# Preliminary results of subintimal angioplasty for limb salvage in lower extremities with severe chronic ischemia and limb-threatening ischemia

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***Objective:*** **This study examined the hypothesis that superficial femoral artery (SFA) subintimal angioplasty ( SI-PTA) can maintain limb salvage with minimal complications in patients with symptomatic occlusive arterial disease.**

***Methods:*** **From March 1, 2004, until April 28, 2006, 78 patients with rest pain (62.2%), gangrene (25.6%), or severe progressive claudication (12.2%) were treated consecutively with 82 SFA SI-PTAs (4 bilateral). The mean age was 59 ± 1.2 years, and 21 (27%) of the patients were female. All patients were treated in the operating room under local anesthesia by using fluoroscopic guidance, and the percentage SFA that was occluded was measured during the diagnostic portion of the procedure. Selective stent placement was performed after successful recanalization of the occluded arterial segments. Patients were treated with chronic aspirin and clopidogrel bisulfate for 3 months and followed up at 30 days and then every 3 months with physical examination and arterial duplex scan.**

***Results:*** **Of the 82 SFA SI-PTA attempts, 76 (92%) were initially successful, with an increase in the ankle-brachial index from 0.46 ± 0.02 to 0.88 ± 0.01 ($P < .001$). Five of the six patients with a failed SFA SI-PTA were female, two of the six had had previous bypass attempts, and one of the six had had a previous SFA SI-PTA attempt by another physician. Forty-nine (64%) of the 76 initially successful SFA SI-PTAs required placement of a stent, and 43 (56.5%) of the successful 76 SFA SI-PTAs required additional PTA of 1 or more arterial segments. The group treated with a successful SFA SI-PTA had 42.5% ± 3.5% SFA occlusion, compared with 82% ± 10% ($P < .05$) in the group with a failed attempt at SFA SI-PTA. Two of the six patients with initial SI-PTA failure underwent leg amputation within 30 days, three were treated with successful leg bypass surgery, and one was lost to follow-up. Of the 76 successful SFA SI-PTAs, 5 (6.5%) failed within 90 days, and the patients were treated successfully with leg bypass surgery. Of the 71 limbs with patent SI-PTAs at 90 days, 68 have remained patent with a mean follow-up 10.4 ± 0.7 months (range, 2-24 months). Three of the 71 SFA SI-PTAs failed between 4 and 7 months (mean, 5 ± 0.7 months): 1 patient was treated with successful bypass surgery, 1 patient is currently considering further intervention, and 1 patient was treated with amputation. Ten (14%) of the 71 successful SFA SI-PTAs required limited PTA for asymptomatic restenosis, as identified by the arterial duplex scan (7.4 ± 1.4 months; range, 2-16 months). There were no perioperative deaths, and three patients have died during follow-up with patent SFA SI-PTAs (9.3 ± 1.4 months).**

***Conclusions:*** **These data suggest that SFA SI-PTA can be successfully used for limb salvage with minimal morbidity and mortality in a group of patients with severe lower extremity occlusive vascular disease. ( J Vasc Surg 2006;44:1239-46.)**

The technique of subintimal angioplasty (SI-PTA) for the treatment of occluded femoropopliteal arteries was first developed by Bolia et al[1] in 1987 and was first reported in 1989. These authors later reported that SI-PTA can be applied to the tibial arteries with very good success.[2,3] Over the ensuing 19 years, a small number of centers in Europe and North America have reported their results, with primary success rates 80% to 90% and limb salvage rates consistently in the 80% to 90% range.[4-20] Despite the publication of Lipsitz et al[14] in 2003, there have been few publications from North American vascular centers.[15-17] Lipsitz et al speculated that this could be due to either skepticism of the procedure or the fact that it may require a steep learning curve.

For this study, SI-PTA was applied to a population of patients who presented with severe critical limb ischemia and occlusive disease of the superficial femoral artery (SFA). This study examined the hypothesis that lower extremity SFA SI-PTA can maintain limb salvage with minimal morbidity and mortality in patients with severe lower extremity chronic ischemia and limb-threatening ischemia.

