small artery disease</td>
<td></td>
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<tr>
<td>2</td>
<td>J.R.</td>
<td>32-91-34</td>
<td>58 M L</td>
<td>Coldness, claudication, generalized atherosclerotic changes. Emotional instability</td>
<td>0</td>
<td>Narrowing of superficial femoral artery in adductor canal</td>
<td></td>
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<tr>
<td>3</td>
<td>H.B.</td>
<td>18-28-16</td>
<td>64 M L</td>
<td>Cold foot and leg with claudication, markedly diminished peripheral pulses, and digital gangrene</td>
<td>0</td>
<td>Complete obstruction of superficial femoral artery in adductor canal. Narrowing of deep femoral collateral vessels</td>
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<tr>
<td>B. Total Obstructions 6 cm. or less in length</td>
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<td></td>
<td></td>
<td>+</td>
<td>Complete trifurcation block. Extensive small artery disease. Microangiopathy</td>
<td></td>
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<tr>
<td>4</td>
<td>M.D.</td>
<td>33-09-99</td>
<td>78 F R</td>
<td>Cold, pulseless extremity with rest pain, ulceration, and extensive gangrene below the knee. Serious infection</td>
<td>+</td>
<td>Complete obstruction superficial femoral at the adductor hiatus. Moderate small artery disease</td>
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<td>6</td>
<td>F.S.</td>
<td>32-61-87</td>
<td>65 M L</td>
<td>Pulseless, cold leg with ischemic skin changes and claudication. Rest pain</td>
<td>+</td>
<td>Complete obstruction superficial femoral artery within the adductor canal. Moderate small artery disease</td>
<td></td>
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<tr>
<td>7</td>
<td>V.H.</td>
<td>33-00-47</td>
<td>67 M L</td>
<td>A cold leg with one block claudication and no distal pulses. Ischemic skin changes and some pain at rest</td>
<td>+</td>
<td>Complete obstruction superficial femoral artery in the adductor canal</td>
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<tr>
<td>8</td>
<td>O.W.</td>
<td>31-10-23</td>
<td>55 M L</td>
<td>Numbness, coldness, and claudication progressing to rest pain and early gangrenous changes</td>
<td>0</td>
<td>Complete obstruction superficial femoral artery in the adductor canal</td>
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<tr>
<td>C. Long-Segment Obstructions</td>
<td></td>
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<td></td>
<td></td>
<td>+</td>
<td>Complete obstruction of popliteal and the vessels of the trifurcation. Severe small artery disease</td>
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<tr>
<td>5</td>
<td>V.S.</td>
<td>5-67-89</td>
<td>62 F R</td>
<td>Cold, pulseless leg with ulceration and rest pain. Ischemic skin changes with ulceration</td>
<td>+</td>
<td>(a) Complete obstruction distal femoral and popliteal arteries</td>
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<tr>
<td>9</td>
<td>G.G.</td>
<td>33-22-45</td>
<td>75 M L</td>
<td>(a) Sudden, severe claudication and rest pain. Cold leg. &quot;Emergency&quot; sympathectomy elsewhere. Gangrene</td>
<td>+</td>
<td>(b) Same</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(b) Sudden onset of rest pain 7 pm 5/19/64</td>
<td>(b) Recurrent obstruction</td>
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<td>V.H.</td>
<td>33-00-47</td>
<td>67 M R</td>
<td>(a) Cold leg with ischemic skin changes and muscular atrophy. Rest pain</td>
<td>+</td>
<td>Complete obstruction of femoral and proximal popliteal. Moderate small-artery disease</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(b) Same</td>
<td>(b) Same</td>
<td></td>
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<td>F.S.</td>
<td>32-61-97</td>
<td>65 M R</td>
<td>(a) Cold leg with no distal pulses. Rest pain + Gangrene</td>
<td>+</td>
<td>Obstruction distal femoral and popliteal. Severe small-artery disease</td>
<td></td>
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<td></td>
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<td></td>
<td>(b) Same</td>
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TRANSLUMINAL TREATMENT OF OBSTRUCTION

Length of narrowing or obstruction, cm. Procedure date After procedures, radiographic findings Follow-up

0.5 1/16/64 Lumen diameter increased to near normal Healing of ulceration. Sharp demarkation and clean healing of sloughed gangrenous toes. Plethysmographic evidence of good pulse and B.P. Residual small-artery disease

2 2/14/64 Increased diameter of lumen Inguinal area hematoma secondary to anticoagulants. No subjective improvement. Plethysmography shows little change. Lesion may not have been a significant obstruction at time of dilatation

0.5 3/12/64 Increased diameter of the lumen of treated deep femoral branch. Superficial femoral was not treated percutaneously The following week, patient had an endarterectomy and patch graft of superficial femoral artery lesion. Now doing well clinically. Slough of gangrenous toe healed well

5 3/25/64 Subatheromatous catheter travel from popliteal to fibular artery No clinical improvement—probably secondary to severe small-artery disease. Amputation became necessary because of persistent severe rest pain

