

Angioplasty and Stent Placement in Chronic Occlusion of the Superficial Femoral Artery: Technique and Results¹

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Abbreviations: ABI = ankle/brachial index, OR = odds ratio, UK = urokinase

PURPOSE: To improve the patency rate for angioplasty in chronic occlusion of the superficial femoral artery by deploying stents after angioplasty.

MATERIALS AND METHODS: Angioplasty and stent placement were performed in 61 arteries in 48 male patients. The mean occlusion length was 13.5 cm and the mean stent length was 30 cm. Patency rates were analyzed at 6 months and at 1, 2, 3, and 4 years. The predictors of restenosis were analyzed by univariate and multiple logistic regression.

RESULTS: Patency rates were 87% at 6 months, consisting of 74% primary, 6% primary assisted, and 7% secondary; 79% at 1 year, consisting of 47% primary, 19% primary assisted, and 13% secondary; 72% at 2 years, consisting of 36% primary, 26% primary assisted, and 10% secondary; 70% at 3 years, consisting of 26% primary, 22% primary assisted, and 22% secondary; and 63% at 4 years, consisting of 25% primary, 0% primary assisted, and 38% secondary. There was a 15% morbidity rate and one mortality as a result of retroperitoneal bleeding. Better patency rates were noted at all time intervals in diabetic limbs, 7-mm-diameter versus 10-mm-diameter stents, shorter obstructions and shorter stents, nonsmokers, in limbs in which urokinase was not necessary after stent deployment, and in limbs with an International Society of Cardiovascular Surgery (ISCVS) classification under 3. Patency rates were not affected by age, race, number of trifurcation vessels patent, experience in performing the procedures, and procedures requiring less time. By multivariate logistic analysis, the independent predictors of patency at 6 months were postprocedure ankle/brachial index (ABI) and shorter stent length; at 1 year, preprocedure ABI, shorter stent length, and the presence of diabetes; at 2 years, preprocedure ABI and the presence of diabetes; and at 3 years, the preprocedure ABI.

CONCLUSIONS: The techniques used to reestablish antegrade flow in these superficial femoral arteries yielded a high success rate. In addition, the use of angioplasty with stents may improve patency rates over angioplasty without stents.

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A common cause of lower extremity claudication is arteriosclerotic occlusion of the superficial femoral artery. A recent analysis of leg arteriograms on 1,000 consecutive pa-

tients with lower extremity claudication from our medical center revealed that in patients with no previous surgical or radiologic intervention in the arteries of the

legs, 40% had occlusion of one or both superficial femoral arteries and the superficial femoral was the most commonly occluded artery in the lower extremity. The first balloon angioplasty, performed by Andreas Gruentzig in February 1974, was in a superficial femoral artery (1). Since then, balloon angioplasty of superficial femoral arteries has been studied by several authors. Matsi et al (2) obtained a 3-year secondary patency rate of 55% after superficial femoral artery angioplasty in patients with leg claudication; Alback et al (3) noted a hemodynamic 2-year patency rate of 55% after angioplasty; Unni et al (4) achieved a primary patency rate of 40% at 3 years; Stanley et al (5) recorded a 2-year primary patency rate of 46% after angioplasty of superficial femoral and popliteal arteries. Stanley et al (5) did not recommend balloon angioplasty to treat claudication because of the low patency rate (5); Marzelle et al (6) observed a primary patency rate of 52% at 4 years after angioplasty in a series of stenosed or occluded superficial femoral, popliteal, or tibial arteries. Clinical trials were undertaken at our medical center to assess laser-assisted balloon angioplasty (7) and transcatheter extraction catheter atherectomy-assisted angioplasty (8,9) to reopen chronic occlusions in superficial femoral arteries. The 6-month primary patency rates for transcatheter extraction catheter-assisted angioplasty, as well as for simple balloon angioplasty, were 45%.

In comparison to surgery, Shah et al (10) noted 81% secondary patency at 5 years for above-the-knee vein grafts and Aune et al (11) achieved a 55% primary and 71% secondary patency at 2 years with use of prosthetic grafts.

The results of simple angioplasty of the superficial femoral artery have been improved by the addition of stents after angioplasty, as reported by The United States Trial on Iliac and Femoral Artery Wallstents (12), by Vorwerk et al (13) with use of Wallstents, by Richter et al (14) with use of Palmaz stents,

and by Strecker et al (15) with use of Strecker stents.

This article reports an attempt at our medical center to improve the patency rate for balloon angioplasty by deploying stents after angioplasty.

MATERIALS AND METHODS

This prospective study was approved by the Research Committee of the Medical Center and informed consent was obtained from all involved patients.

Criteria for inclusion were (i) symptoms and signs of lower extremity ischemia, (ii) no aneurysm and no stenosis greater than 50% in the aorta or iliac or common femoral arteries supplying the superficial femoral that was being treated, (iii) no stenosis in the deep femoral artery of the treated limb, (iv) angiographic evidence of complete occlusion of any portion of the superficial femoral artery, (v) evidence that the occlusion was chronic and not due to soft thrombus, (vi) patent popliteal artery and at least one of the trifurcation arteries, and (vii) no previous surgical or radiographic interventional procedures in the arteries of the treated limb.

During the 4 years the study was in progress, all patients fitting the criteria seen in the interventional radiology section of our medical center were consecutively included, with the exception of nine patients: five patients either refused the procedure or did not show up for a scheduled procedure; one patient had nonpalpable (but patent) femoral pulses in whom an axillary approach was used; one patient had gangrene of several toes of the involved limb and it was determined that amputation was more critical than superficial femoral artery stent placement; extreme obesity in one patient made an antegrade femoral approach too hazardous; and one patient was on dialysis.

Limbs were classified according to criteria for chronic ischemia suggested by the International Society for Cardiovascular Surgery (ISCVS) in 1986, and modified in 1993 and

1997 (16–18). Ankle/brachial indices (ABI) were obtained from all limbs before and after stent placement. Results of a treadmill test, along with toe and/or ankle systolic pressures before and after exercise, were obtained in seven of the 61 limbs and were used in categorizing the disease in these seven patients. The remaining limbs were categorized on clinical grounds, ankle pressures, and how far the patient could walk.

Sixty-one limbs were treated between August 1994 and December 1998. All procedures were performed in the same radiology suite by means of cut-film technique and use of Philips Polydiagnost UV equipment (Philips, Eindhoven, the Netherlands) and a long cassette BCM film changer (BCM, Montreal, Quebec). Measurements were corrected for magnification factors. The initial diagnostic arteriograms were obtained via a common femoral approach. When the occlusion was contralateral to the approach from which arteriography was performed, angioplasty and stent deployment were attempted at the time of the diagnostic arteriography via the same arterial puncture. If angioplasty and stent placement from the contralateral approach proved technically impossible, an ipsilateral antegrade common femoral approach was scheduled for a different day. The technique for traversing the occluded superficial femoral artery from a contralateral approach was similar to that described subsequently for an ipsilateral approach.