## METHODS

From March 1, 2004, until April 28, 2006, we prospectively evaluated 122 consecutive patients who presented with 126 lower extremities with severe chronic ischemia at the McGuire VA Hospital or Medical College of Virginia Hospital. Eighteen patients with SFA origin occlusions were treated with femoral-distal bypasses and are not included in this article. Seventy-eight patients (82%) with severe chronic ischemia of 82 limbs and SFA occlusions (82% of limbs treated with SFA occlusions) with at least 0.5

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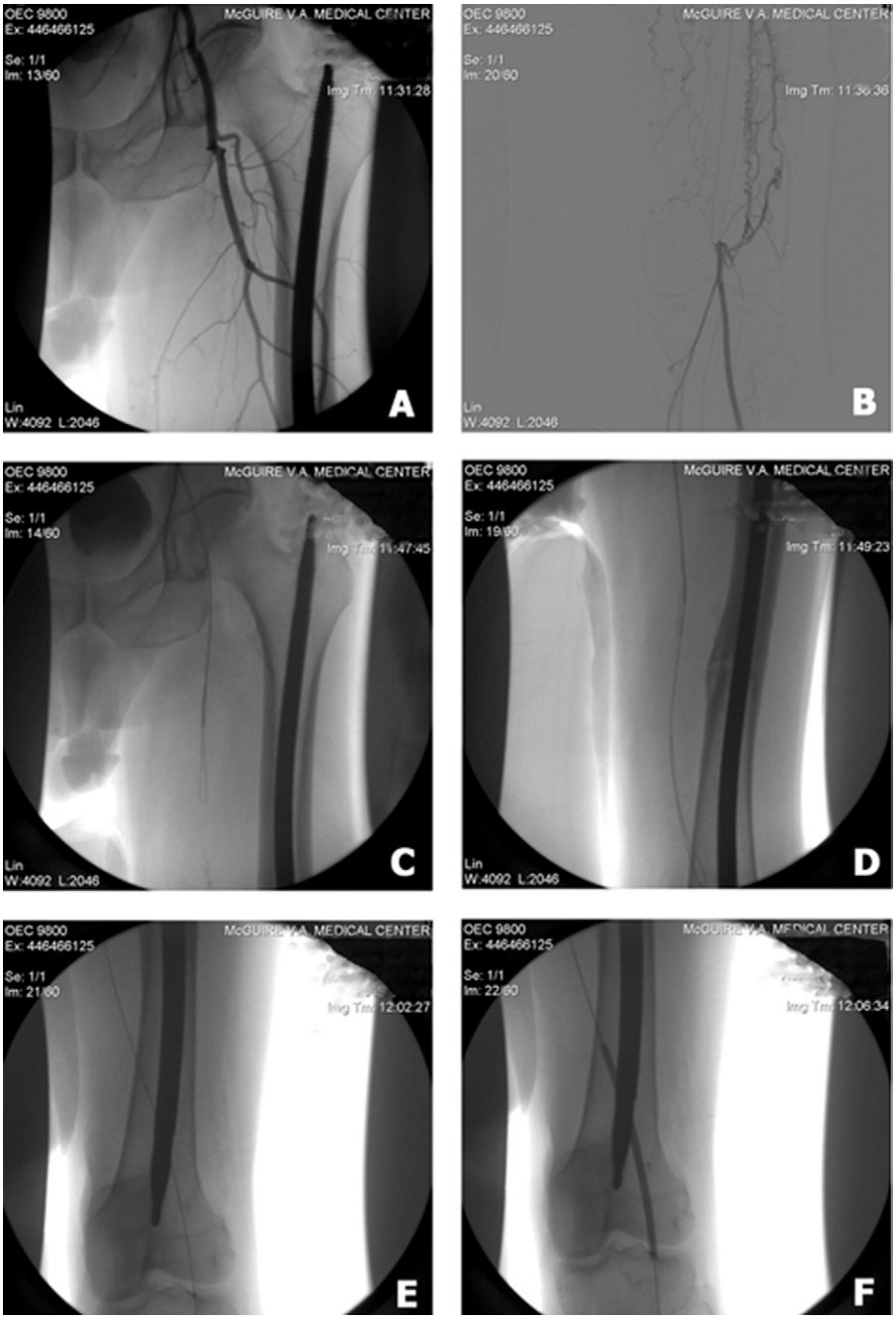


**Fig 1.** Subintimal angioplasty of a flush superficial femoral artery (SFA) occlusion performed via a contralateral common femoral artery approach. Preintervention angiogram of the SFA origin (**A**). Preintervention angiogram of the reconstituted popliteal artery, just above the knee joint (**B**). Initiation of the subintimal dissection with creation of the wire loop (**C** and **D**). The wire has re-entered the popliteal artery lumen with the angioplasty balloon catheter before expansion: nonexpanded (**E**) and after balloon expansion (**F**).

cm of a patent proximal SFA (except 1 patient) were treated with SFA SI-PTA. One patient had a occlusion of the SFA at the origin and was treated with SFA SI-PTA (Figs 1 and 2). All 82 limbs (78 patients) had a patent SFA or popliteal artery distal to the occluded SFA segment that we considered adequate to permit re-entry of the wire and catheter. Twenty-six of the 122 patients evaluated for severe distal leg chronic ischemia had SFA stenoses and were excluded from this study (all were treated with successful endovascular reconstructions).