2 4/23/64 Patent lumen Plethysmographic pulses and B.P. returned. Leg warmth increased. Skin changes decreased. Good B.P. levels to present. Excellent clinical results

6 4/29/64 Patent lumen Increased warmth. Plethysmographic increase in B.P. and pulse. Distal pulses returned. Excellent clinical results

1 4/30/64 Patent lumen Relief of pain, coldness, and numbness. Dorsalis pedis pulse now visible. Plethysmographic return of B.P. and pulse to good levels

10 4/9/64 Patent lumen, popliteal to fibular artery Fair progress in ulcer healing. No distal pulses because of severe small artery disease. Amputation for pain 3 mo. later

35 5/1/64 (a) Patent lumen (a) Relief of severe rest pain. Leg warmth increased. Additional dilatation of vessel will be needed. Amputation canceled

5/20/64 (b) Patent lumen to present (b) Relief of rest pain. Amputation again averted. Pt. awaits development of "concentric dilating catheter"

30 5/5/64 (a) Unsuccessful procedure; extravasation (a) Unchanged

6/5/64 (b) Partial extra-atheromatous course of the channel (b) Improved warmth and B.P. for 5 days

6/12/64 (c) Partial extra-atheromatous course of the channel (c) Unchanged

30 4/23/64 (a) Partial extra-atheromatous course of the channel (a) Unchanged

5/5/64 (b) Small patent lumen—clotted after 3 days (b) Return of popliteal pulse and capillary circulation. No distal pulse. Clotted after 3 days. Amputation not averted
are the irregularities likely to develop at the site of graft or endarterectomy (fig. 12). Abrupt variations in caliber and configuration of the postoperative lumen often cause turbulent blood flow and, thereby, undesired dilatation, mural trauma, platelet deposition, and thrombosis.

Several of the foregoing limitations can be avoided or minimized by use of a transluminal approach. Recanalization or luminal dilatation, the therapeutic objective, is brought about through relatively nontraumatic remodeling and lateral displacement of the encircling atheromatous material. Postmortem studies have shown that forceful intraluminal hydraulic injections can lead to surprising increases in perfusion rates. From this it appears that diffuse hydraulic, as well as local catheter dilatation, may have therapeutic value. Since in either case, surgical exposure, mural incision, and intra-arterial tissue dissection are eliminated, percutaneous arterial dilatation is, in comparison to surgery, remarkably free from trauma, especially at the site of the lesion.

The value of catheter recanalization in arteriosclerotic narrowing has been challenged by some of our colleagues on the hypothetical grounds that coexistent disease in distal branches defeats its purpose. (Similar faulty speculation retarded now-accepted corrective surgery for occlusive disease of the abdominal aorta, carotid, and renal arteries.) It is a simple, physical fact that removal of a proximal, gradient-producing stenosis causes an increase in the distal blood pressure and, therefore, a corresponding increase in flow through all patent run-off branches, narrowed or not. A further advantage presumably exists in the form of secondary pressure-induced dilatation of nonrigid elements of the run-off bed. (Even a rusty sprinkler may prove capable of doing a creditable job once the faucet is fully opened!)

It has been argued that attempted catheter dilatation will dislodge and make emboli of atheromatous plaques. The use of a gradually tapered recanalizing catheter (or a centrically dilating catheter under development) was adopted to reduce the likelihood of this. Its rarity is evidenced by prior practical experience of a related nature. In connection with approximately a thousand arterial catheterizations done at the University of Oregon Medical School, we know of but one instance of embolization by dislodged atheromatous material. Minor, clinically undetected embolization probably occurs in the course of most arterial catheterizations done on patients with intimal atherosclerosis, a suspicion supported by reported funduscopic findings. In any event, if the dislodgment of a localized, proximal atheroma coincides with the relief of a proximal block, impingement of the embolic fragment in a distal branch would not necessarily prevent a decided improvement in over-all blood flow through most of the run-off vessels. (This might not always hold if a previously active collateral route were blocked as could occur in the coronary arteries.) Recognized clinical or radiographic evidence of embolization has not occurred in any of the patients in this series.

Atheromatous material has the characteristics of what an engineer would term a "cold-flow" substance; thus, it can be molded into a configuration that permits it to serve as an autogenous, in-situ graft. If intima existed before the remodeling, it presumably would remain afterwards, however stretched.

Transluminal recanalization is a simple technic. The hard-won skill of the vascular surgeon is not required, for the technic can be learned by any physician familiar with vascular catheterization. This is fortunate. A therapeutic approach to arteriosclerotic disease which requires the services of a highly trained vascular surgeon would hardly scratch the surface in the treatment needed for a disease responsible for the death of a million Americans every year!

Since the procedure is suitable for outpatient application, and at most requires brief hospitalization, the expense for the patient is kept to a minimum.

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Present and Projected Clinical Applications of the Method

Transluminal recanalization is routinely considered in all patients who otherwise would require amputation because of arteriosclerotic ischemia. Such patients have little to lose and much to gain through trial of this experimental procedure. In any case, they can add to our knowledge and have always wished to do so when given the option.