For an ipsilateral approach, a proximal common femoral artery puncture was made and a 7.5-F sheath was placed in the puncture site. With use of measurements based on the diagnostic arteriogram, a metal marker was stuck to the skin to mark the distal point of occlusion. A 5-F Glidecath angled taper (Boston Scientific/Medi-tech, Watertown, MA) catheter was advanced into the superficial femoral artery and pressed against the beginning of the occlusion. A second metal marker was placed on the skin over this proximal point of occlusion. A straight 0.035-inch, 150-

cm-long Glidewire was pushed 1–2 mm into the occlusion and the catheter was advanced over the wire the same distance. The wire was removed and 1 mL of contrast material was forcefully hand-injected into the occlusion. The hydraulic force of the injection dissected internally through the occlusion along the course of the artery. The Glidewire was gently passed along the dissection plane outlined by the contrast material. If the Glidewire became “hung up” before the termination of the dissection, the Glidecath angled taper catheter was advanced over the wire to aid in directing the wire along the dissection. The maneuver of forceful injection of contrast material followed by advancement of the catheter along the dissection plane was repeated until the dissection plane reached the metal marker on the skin indicating the area of reconstitution of the occluded superficial femoral artery. Subsequent maneuvers depended on whether injected contrast material (i) entered the patent portion of the reconstituted artery, or (ii) continued in a subintimal course beside the patent reconstituted portion of the artery.

If contrast material entered the reconstituted artery, the Glidewire was passed into the reconstituted artery, followed by the 5-F angled Glidecath. A bolus of 10,000 units of intravenous heparin was administered and continuous intravenous heparin at 1,000 units per hour was started. The patient’s clotting time was monitored each hour and the heparin administered in such a manner that the clotting time was kept at twice the normal level. The occluded segment of superficial femoral artery, identified by the metal markers stuck to the skin, along with any adjacent stenoses of 30% or more in diameter were segmentally enlarged to 6 mm by means of angioplasty. The balloons were dilated with hand pressure for 1 minute at each inflation site. Wall-stents (Schneider, Pfizer Hospital Products Group, Minneapolis, MN) were deployed in the enlarged segment from distal to proximal and, if more than one stent was used, the

stents were overlapped by approximately 5 mm. An occasional Palmaz stent (Johnson & Johnson Interventional Systems, Warren, NJ) was used if accurate deployment over a short segment of artery was necessary, usually in the proximal 1 cm of the superficial femoral artery to avoid intrusion across the origin of the deep femoral artery. A high-pressure, 7-mm-diameter, 10-cm-long angioplasty balloon was used to ensure the stents were dilated as much as possible. An intravascular ultrasound (US) examination was performed. Follow-up angiography was done through the femoral sheath and more stents were deployed if necessary. If no embolus or thrombus was seen on follow-up angiography or the intravascular US study, the clotting time was allowed to return to normal and the sheath withdrawn. If thrombus or embolus was observed, urokinase (UK; Abbott Laboratories, Abbott Park, IL) was administered at 60,000–240,000 units per hour, usually overnight. During UK infusion, the partial thromboplastin time was maintained at 60 seconds with use of intravenous heparin.

If contrast material injected into the occluded portion of the artery remained subintimal and did not re-enter the patent lumen, the following combined femoral and popliteal technique was used to move the catheter from the occluded into the reconstituted portion of the artery. A straight 5-F catheter was positioned in the dissection plane that had been created in the occluded segment of the superficial femoral artery. The patient was placed in the prone position on the fluoroscopy table and the popliteal area was prepared and draped. Approximately 5 mL of contrast material was hand injected through the sheath in the common femoral artery. By means of fluoroscopic observation of this contrast agent as a target, the popliteal artery was punctured in a proximal direction. A 0.035-inch, 260-cm straight Glidewire was passed retrogradely from the popliteal artery until the occluded segment of superficial femoral artery was encountered. A 5-F

Glidecath angled taper was passed over the wire up to the occlusion. The occluded segment was perforated with the Glidewire and the Glidecath was advanced over the wire into the occlusion. At this stage both the femoral and popliteal catheters were in separate dissection planes in the occluded artery. The two catheters were rotated and positioned in a proximal or distal direction until both catheters were in the same dissection plane. The two catheters were aligned end-to-end by manipulating the popliteal catheter. With use of this “kissing catheter” technique, the 260-cm Glidewire was passed from the popliteal catheter into the femoral catheter and out the hub end of the femoral catheter. The popliteal catheter was withdrawn as the femoral catheter was advanced over the guide wire until the femoral catheter was in the lumen of the popliteal artery. The popliteal catheter and the guide wire were removed and pressure was applied to the popliteal puncture site until bleeding ceased. The patient was again placed in the supine position, 10,000 units of intravenous heparin was administered, and the same steps were followed (as previously described) after the administration of heparin.

After completion of the procedure, the patient was observed in the surgical intensive care unit until the next morning.

The day after stent deployment, baseline duplex US imaging of the stents was performed in the medical center vascular laboratory by a certified US vascular technologist. The patient was anticoagulated for 1 month with warfarin in a dose sufficient to keep the international normalized ratio between 2.0 and 2.5 (19). One aspirin every day for 1 month was also administered. The patients were seen at monthly intervals for 5 months, during which duplex US imaging studies were obtained. If these monthly examinations showed evidence of occlusion or greater than 30% diameter stenosis in the stents (determined by a velocity greater than 125 cm/sec and the duplex image), high-pres-

sure angioplasty to 7 mm diameter was performed and/or UK therapy was instituted. At 6 months, angiography was performed on all patients from whom consent was obtained. If angiography could not be performed at 6 months, duplex US imaging was used for assessment and angioplasty for any stenoses greater than 30% diameter in the stents was performed. After 6 months, the patients were seen at 3-month intervals and duplex US imaging studies were done. Angioplasty and/or UK administration were performed if there was evidence of obstruction or 30% stenosis.

Statistical analysis was performed on a Macintosh computer (Macintosh, Cupertino, CA) with use of commercially available software programs (Statview 4.5, Abacus Concept, Berkeley, CA and JMP 3.1, SAS Institute, Cary, NC). Values were expressed as mean \pm SD. Differences between groups were evaluated by χ^2 analysis or Fisher exact test for categorical variables and Student *t* test for continuous variables. *P* values $< .05$ were considered significant. Univariate logistic regression analysis was used to select the clinical, procedural, or angiographic predictors of patency, which then were entered into a multivariate logistic model. An odds ratio > 1 means an increase in the predicted probabilities of patency for the variable listed.