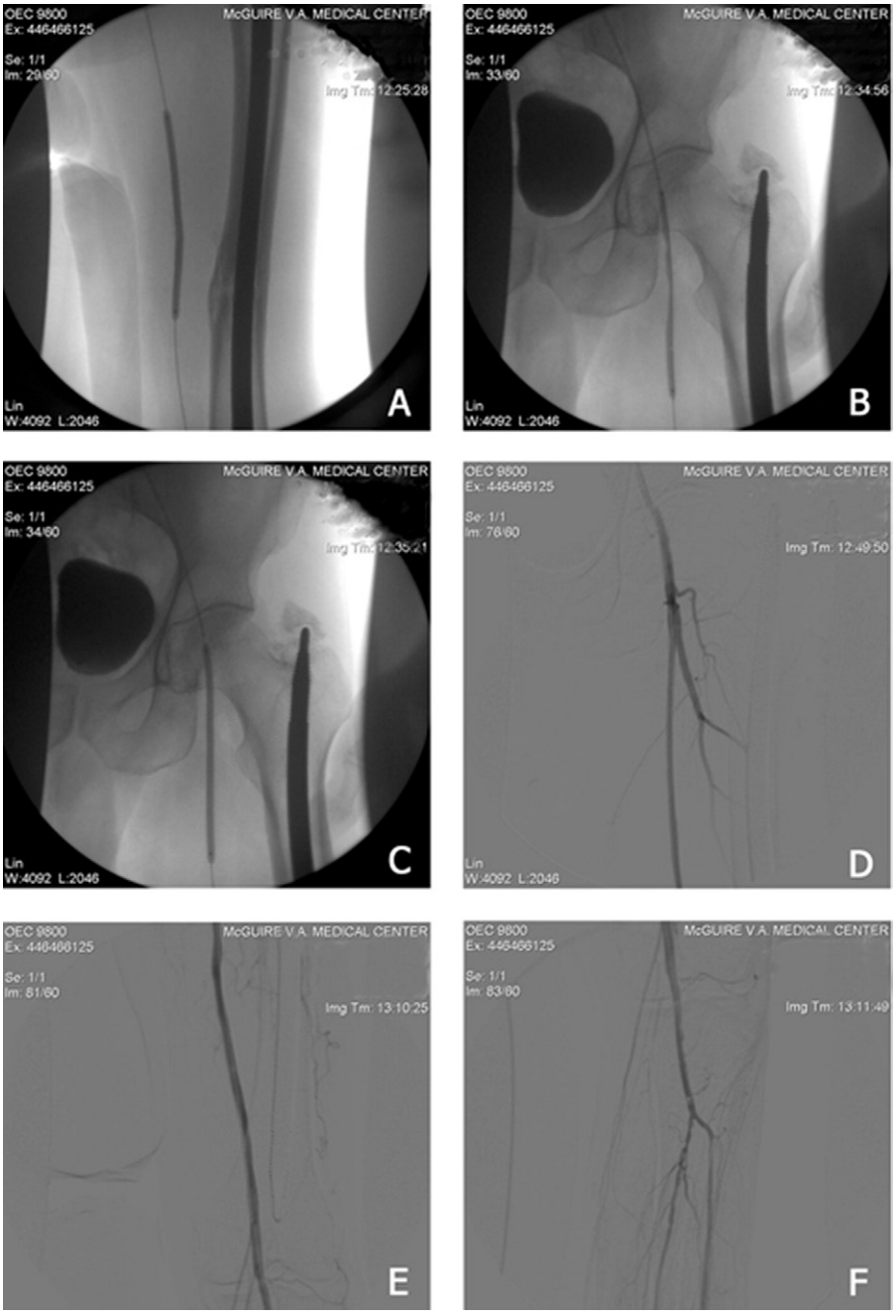


**Fig 2.** Subintimal angioplasty of a flush superficial femoral artery (SFA) occlusion performed via a contralateral common femoral artery approach. The angioplasty balloon expanded toward the origin of SFA in an ascending manner (**A**-**C**). Completion angiogram showing patent SFA, popliteal, tibial perineal trunk, posterior tibial, and anterior tibial arteries (**D**-**F**).