To date, this method has been most successful in recanalization of relatively short segment blocks (up to 10 cm. in length) of the femoropopliteal system. Long-segment block failures have been primarily due to our mechanical inability to dilate an established 2-mm. lumen-to-lumen channel, a situation that could readily be reversed through the development and use of better instruments.

Transluminal recanalization appears quite applicable to other arterial systems, particularly those smaller than are usually considered suitable for conventional reconstructive arterial surgery. If its use in femoral disease can be taken as an indication, severe proximal narrowing of the coronary artery will be amenable to a manually guided dilator inserted via aortotomy or via the brachial artery by the Sones technic. Proximal stenosis of the renal, carotid, and vertebral arteries appears suitable for transvascular treatment. The technic is of potential usefulness in other than arteriosclerotic causes of narrowing, both anatomic and functional in character. Intense, gangrene-producing spasm has resulted from the prolonged use of vasoconstricting drugs and, here, catheter or hydraulic dilatation may prove useful.

In order to improve the technic, a major instrumental design effort is underway. It consists of the development of a device suitable for percutaneous insertion, which is a functional equivalent of the present spring guide but capable of externally controlled concentric expansion over a suitable portion of its length. Expansion from an initial OD of 0.05 to a final OD of 0.2 inch would be desirable. This, it is hoped, will minimize the possibility of inadvertent dislodgment of atheromatous fragments, since the dilator will be positioned in the form of a thin, flexible guide, prior to providing forceful, local expansion as needed. In addition, our efforts are being directed toward the design and construction of a self-guiding, lumen-seeking guide to facilitate penetration as the first step in the recanalization of totally occluded arteries. Once a pathway has been created across an occluded segment, repeated dilatation or the temporary use of a Silastic endovascular (or, in some cases, paravascular) splint could maintain an adequate false lumen until the natural processes of fibrosis and re-intimalization had taken place. We believe re-intimalization is as likely to occur on the walls of a lumen formed by the patient’s own tissues as on the fibers of a plastic prosthesis.

Conclusions

It seems reasonable to expect that the transluminal technic for recanalization will extend the scope of treatment beyond the limits of present-day surgery. The method offers early treatment for the ischemic leg. In view of its simplicity and low morbidity, it is now feasible to treat intermittent claudication without waiting for more serious symptoms to occur or collateral circulation to develop.

Although long-term results are not yet available, we are convinced that transluminal recanalization is the treatment of choice for patients suffering from arteriosclerotic ischemia of the lower extremities, especially two classes of patients, those generally regarded as the best candidates for surgical revascularization (i.e., those with short-segment obstructions of the adductor hiatus), and those beyond its aid and, therefore, candidates for amputation. Although most of our patients came from the latter category, all are now alive, only three of 11 extremities have been lost, subjective improvement resulted in seven of the remaining nine legs, and pulsating, near-normal blood flow has been restored to four. No patient was made worse by the procedure. While uncomplicated segmental blockage of the adductor hiatus of the superficial femoral artery is generally considered suitable for surgery, it is even more suitable for a nonsurgical procedure of equal potential benefit. The
transluminal approach can be applied when distal disease offers a significant contraindication to conventional surgery. In any case, it does not preclude or complicate future surgery and should be tried first. Since our first patient was treated on January 16, 1964, nine patients have had transluminal therapy for arteriosclerotic ischemia of the leg. Eight other comparable patients at this institution were subjected to amputation. All of those treated transluminally are alive and six have not required amputation. Of the eight others who were not available to us for attempted recanalization, all have lost a leg and two have lost their lives as well (one from gas gangrene of the stump; the other from postoperative myocardial infarction). Thus, however primitive its present state of development and though its application has largely been confined to surgical "cast-offs," transluminal recanalization has proved to be an effective alternative to surgical reconstruction and a safer and otherwise more attractive alternative to amputation. As such, it deserves a serious trial in the hands of competent physicians.

**Summary**

The rationale and technic of a new procedure—transluminal recanalization of arteriosclerotic obstructions—has been described.

Of the 11 extremities treated, six have shown marked improvement (four amputations averted). It is reasonable to assume that with a perfected technic and patients with less advanced disease, the percentage of successful recanalizations would increase.

Early treatment with this technic may well prevent otherwise serious disease, not just prevent amputation of extremities not suitable for definitive surgery. We are satisfied that percutaneous transluminal recanalization is the treatment of choice for many lesions of the femoral and popliteal arteries. We believe this method is ready for application to obstructions up to approximately 10 cm. by those skilled in the use of vascular catheters. No doubt the interest and ingenuity of others will lead to refinements of technic as well as further clarification of the role of this attack on arteriosclerotic obstructions.

**Addendum**

Since this report was completed the number of treated patients has approximately doubled. There have been no further amputations and the success rate appears to have improved with experience in the selection of patients and the conduct of the procedure. Late thrombosis appears to be unlikely in the light of results to date.

**References**

Transluminal Treatment of Arteriosclerotic Obstruction: Description of a New
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