Patency rates were calculated according to the method suggested by the ISCVS committee on reporting standards (7). According to these standards, primary patency is patency that "has had uninterrupted patency with either no procedure performed on it or a procedure to deal with disease progression in the adjacent native vessel." Primary assisted patency is "patency (that was) never lost but maintained by prophylactic intervention." Limbs in which angioplasty was performed again after patients left the hospital were included in this category. Secondary Patency is patency in arteries that became occluded and required embolectomy or thrombectomy or lytic therapy to



Figure 1. (a) Arteriogram showing a 24-cm segment of occluded superficial femoral artery. (b) After angioplasty and stent placement. The segment with the stent is 31 cm long (arrows).

maintain patency. "Obstruction" means an occlusion detected by duplex US or angiography that could not be corrected by surgery or lytic therapy.

RESULTS

The study group consisted of 48 male patients, of whom 13 had both limbs treated and 35 had one limb treated, for a total of 61 limbs.

The ISCVS classification of the 61 treated limbs was: category 0, zero limbs (0%); category 1, three limbs (5%); category 2, 32 limbs (52%); category 3, 22 limbs (36%); category 4, zero limbs (0%); category 5, two limbs (3%); and category 6, two limbs (3%).

Traversing, angioplasty, and stent placement were successful in all occlusions (Fig 1). An antegrade femoral approach alone was used in 24 limbs, a combined femoral and popliteal technique was used in 23 limbs, and a contralateral femoral approach was used in 13 limbs. One procedure was done entirely via a

popliteal approach. The mean length of the occlusions was 13.5 cm (range, 1–38 cm) and the mean length of deployed stents was 30 cm (range, 2.7–46.6 cm). A total of 50 ten-mm-diameter Wallstents were used for the first 15 limbs and a total of 122 seven-mm-diameter Wallstents for the last 46 limbs. Six 10-mm-length \times 6-mm-diameter Palmaz stents were used. An average of 2.8 stents (range, 1–5) were used per limb.

The average time required to complete the procedure in the 43 limbs not requiring UK was 4 hours (range, 1.83–7.83 hours). The average time required to complete the procedure in the 18 limbs requiring UK was 9.9 hours (range, 3.9–33 hours).

The average increase in ABI immediately after stent deployment was 0.26 (range, 0–0.62).

There were 18 limbs that required UK therapy due to thrombus or embolus immediately after stent deployment. Seventeen of these 18 limbs were followed for 6 months or longer. The patency rates for these 17 limbs are listed in Table 1. Two of these limbs required a surgical embolectomy because of failure of UK to dissolve the occlusion. Both limbs requiring surgical embolectomy had patent stents at 6 months.

Seven limbs, all categories 2 or 3, became obstructed within 6 months of stent deployment. The obstructions were suspected on clinical grounds and confirmed with use of duplex US imaging. Four were re-opened with use of UK and two of these underwent additional angioplasty. On the 6-month follow-up examinations, these four limbs had patent stents. The remaining three limbs could not be re-opened with use of UK. One of these three limbs required an amputation at 4 months due to gangrene. The other two limbs had obstructed stents at 6 months but the limbs were viable.

In the limbs studied with use of angiography at 6 months, the diameter at the middle of each Wallstent and the length of each Wallstent was measured at the time of deployment and at 6 months. At 6

Table 1
Segregated Patients % Patency (Primary + Primary Assisted + Secondary)

Category	6 Mo	1 y	2 y	3 y	4 y
All Patients	87	79	72	70	63
Nondiabetics	81	71	61	59	60
Diabetics	100	94	92	90	67
7-mm Stents	90	83	75	75	N/A
10-mm Stents	79	67	64	63	63
Obstruction Size (cm)					
<13.5	92	82	79	75	75
≥13.5	82	76	65	67	50
Stent Size (cm)					
<30	96	91	81	83	75
≥30	79	68	65	60	50
Nonsmokers	88	87	85	87	80
Smokers	85	71	58	50	33
Urokinase					
Not needed	89	81	76	80	80
Needed	82	73	64	58	33
Age (y)					
<65	92	87	72	66	67
≥65	81	71	71	72	50
Race					
Black	91	82	67	71	67
White	80	75	78	71	60
Trifurcation Artery Obstructions					
0	88	75	71	67	50
1 or 2	86	81	73	72	75
Experience 1st 27 Limbs*	89	83	76	75	63
Experience 2nd 26 Limbs*	85	75	67	58	N/A
ISCVS Classification					
<3	97	88	86	80	50
≥3	78	68	53	58	66

Note.—ISCVS = International Society of Cardiovascular Surgery.

* Patients receiving overnight urokinase excluded.

months, each of the stents had decreased in length, varying from 1 to 15 mm for the 10-mm-diameter stents and from 1 to 18 mm for the 7-mm-diameter stents. They also had increased in diameter, varying from 0 to 3 mm for the 10-mm-diameter stents and from 0 to 2 mm for the 7-mm-diameter stents (**Fig 2**). No increase in intimal hyperplasia was noted as a result of these stent changes. Conversely, when stents became separated due to shrinkage, hyperplasia was noticeably absent in the segment between stents.

As of the end of 1998, 6-month follow-up was available on 53 limbs, 1-year follow-up was available on 47 limbs, 2-year follow-up was available on 39 limbs, 3-year follow-up was available on 27 limbs,

and 4-year follow-up was available on eight limbs. Also, an additional five limbs at 6 months, four limbs at 1 year, two limbs at 2 years, and one limb at 3 years could not be included in the analysis because of death or inability to locate the patients. Limbs lost to follow-up were not included as patent or occluded in subsequent time intervals.

All angiographic and duplex US studies from 6 months to 4 years showed evidence of intimal hyperplasia as typified in **Figure 3b**. The diameter of maximum stenosis due to intimal hyperplasia was measured on each of the 6-month angiograms and was found to average 49%, while the minimal diameter averaged 13%. After angioplasty of the intimal hyperplasia, the maximal diameter stenosis was reduced

to an average of 24%. The progress of the intimal hyperplasia was demonstrated by the fact that 32% of limbs studied by angiography at 6 months had intimal hyperplasia of 50% or more but, at 1 year, 89% had intimal hyperplasia of 50% or more.

• Results at 6 Months

The 6-month patency rate was 87%, consisting of 74% primary, 6% primary assisted, and 7% secondary patency.

Of the 53 limbs available for analysis at 6 months, 30 were studied with use of angiography alone or with the combination of angiography and duplex US, and 23 were studied with duplex US alone. Ten of the 30 limbs studied with use of angiography underwent repeated angioplasty of the stents at the time of the 6-month angiography (**Fig 3**).