All 82 SFA SI-PTAs were performed in the operating room with a C arm (OEC, 9800 Plus; GE Healthcare, Salt Lake City, UT) with patients under local anesthesia. All patients who presented with a serum creatinine level greater than 1.1 mg/dL were treated with the sodium bicarbonate protocol, as previously described.[21] The arterial occlusions were approached either by an antegrade common femoral artery puncture or by a contralateral common femoral artery puncture. When a contralateral femoral artery puncture was used, a 45-cm 6F sheath was placed over the aortic bifurcation. One technical modification for going up and over difficult aortic bifurcations was the use of a guiding

catheter through the 6F 45-cm sheath to allow 100% success. Before each SFA SI-PTA attempt, the percentage of SFA occluded or involved with a stenosis greater than 50% was recorded during the diagnostic portion of the arteriogram. The authors believed this to be a more accurate assessment of the true length of SFA involved with occlusion or severe stenosis, because measuring the length of disease segments in centimeters would reflect a different percentage of the SFA involved when comparing patients with different limb lengths. After the diagnostic portion of the arteriogram, a subintimal dissection plane was created with an angled floppy hydrophilic wire (Aqwire, hydrophilic .035 standard body, $EV_3$, Minneapolis, Minn; Terumo hydrophilic .035 angled floppy Glidewire, Boston Scientific, Natick, Mass) supported by a 5F or 4F angled catheter. Re-entry into the true lumen below the arterial occlusion was confirmed by angiography. The recanalized segment was then subjected to balloon insufflation, and the need for stent placement was determined by the results of the completion arteriogram. A stent was placed if there was significant recoil of the lesion or residual stenosis greater than 30% or for intimal dissections causing a flow-limiting lesion or thought to be a high risk for progression to a flow-limiting lesion. The stents were all self-expanding bare stents. The length of the stent (or stents) was determined by the length of artery that needed to be treated. The senior author used long stents (100-120 mm) when the segment of SFA requiring a stent was of a similar length. The site of re-entry of the subintimal dissection was purposely chosen both to be below the arterial occlusion and to avoid using an arterial segment that could be used for future bypass grafting (Figs 1 and 2).

SI-PTA has been previously described,[1-20] and its description will not be repeated here. Significant arterial stenoses proximal or distal to the recanalized subintimal segment were treated concurrently with balloon PTA with or without stent placement.

All patients were continued on chronic aspirin treatment, and clopidogrel bisulfate was given for 3 months after the SFA SI-PTA. The patients were evaluated with physical examination, segmental limb pressures, pulse volume recordings, and arterial duplex scanning before the procedure, before discharge, 30 days after discharge, and every 3 months thereafter.

Risk factors, demographics, initial technical success, short-term and long-term morbidity and mortality, recurrent disease, and short-term patency were evaluated with the reporting standards developed by the Joint Council of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery.[22] Patency of the arterial SI-PTAs was defined as antegrade flow without significant stenoses (<30%). Lesions were considered to be recurrences when the stenosis was 50% (ratio of the peak systolic velocity of the involved SFA compared with the proximal normal segment >2, as identified by the duplex scan). Long-term assisted primary patency and limb survival were calculated by using Kaplan-Meier curves. Comparisons between the survival plots were made by using a log-rank statistic for the 76 SFA SI-PTAs that were initially successful. The primary assisted patency combines patency after the initial SFA SI-PTA and treatment of recurrent lesions with additional endovascular interventions.

**Table I.** Risk factors for the patient population

| *Variable* | *Data* |
|---|---|
| Tobacco use | 94.8% |
| Hypertension | 75.6% |
| Lipid abnormalities | 65.0% |
| Diabetes mellitus | 63.0% |
| Coronary artery disease | 46.0% |
| Mean serum creatinine | 1.37 mg/dL |
| Chronic obstructive pulmonary disease | 14.6% |
| History of stroke | 10.0% |
| Drug/alcohol abuse | 10.0% |

**Table II.** Outcome of SFA SI-PTA attempts (<90 days)

| *Variable* | *Data* |
|---|---|
| Total No. limbs at risk | 82 |
| Successful initial SFA SI-PTA | 76 (92.6%) |
| Unsuccessful initial SFA SI-PTA | 6 (7.4%) |
| Failure of SFA SI-PTA <90 d | 5 (6.1%) |
| Patent SFA SI-PTA >90 d | 71 (86.6%) |
| Total amputations <90 d | 2 (2.4%) |
| Bypass <90 d | 8 (9.7%) |
| Lost to follow-up <90 d | 1 (1.2%) |

Superficial femoral artery subintimal angioplasty.

## RESULTS

**Demographic data.** From March 2004 to April 2006, 78 patients with 82 limbs with severe chronic ischemia and SFA occlusions were treated consecutively with SFA SI-PTA. The 57 men (73%) and 21 women (27%) ranged in age from 42 to 88 years (mean, 59.4 ± 1.2 years). Fifty-one limbs (62.2%) were treated for rest pain (category 4), 21 limbs (25.6%) were treated for nonhealing ulcers or gangrene (category 5), and 10 limbs (12.2%) were treated with severe progressive claudication (category 3). A large percentage of the patients had multiple significant medical comorbidities, which are listed in Table I. It should be noted that 15 of the 78 patients presented with a serum creatinine level greater than 1.4 mg/dL (upper limits of normal in our laboratory).

**Technical outcomes.** Seventy-two patients (92.6%) underwent 76 successful SFA SI-PTAs, whereas 6 (7.4%) attempts at SFA SI-PTA failed (Table II). The technical reasons for failure to perform SFA SI-PTA were inability to pass a wire through the SFA occlusion in five patients and inability to follow successful wire placement with catheter advancement in one patient. Five of the six patients who did not have successful SFA SI-PTA were female. One of these female patients had two previous leg bypasses, and one had an unsuccessful attempt at SFA SI-PTA by another physician. Of the six patients with unsuccessful SFA SI-PTA,

**Table III.** Indications for intervention and short-term and long-term failures

| *Variable* | *% SFA occluded* | *% SFA with stenosis* | *% Total SFA disease* |
|---|---|---|---|
| Group 1 (76 successful initial SFA SI-PTAs) | 42.5% ± 5.5% | 31.5% ± 2.3% | 77.2% ± 4.6% |
| Group 2 (6 initial SFA SI-PTA failures) | 82% ± 10%* | 17% ± 11% | 99% ± 0.2%* |
| Group 3 (5 occlusions after initial technical success; < 90 d) | 77% ± 12%* | 15% ± 7% | 92% ± 5.8% |
| Group 4 (10 recurrent lesions) | 23.4% ± 12%* | 40% ± 6.4% | 63.4% ± 7% |

*SFA,* Superficial femoral artery; *SI-PTA,* subintimal angioplasty.
*$P < .05$ vs group 1 by the Student *t* test.

**Table IV.** Indications for intervention and short-term and long-term failures

| *Variable* | *Category 3 (severe claudication)* | *Category 4 (rest pain)* | *Category 5 (ulcer/gangrene)* |
|---|---|---|---|
| Initial technical failure | 0 | 5 | 1 |
| Occlusion after initial technical success (<90 d) | 0 | 4 | 1 |
| Total | 1 | 9 | 2 |

three were treated successfully with leg bypass, one was lost to follow-up, and two required below-knee amputation because they were referred from other institutions after attempts at unsuccessful bypass surgery. Five patients with a successful SFA SI-PTA experienced treatment failure within 90 days and were termed the *open/close group* (see below). Two of these five patients did not take the suggested antiplatelet agents. All were treated successfully with leg bypass surgery. Table III provides a summary of the total number of patients in whom SFA-SI-PTA failed within 90 days of the procedure.

Forty-three (56%) of the 76 successful SFA SI-PTAs required a stent. Of the 11 SFA SI-PTAs that failed either initially or by 90 days after the procedure, 7 were treated with a stent.

Forty-three (56%) of the 76 successful SFA SI-PTAs required a PTA or SI-PTA of additional arterial segments. These included the iliac artery (n = 10), proximal SFA (n = 4), popliteal artery (n = 16), tibial/peroneal trunk (n = 12), and tibial arteries (n = 20).

Table III details the percentage occlusion and percentage diseased SFAs for all patients, for those with initial treatment failures, for those who had treatment failures within 90 days, and for those who had recurrence. The percentage occlusion of SFA in the initial failure group and in the group who had failure by 90 days was significantly higher than the percentage occlusion in the group with initial SFA SI-PTA success ($P < .01$). Only the initial failure group had a significant combined percentage occlusion and severe stenosis compared with the initial success group. Although this finding would suggest that SFA SI-PTA has a higher success rate in SFAs with less percentage occlusion, one must be cautious, because 15 limbs with percentage occlusions ranging from 75% to 90% underwent successful SFA SI-PTA. It is interesting to note that the percentage occlusion in the recurrence group was less than the percentage occlusion in the initial successful SFA SI-PTA group. Table IV demonstrates that 10 of the 11 patients who had initial or long-term failure of the SFA SI-PTA presented with either category 4 or category 5 indications for intervention. These findings suggest that factors other than the length of SFA occlusion contribute to the initial and short-term success of the SFA SI-PTA.