• Results at 1 Year

The 1-year patency rate was 79%, consisting of 47% primary, 19% primary assisted, and 13% secondary patency.

Of the 47 limbs available for analysis at 1 year, 13 were studied with use of angiography alone or the combination of angiography with duplex US, and 34 were studied with use of duplex US imaging alone. Seven of the 13 limbs studied with use of angiography underwent repeated angioplasty of the stents at the time of angiography. Four of the seven limbs had undergone previous angioplasty at 6 months.

• Results at 2 Years

The 2-year patency rate was 72%, consisting of 36% primary, 26% primary assisted, and 10% secondary.

Of the 39 limbs available for analysis at 2 years, 11 were studied with use of angiography alone or the combination of angiography with duplex US, and 25 were studied with use of duplex ultrasound imaging alone. Seven of the 11 limbs studied with use of angiography underwent repeated angio-

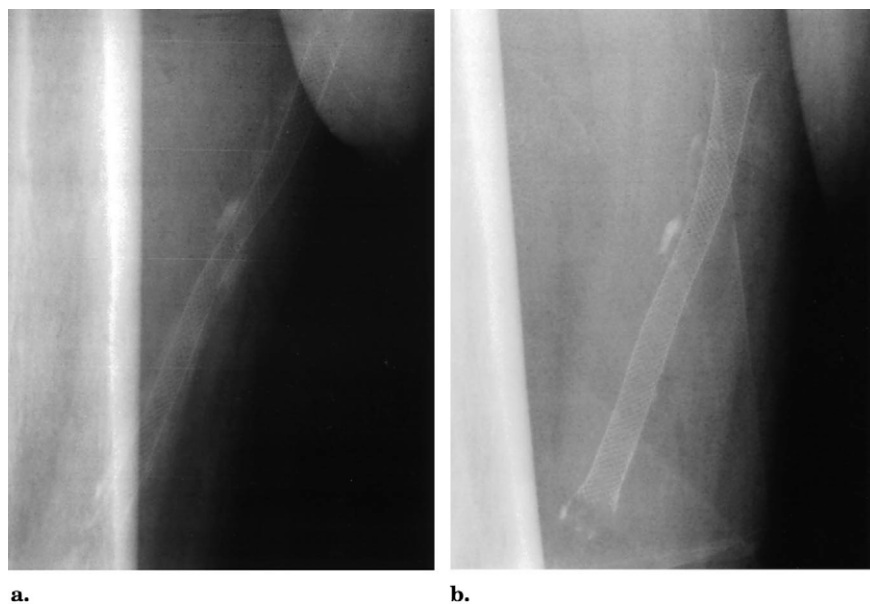


Figure 2. An example of dilation and shortening of a Wallstent. This Wallstent was designed to be 7 mm in diameter and 90 mm long. **(a)** After deployment, the stent measured 5 mm in diameter at the middle of the stent and 123 mm long. **(b)** At 6 months, the stent had shortened to 105 mm long and had dilated to 7 mm in diameter at the middle of the stent.

plasty of the stents at the time of angiography. Five of the seven angioplasty procedures were new, one limb had undergone angioplasty at 1 year but not at 6 months, and one limb had undergone angioplasty at both 6 months and 1 year.

• Results at 3 Years

The 3-year patency rate was 70%, consisting of 26% primary, 22% primary assisted, and 22% secondary.

Of the 27 limbs available for analysis at 3 years, six were studied with use of angiography alone or the combination of angiography with duplex US, and 15 limbs were studied with use of duplex US only. Three of the six limbs studied with use of angiography underwent repeated angioplasty of the stents at the time of angiography. These three limbs had undergone previous angioplasty: one at 6 months, one at 1 year, and the third had undergone three previous angioplasty procedures, one each at 6 months, 1 year, and 2 years.

• Results at 4 Years

The 4-year patency rate was 63%, consisting of 25% primary, 0% primary assisted, and 38% secondary. The 4-year patency rates were not segregated because there were only eight limbs followed.

Of the eight limbs available for analysis at 4 years, two were studied with use of angiography and duplex US, and three were studied with use of duplex US only. One of the two limbs studied with use of angiography had undergone repeated angioplasty of the stents at the time of angiography. This same limb had undergone previous angioplasty at 6 months and 1 year, for a total of three repeated angioplasty procedures.

Grouped data comparing clinical, procedural, and angiographic characteristics between the patent group and the occluded group were analyzed by an unpaired *t* test at 6 months, 1, 2, and 3 years. The 4-year characteristics were not analyzed because there were only eight limbs followed. At 6 months, the only variable that was significantly

different was the stent length, which was shorter in the patent group (27.9 ± 10.6 cm) than in the occluded group (39.3 ± 8.2 cm) ($P < .009$). At 1 year, the only variable that was significantly different was the stent length, which was shorter in the patent group (27.6 ± 10.3 cm) than in the occluded group (36.1 ± 11.0 cm) ($P < .02$). At 2 years, the preprocedure ABI was significantly higher in the patent group (0.64 ± 0.12) than in the occluded group (0.55 ± 0.10) ($P < .04$) and there was no statistical difference in the stent length. The presence of diabetes was higher in the patent group ($P < .04$). At 3 years, the preprocedure ABI was significantly higher in the patent group (0.65 ± 0.09 cm) than in the occluded group (0.52 ± 0.09 cm). The incidence of smoking was greater in the group with occluded arteries ($P < .04$). There was no difference in the stent length between the two groups at 3 years.

Univariate logistic regression analysis was performed to choose the variables to be entered into a multivariate logistic regression model for the predictors of patency. A *P* value $< .2$ was used as the criteria for entrance into the model. As shown in **Table 2**, four variables at 6 months, five variables at 1 year, five variables at 2 years, and five variables at 3 years met the criteria for entrance into the model. As shown in **Table 3**, at 6 months, multivariate analysis identified the stented segment length (odds ratio [OR] = 0.8) and the postprocedure ABI (OR = 3.5) as the independent predictors for patency. At 1 year, a higher pre-ABI (OR = 3.0), a shorter stented segment length (OR = 0.89), and the presence of diabetes (OR = 3.8) were independent predictors of patency. At 2 years, a higher pre-ABI (OR = 2.5) and the presence of diabetes (OR = 3.9) also were independent predictors of patency. At 3 years, only the pre-ABI (OR = 5.9) was an independent predictor of patency.