**Clinical outcomes.** All patients with a successful SFA SI-PTA underwent duplex imaging of the treated arteries and measurement of ankle-brachial indexes (ABI). For the group of successful SFA SI-PTAs, the duplex scans showed patent SFA SI-PTAs and the other arteries treated with PTA and SI-PTA. The ABI was measured in patients who had compressible vessels (n = 76) and increased from 0.45 ± 0.02 to 0.86 ± 0.02 after the procedure. The patients with successful SFA SI-PTAs experienced resolution of claudication and either resolution or a marked improvement of rest pain. The patients who presented with ulcers and areas of gangrene have responded to aggressive surgical debridement and wound care, and have all healed.

There were three late failures after successful SI-PTA. One patient who had two previous attempts at limb salvage with bypass surgery had an occluded SFA SI-PTA at 7 months and refused further reconstruction. Two other patients had occluded SFA SI-PTAs at 4 months and are being closely followed up with severe but stable claudication and will be offered open surgical bypass options in the near future. One patient was lost to follow-up 5 months after successful SFA SI-PTA.

The 71 patients who had successful SFA SI-PTAs that were patent 90 days or more have a cumulative patency rate of 86% with a mean follow-up of 10.0 ± 0.76 months. Ten (14%) of the 71 SFA SI-PTAs that were patent for longer than 90 days have required a limited PTA for asymptomatic stenosis, which was identified during routine outpatient follow-up duplex scanning. None of the 10 patients had a decrease in ABI despite the demonstration of a 50% or more recurrence on duplex scan. Asymptomatic recurrent stenoses occurred at 7.4 ± 1.4 months (range, 2-16 months). All 10 of these patients have continued to have

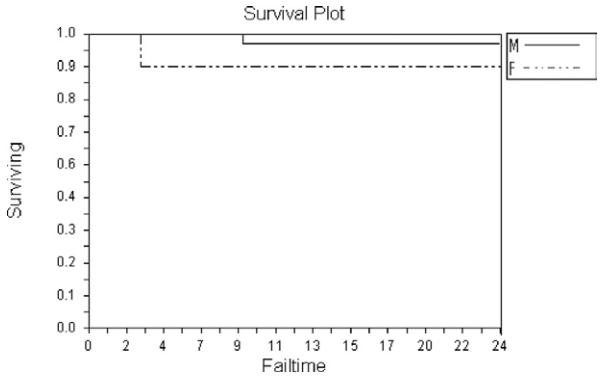


**Fig 3.** Kaplan-Meier survival comparing the patency of initially successful superficial femoral artery (SFA) subintimal angioplasties between male *(solid line)* and female *(dashed line)* patients. With the log-rank test, a *P* value of .0151 indicates decreased survival of the patent SFA in female patients. *M,* Male; *F,* female.

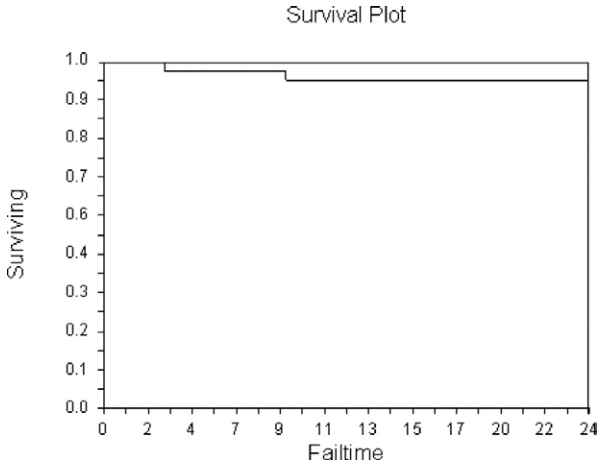


**Fig 4.** Kaplan-Meier analysis for limb salvage for all patients after initially successful superficial femoral artery subintimal angioplasties.

patent SFA SI-PTAs on subsequent duplex scans. Figure 3 shows the pattern for primary assisted patency of the initially successful SFA SI-PTAs grouped by sex. With the log-rank test, a *P* value of <.0151 indicates that there is a decreased primary assisted patency in female patients compared with male patients. Figure 4 shows that the aggressive use of arterial bypass for failed SI-PTAs and the treatment of recurrent lesions by endovascular methods resulted in a excellent limb salvage rates for all patients, because no significant differences were found between male and female patients.

**Complications.** One patient with known nonreconstructible three-vessel coronary artery disease developed symptomatic angina the night after successful SFA SI-PTA, but it responded quickly to medical treatment. One patient had a femoral artery sheath accidentally pulled during transfer from a stretcher and required surgical repair of the femoral artery under local anesthesia. There were no periprocedural myocardial infarctions, cerebrovascular accidents, renal failures, or pulmonary complications. There were no instances of pseudoaneurysm of the femoral artery puncture site, and there was no evidence of distal embolization after SFA SI-PTA.

**Mortality.** During follow-up, three patients died with patent SFA SI-PTAs and intact limbs. Two patients succumbed to known cancer at 7 and 9 months, and one patient died of an acute myocardial infarction at 12 months with a patent SFA SI-PTA reconstruction. One patient was diagnosed with cancer of the pancreas 13 months after successful SFA SI-PTA but continues to do well.

## DISCUSSION

As described previously, SI-PTA is not new; it was first performed in 1987 and reported in 1989 by Bolia and colleagues[1-3] for the treatment of occluded infrainguinal arteries. The senior author learned the technique of SI-PTA during a 13-week endovascular fellowship in which training occurred 1 to 2 weeks per month over a 9-month period. Thus, the senior author was in an excellent position to evaluate SFA SI-PTA in a prospective manner to determine whether this technique can be easily learned and rapidly applied by one who recently completed endovascular training.

The initial technical success rate of 92.6% and the 90-day technical success rate of 86.5% in this series are well within the range of the 80% to 90% technical success rates previously reported.[1-20] The combined patency rate of 82.3% at 10.5 ± 0.7 months in this series is also well within the 60% to 89% patency rates reported at 6 months' follow-up.[1-20] It should be noted that the senior author did not attempt to perform an SFA SI-PTA alone until after participating in 15 SI-PTAs with experienced mentors during endovascular training. This author strongly believes that receiving advanced endovascular training with SI-PTAs has allowed successful performance of these procedures, with results compatible with the data reported in the literature. Five of the six initial failed attempts at performing SFA SI-PTA in this series occurred within the first 10 months of the study, whereas one of the initial failures occurred in the last 14 months of this study. These data suggest that SFA SI-PTA, as with all surgical and endovascular procedures, has a learning curve and reinforce the notion that SFA SI-PTA should be performed only after adequate training.

Aggressive use of the duplex scan during follow-up helped to identify 10 patients who developed asymptomatic recurrences with a 50% diameter reduction. These 10 patients with asymptomatic recurrences have all been treated successfully with limited PTAs and have maintained patent SFA SI-PTAs on subsequent follow-up. One patient who underwent successful SFA SI-PTA in May 2005 was treated with a PTA for a recurrence 7 months later. This patient continues to have a patent SFA and remains symptom free 19 months after the original procedure.

As noted previously, the indications for intervention were rest pain, nonhealing ulcers or gangrene, or severe

progressive claudication. No patient was treated in this series for stable intermittent claudication. Several of the previously reported series have described performing SI-PTAs for stable claudication and have dwelt more on the anatomy of the treated occlusions than on the indications for the interventions. Even though this procedure can be performed with patients under local anesthesia with minimal morbidity and mortality, the indications for SFA SI-PTA should be the same as those used for open surgical lower extremity bypass (rest pain, nonhealing ulcers or gangrene, and severe progressive claudication).

The data in Table III suggest that the rate of initial SFA SI-PTA failure correlates with the length of total occlusion, as well as total SFA occlusion combined with total diseased SFA. One must be cautious in interpreting these findings, because the number of initial SFA SI-PTA failures was small and because 15 of the successful SFA SI-PTAs (short-term and long-term) had percentage occlusions of the SFA that ranged from 75% to 90%. This information, as well as the smaller percentage of SFA occlusions in the recurrence group, would suggest that other factors, such as the character of the plaque (calcification, amount of inflammation, and so on), may be just as important as the percentage of SFA occluded in determining initial and long-term SFA SI-PTA success. Lipsitz et al[14] thought that the inability to place the wire in the subintimal plane or follow a successfully placed wire with a catheter occurred in SFA lesions that were extremely dense with severe calcific plaque.