The patency rates of the limbs that were followed for 6 months or longer were segregated as: obstructions longer and shorter than

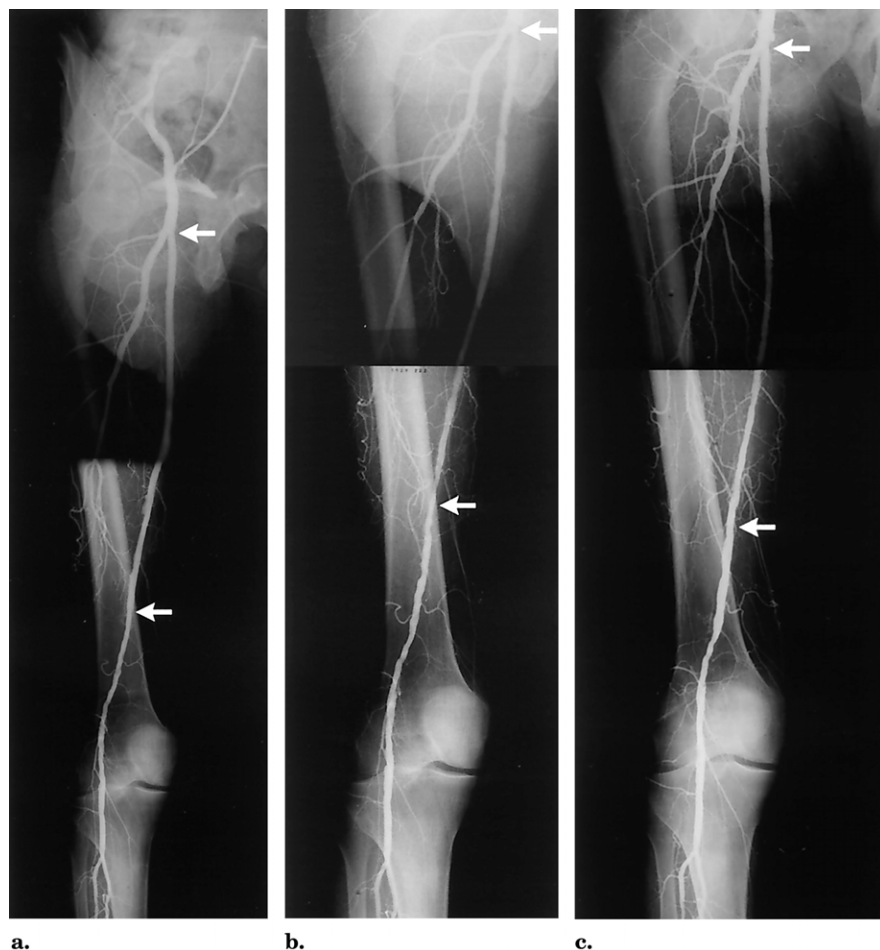


Figure 3. Example of angioplasty of intimal hyperplasia that developed in stents after angioplasty and stent placement in an occluded superficial femoral artery. (a) Angiogram of the superficial femoral immediately after stent placement (arrows). (b) At 6 months, intimal hyperplasia is evident within the stents. (c) Angiogram after angioplasty to 7 mm of the intimal hyperplasia in (b).

the median obstructed length (median, 13.5 cm; range, 1–38 cm), stents longer and shorter than the median stent length (median, 30 cm; range, 6.3–49 cm), patients older and younger than the median age (median, 65 years; range, 46–83 years), smokers and nonsmokers (27 limbs in smokers, 26 limbs in nonsmokers), diabetic and nondiabetic patients (17 diabetic limbs, 36 nondiabetic limbs), race (33 white limbs, 20 black limbs), stent diameter (14 limbs with 10-mm stents, 39 limbs with 7-mm stents), limbs requiring more or less time than the median time required to complete the procedure (median, 4 hours; range, 1.75–7.8

hours; limbs requiring UK overnight were excluded), limbs requiring UK (36 limbs did not require UK, 17 limbs required UK), the number of trifurcation arteries patent (24 limbs had no trifurcation artery obstruction, 29 limbs had one or two trifurcation arteries obstructed), increase in ABI (median, 0.27; range, 0–0.62), effect of experience (first 27 limbs, second 26 limbs), and effect of ISCVS classification of severity of disease (31 limbs were under class 3, 22 limbs were class 3 and over). The patency rates of these segregated patients are outlined in **Table 1**.

The figures for a life-table

method of analysis are presented in **Table 4** and a graph of the life-table in **Figure 4**.

• Complications

One category 3 patient died of a retroperitoneal bleed of the puncture site. Heparin therapy had been started immediately after the procedure. The bleeding was detected 2 days later while the patient was being anticoagulated with warfarin. Despite surgical drainage of the hematoma and repair of the puncture site, the patient remained hypotensive, went into renal failure, and died 3 days after stent deployment.

There were four hematomas at the common femoral puncture site. One class 6 limb required surgical closure of the artery puncture at 1 day after stent deployment because of persistent and continuous bleeding into the scrotum and penis. Three of the hematomas, in limbs classified 2, 2, and 1, did not require surgical intervention or transfusions and had no clinical sequelae. The four limbs that developed hematomas had patent stents at 6 months.

In one category 2 limb, a sheath delivering UK into the common femoral artery overnight came out of the artery sometime during the night. The next morning, there was a subcutaneous bulge at the puncture site, due to blood and/or UK. The effect of heparin was reversed with the use of intravenous Protamine and pressure was applied to the puncture site. At 1 year, the stents were patent but were occluded at 2 years.

UK was administered to nine of the 23 limbs that had a combined femoral-popliteal approach. The UK was delivered proximal to the popliteal puncture site in six limbs and distal to the popliteal puncture site in three limbs. There was no incidence of bleeding from the popliteal puncture site in these nine patients, or in the remaining 14 popliteal punctures.

One patient with a category 5 limb developed retroperitoneal bleeding 6 months after stent deployment during UK therapy for

Table 2
Predictors of Patency by Univariate Logistic Regression Analysis

Variables	Estimate	SE	χ^2	P Value*
At 6 Mo				
Stent Length	-0.1506	0.0652	5.34	.021
Post ABI	6.5941	3.7499	3.09	.079
Occlusion Length	-0.0493	0.0366	1.81	.178
Pre ABI	4.4431	3.3378	1.77	.183
At 1 y				
Stent Length	-0.0963	0.0461	4.36	.037
Pre ABI	5.8698	3.1527	3.47	.063
Post ABI	6.2916	3.4701	3.29	.069
Diabetes	0.9071	0.5529	2.69	.101
Smoking	-0.5049	0.3824	1.74	.186
At 2 y				
Pre ABI	6.9088	3.4552	4.00	.045
Post ABI	6.3822	3.4650	3.39	.065
Smoking	-0.7081	0.3899	3.30	.069
Diabetes	1.0074	0.5581	3.26	.071
Stent Length	-0.0589	0.0391	2.27	.132
At 3 y				
Pre ABI	17.8191	7.1569	6.20	.013
Smoking	-0.9359	0.4770	3.85	.049
Post ABI	9.8443	5.4493	3.26	.071
Diabetes	0.9203	0.5818	2.50	.114
Age	0.1467	0.0941	2.43	.120

Note.—Patency is defined as primary and secondary patency. ABI = Ankle-Brachial index.

* Variables with a P value <.2 are listed.

Table 3
Predictors of Patency by Multivariate Logistic Regression Analysis

Variables	Estimate	SE	χ^2	P Value*	OR	95% CI
At 6 Mo						
Stent Length	-0.1968	0.0829	5.63	.018	0.82	0.70–0.97
Post ABI	12.6373	5.4555	5.37	.021	3.54	1.21–10.31
At 1 y						
Pre ABI	11.0009	4.4976	5.98	.014	3.00	1.24–7.25
Stent Length	-0.1120	0.0515	4.73	.029	0.89	0.81–0.99
Diabetes	1.3447	0.6788	3.92	.048	3.84	1.01–14.51
At 2 y						
Pre ABI	9.0321	3.8118	5.61	.018	2.47	1.17–5.21
Diabetes	1.3641	0.6509	4.39	.036	3.91	1.09–14.01
At 3 y						
Pre ABI	17.8191	7.1569	6.20	.013	5.94	1.46–24.16

Note.—Patency is defined as primary and secondary patency. ABI = ankle-brachial index.

* P values <.05 were considered significant.

reocclusion. He was treated for hypotension, including transfusion of six units of blood, and developed temporary renal failure but ultimately was discharged from the intensive care unit. His stents could

not be reopened, although he retained his limb.

A total of six Palmaz stents were deployed in six patients. Two of these Palmaz stents became flattened. The flat configuration was

observed in both cases by duplex US imaging and confirmed by fluoroscopic observation. The first flat Palmaz stent was discovered in a category 1 limb by routine duplex US imaging 9 months after deployment. It was located between two Wallstents in the distal superficial femoral artery. Five stents had been deployed, four Wallstents and one Palmaz stent. Despite the turbulent flow around the stent, the artery was patent. By means of a contralateral femoral approach, the flat stent was opened by inflating an angioplasty balloon inside the flattened stent, followed by deployment of a 7-mm-diameter \times 2-cm-long Wallstent inside the Palmaz stent. These stents were still patent 27 months after redilation. The second flat Palmaz stent was discovered by duplex US imaging 10 months after deployment, when the patient reported sudden return of claudication. The flat stent was in the initial 1 cm of the superficial femoral artery in a category 2 limb. At angiography, the Palmaz stent, along with the other deployed Wallstents, was found to be occluded with soft thrombus. Overnight UK therapy lysed the thrombus. The flat Palmaz stent was reopened with use of an angioplasty balloon, followed by deployment of a 7-mm-diameter \times 2-cm-long Wallstent inside the Palmaz stent (**Fig 5**). Seven months after the reopening, the stents were occluded and could not be reopened with use of UK.

On the routine 6-month follow-up angiogram of one category 2 limb, a total of three stent breaks were noted, one break each in three 10-mm-diameter \times 94-mm-long Wallstents. The breaks were manifest by interruption in the wires (**Fig 6**). Although the lumen through the broken portions of the stents was patent, 60%–80% stenosis due to intimal hyperplasia at two of the three breaks required angioplasty. There was similar narrowing, not located at breaks, in other portions of the stents that also required angioplasty. The ABI increased from 0.66 before the angioplasty to 1.0 after the angioplasty. The reason for the broken stents was

Table 4
Life Table Analysis for Secondary Patency of Superficial Femoral Artery Stents

Interval (mo.)	No. Limbs at Risk at Start	No. of Failed Stents	Withdrawn during Interval	Interval Patency (%)	Cumulative Patency (%)	SE (%)
0 to 1	58	2	2	0.96	100	0
1 to 2	54	0	0	1.00	96	2.61
2 to 3	54	1	1	0.98	96	2.61
3 to 4	52	2	1	0.96	94	3.39
4 to 5	49	0	0	1.00	90	4.52
5 to 6	49	2	1	0.96	90	4.52
6 to 12	46	3	6	0.93	86	5.52
12 to 24	37	2	8	0.94	80	7.35
24 to 36	27	0	10	1.00	75	9.62
36 to 48	17	0	14	1.00	75	12.13

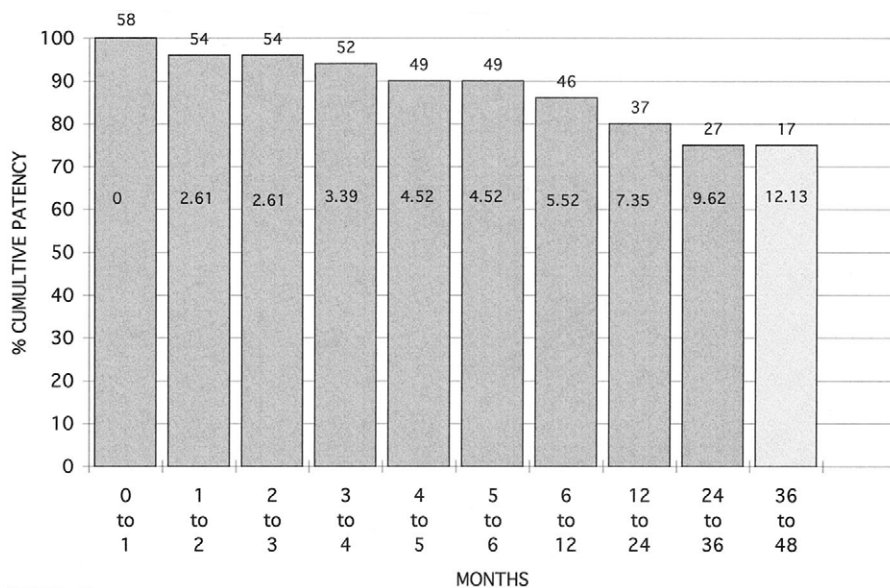


Figure 4. Graph of life-table analysis. The numbers at the tops of the columns indicate “number of patients at risk.” The numbers within the columns indicate SE.

not evident and the patient was lost to follow-up after 6 months.