Several technical modifications have been used in this study to perform successful SFA SI-PTA in very difficult arterial lesions. First, when using a contralateral approach to an extremity, one must have long guide catheters and balloon and stent catheters with long shafts to be able to reach the contralateral below-knee arterial segments. When using an antegrade femoral artery approach, shorter catheter shaft lengths are more appropriate. Second, when approaching arterial occlusions involving long arterial segments, the author has found that using balloon lengths of 120 mm and long stent lengths (80-120 mm) helps to minimize the time spent during the procedure as well as to achieve excellent technical results. Third, when it is difficult to advance a guide catheter through the subintimal plane over a successfully placed hydrophilic wire, one can switch to a 3-mm/120-cm low-profile balloon and angioplasty the plaque. This almost always allows advancement of the balloon catheter over the wire, through the subintimal space, and into the area of arterial re-entry.

This study did not use several other techniques described for use in difficult SI-PTAs. Retrograde SI-PTA has been described for flush SFA occlusions.[17,23,24] A retrograde puncture of the popliteal artery by using duplex ultrasonography is performed, and SFA SI-PTA is performed from the distal SFA to the proximal SFA, which is opposite the direction used for the standard approach. The retrograde SFA SI-PTA approach has a reported patency rate of 62% at 1 year.[20] This study also did not use the technique described by Balas et al,[25] which approaches flush occlusions of the SFA with a combination of open surgery and endovascular techniques. The third technique not used in this study is one that uses one of several re-entry devices for locating and puncturing the distal "re-entry" artery. Although these devices were not available to the author during this study, the author believes that their use, as well as the other techniques described previously, will decrease the initial failure rate of SFA SI-PTA and extend its use for all patients with flush SFA occlusions.

There are several limitations of this study. First, although the study was prospective, it does not provide a prospective comparison of SFA SI-PTA to bypass surgery. However, the authors do not view these techniques as competitive, but as complementary, in terms of extending the time of total limb salvage. Second, as described previously, this series did not use the new re-entry devices or the techniques described that use retrograde SFA SI-PTA or open SFA-SI-PTA. It would seem logical that these devices and techniques would help to decrease the initial failure rate of the procedure and extend its use to more patients. Third, the data in Figs 1 and 2 must be interpreted carefully, because the analysis was performed only on the 76 patients with initial SFA SI-PTA success. This statistical approach was used to focus on the patterns of survival for patency and limb salvage when the SFA-SI-PTA was successfully performed.

On the basis of the results of this study and those reported in the literature, several conclusions can be drawn. First, SFA SI-PTA can be performed successfully with a low complication rate and a high initial success rate and with patients under local anesthesia. This minimally invasive approach avoids wound complications and most likely will reduce hospital lengths of stay because patients typically leave the hospital the day after the procedure. The other techniques described previously[7,23-25] may help to further increase the initial technical success rate. Second, one should not attempt these procedures without appropriate training and equipment. There is a learning curve to all invasive procedures, including SFA SI-PTA. Third, as described by Lipsitz et al,[14] the indications for treating patients with SI-PTA should be the same as those used for open bypass surgery and therefore should not include stable intermittent claudication. Fourth, SFA SI-PTA is not viewed by the authors to take the place of open bypass surgery, but rather to extend the time of limb salvage. Although the short-term primary assisted patency rate and limb salvage rates were quite good, it was clear during the course of follow-up that an increasing number of patients were developing either recurrent lesions or progression of more proximal or more distal disease. Aggressive use of duplex arterial scanning in combination with history and physical examinations allowed treatment of recurrent lesions before the patency or limb salvage rates were altered. It is our opinion that one cannot perform any endovascular treatment of the lower extremity without an aggressive follow-up. The long-term patency and limb salvage rates of SFA SI-PTA are not known. However, even if one can provide limb salvage or resolution of severe critical limb ischemia for 1 to 2 years, the patients can still be treated

with bypass surgery, thus extending the total time of limb salvage. Fifth, the use of SFA SI-PTA with its minimally invasive approach may provide an alternative for patients presenting with critical limb ischemia who are deemed at high risk for open operative procedures. Sixth, the data in Table IV suggest that lower success rates with SFA SI-PTA may be anticipated when treating patients who present with rest pain and gangrene as compared with patients with severe progressive claudication.

## AUTHOR CONTRIBUTIONS

Conception and design: SIM, AA, VR
Analysis and interpretation: SIM, DJM, AA, VR
Data collection: SIM, DJM
Writing the article: SIM, DJM, AA, VR
Critical revision of the article: SIM
Final approval of the article: SIM
Statistical analysis: DJM, AA, VR
Overall responsibility: SIM

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