• **Amputations**

Four patients required amputations of stented limbs from 2 to 6 months after stent deployment. The ISCVS categories of the amputated limbs were 6, 6, 3, and 2. Category 2 is “moderate claudication,” category 3 is “severe claudication,” and category 6 is “major tissue loss with a functional foot no longer salvageable.” In the first limb, a category 6 in a diabetic nonsmoker, the patient

required a Symes amputation at 6 months. The stents were patent at the time of the amputation and 4 years after deployment. In the second limb, a nondiabetic smoker classified as category 3, the stents were occluded clinically and by duplex US imaging at 4 months. Despite what appeared to be soft clot at angiography, 2 days of UK therapy failed to reopen the lumen within the stents. A subsequent femoropopliteal bypass graft also became occluded. The graft was reopened with use of UK but reoccluded within 1 day and patency

could not be maintained. The third patient, a nondiabetic smoker with a category 2 limb developed thrombus in the stents immediately after and at 1 week after stent deployment. At both times the thrombus was cleared by means of overnight UK infusion. The final ABI was 0.85. The patient was lost to follow-up for 5 months, then reappeared in the clinic with gangrene of two toes and the dorsum of the foot. His stents were occluded on duplex US and he required a below-the-knee amputation. The fourth patient, a nondiabetic smoker with category 6 disease, requested amputation 2 months after stent deployment because of constant rest pain, unchanged from before stent deployment. His stents were patent at the time of amputation, and for 1.5 years after stent deployment.

DISCUSSION

In an attempt to improve the patency rate of simple angioplasty in occluded superficial femoral arteries, 61 occlusions were traversed with hydraulic dissection with or without a kissing catheter technique, and underwent angioplasty and stent placement. The results in the total population, as well as various categories of patients, were analyzed at 6 months, 1, 2, 3, and 4 years.

The 100% technical success rate was dependent on the use of the combined femoral and popliteal approach, with the kissing catheter technique, to traverse from the occluded portion into the reconstituted portion of the superficial femoral arteries. This technique was necessary in 23 of the 61 treated limbs.

A technique of advancing a wire through an occluded superficial femoral artery was described by Biola et al in 1990 (20). Biola assumed the wires were subintimal when they traversed the occluded segment. Random observations with intravascular US after stent deployment suggested the stents were sometimes subintimal, and sometimes entirely within the occluded

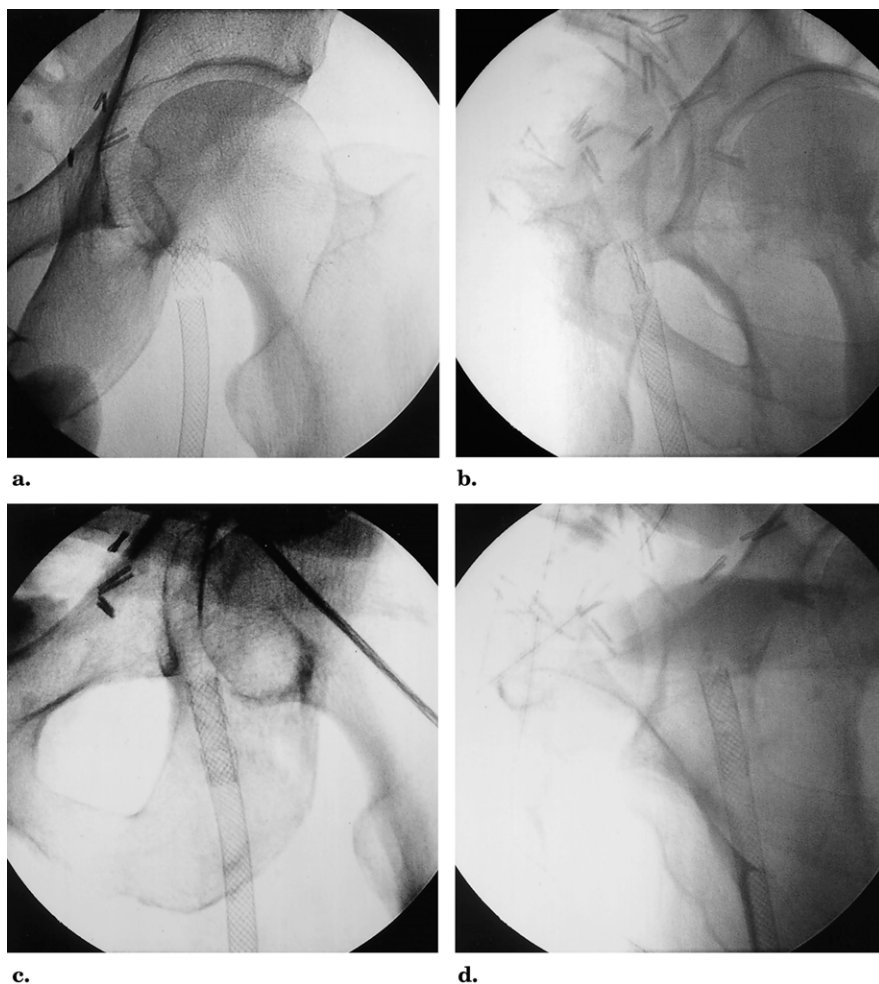


Figure 5. Flat Palmaz stent in the proximal superficial femoral artery. (a,b) Anteroposterior and lateral views of the flat stent. (c,d) Anteroposterior and lateral views of the Palmaz stent after dilatation and deployment of a Wallstent within the Palmaz stent.

lumen, and not subintimal. It is possible that wires that were in the lumen when they exited the occluded segment were never subintimal as they traversed the occlusion.

There was a decrease in primary patency from 74% at 6 months to 47% at 1 year, 36% at 2 years, 26% at 3 years, and 25% at 4 years. This decrease in primary patency occurred because, on follow-up, there was intimal hyperplasia of 30% or more within the stents, which was sufficient to warrant repeated angioplasty. When angioplasty was used to treat the intimal hyperplasia, the category changed from primary patency to primary assisted

patency. This was noted in 11 limbs at 6 months, seven limbs at 1 year, eight limbs at 2 years, three limbs at 3 years, and one limb at 4 years. Choice of the 30% criterion for repeated angioplasty of stents, as well as for angioplasty of stenoses adjacent to occluded segments at the time of initial stent deployment, was influenced by the ISCVS 1993 article defining "anatomic success of treatment . . . as residual luminal stenosis of less than 30% of normal diameter" (17). Stenoses of greater than 30%, rather than the customary 50%, adjacent to the occlusions underwent angioplasty and stent placement to afford the best chance

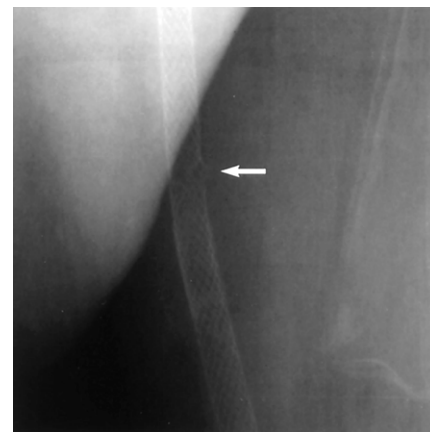


Figure 6. Broken Wallstent. The arrow indicates the break. The stent is located midway along the course of the superficial femoral artery.

of patency in the stents by providing optimal inflow and outflow. This accounts for the fact that the mean occlusion was 13.5 cm, while the mean stent length was considerably longer at 30.0 cm. Although 30% stenosis was chosen as the lower limit for angioplasty of intimal hyperplasia, the average diameter stenosis that underwent angioplasty on follow-up angiography was 49%.

Because of a limited number of cases, none of the patency rates in the segregation of patients in **Table 1** was statistically significant. However, some interesting trends were noted. Diabetic limbs had better patency rates than nondiabetic limbs. The average length of the stents in diabetic limbs was 18 cm and in nondiabetic limbs was 31 cm. The shorter stent length may account for the better patency rates in diabetics. Seven-millimeter-diameter stents had better patency rates than 10-mm-diameter stents. The average length of the 10-mm-diameter stents was 36 cm; the average length of the 7-mm-diameter stents was 29 cm. The shorter stent lengths in 7-mm-diameter stents may account for their better patencies. Some of the trends were expected: shorter obstructions and shorter stents had better patency rates than longer obstructions and longer stents, nonsmokers better than smokers, limbs in which use of

UK was not necessarily better than those in which use of UK was necessary, and limbs with a lower ISCVS classification of disease better than limbs with a higher classification. Age, race, the number of trifurcation vessels patent, and experience in performing the procedure did not affect patency rates, as noted in **Table 1**.

The time required to complete the procedures was less for the last 26 limbs (average, 4.2 hours) than for the first 27 limbs (average, 4.7 hours) (limbs requiring overnight UK were excluded from this time analysis). This probably means that with increased experience comes increased expertise.

The results of the multiple logistic regression analysis indicate the chance of having a patent stented artery at 6 months was increased 3.5 times for every 10% increase in the postprocedure ABI. Also, the likelihood of occlusion at 6 months increased 20% for every 1 cm of stent length. The strongest predictor of patency at 1 or 2 years after the procedure was the baseline ABI. For every 10% increment of preprocedural ABI, the likelihood of patency increased 3 times at 1 year and 2.5 times at 2 years. The presence of diabetes remained a significant predictor of patency at 1 or 2 years but some of this association could be explained by the shorter length of stents used in the diabetic patients. For the 27 limbs followed for 3 years, the only independent predictor of patency was the pre-ABI. This measure of the severity of baseline disease increased the likelihood of patency by 5.9 times for every 10% increment of pre-ABI.

Regarding the one fatality, the initiation of heparin immediately after completion of stent deployment may have been a factor in the retroperitoneal bleeding. After this death, in subsequent limbs, heparin therapy after stent deployment was withheld until 24 hours after completion of the procedure.

Mechanical deformity occurred in some Wallstents and in some Palmaz stents used in this series. The Wallstent deformity was manifest by three breaks in different

stents in the same superficial femoral artery, possibly due to metal fatigue caused by repeated leg movement. The lumen was not occluded at any of the breaks. The two flat Palmaz stents were presumably due to external compression and, in one of these limbs, the compression probably resulted in occlusion of the superficial femoral artery. Rosenfield et al (21) found compression in all of a series of 11 patients in whom balloon-expandable stents were used in superficial femoral arteries and in hemodialysis fistulas. The phenomenon of mechanical stent deformity requires further study, which may suggest that balloon-expandable stents are more suitable for locations not subject to external compression.

The use of stents after angioplasty in chronically occluded superficial femoral arteries improved the 6-month primary patency rate from 45% to 74% when compared with angioplasty alone. The 1- and 2-year total patency rates of 79% and 72% compare favorably with the results of the United States Trial On Iliac and Femoral Artery Wallstents, which reported a total patency rate of 84% and 72% at 1 and 2 years in opening occluded superficial femoral arteries (12). Vorwerk and Gunther had a primary patency rate 63% and a secondary patency rate of 83% at 1 year with use of Wallstents after angioplasty in occluded superficial femoral arteries (13). Richter et al (14) obtained an 80% 6-month success rate in stenosed and occluded superficial femoral arteries with use of Palmaz stents after angioplasty. Strecker et al (15) reported a 2-year primary patency rate of 30% with use of Strecker stents in femoropopliteal artery occlusions. Vroegindewij et al (22) reported a 1-year primary patency rate of 62% with use of Palmaz stents in a series of stenosed and occluded superficial femoral arteries. They concluded balloon angioplasty alone was more effective than stent placement in these femoropopliteal lesions. However, stents were placed in only four occlusions, all 5 cm or less in length (22).

It should be noted that all the complications, including the one death and four amputations, were from the group of 48 limbs in which an ipsilateral femoral approach was used. This technique requires a high (ie, proximal) puncture of the common femoral artery to have sufficient distance to maneuver a catheter from the common femoral artery into the superficial femoral artery. Because of the proximal position of the puncture in the common femoral artery, it is difficult to compress at the end of the procedure. Also, it is difficult to determine when there is bleeding from the puncture site, especially if the bleeding is retroperitoneal. A possible way of avoiding this high femoral puncture would be to use a contralateral femoral approach combined with an ipsilateral popliteal puncture when necessary (ie, when the dissection plane remains subintimal and does not re-enter the artery distal to the occlusion). This particular approach was not attempted in any of the 13 limbs in which a contralateral approach was used.

The results of this study suggest that stent placement after angioplasty in chronic occlusion of the superficial femoral artery may increase the patency rate when compared with angioplasty alone. However, the complication rate in this series of 61 limbs in 48 patients was high. There were four amputations within 6 months of stent deployment. Two of the amputations were in category 6 limbs with irreversible ischemic damage. In both of these limbs, the stents were patent at the time of amputation. However, the remaining two amputations can be considered as complications of the angioplasty-stent placement procedure. The first of these two amputations was in a category 3 limb (severe ischemia) that had occluded stents 4 months after the procedure. The circulation could not be restored with use of UK or with a femoropopliteal bypass. The second limb, a category 2 limb (moderate claudication), became occluded at 4 months, requiring a below-the-knee amputation due to gangrene. The secondary patency rate in this study of 72% at 2 years

is not as good as Shah's 81% secondary patency at 5 years for above-the-knee vein grafts (10), and is similar to Aune's 71% secondary patency for above-the-knee prosthetic grafts (11). The amputations in category 2 and 3 limbs, along with one death, suggest this recanalization procedure should be reserved for patients with threatened limb loss who are poor surgical risks for bypass surgery.

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