Subintimal Angioplasty With Nitinol Stenting

Results of combined femoropopliteal subintimal angioplasty and nitinol stent placement for limb salvage in patients unsuitable for distal bypass.

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Since its initial description by Bolia,[1] subintimal angioplasty has been widely accepted, and it currently serves an emerging role in the armamentarium of contemporary vascular interventionists. Short-term safety and feasibility have been established primarily by centers in Europe where stenting is not performed as an adjunct to angioplasty of an occluded arterial segment. Data suggest a technical success rate of 75% to 80% and a 1-year patency rate ranging from 55% to 74%.[2,3] A recent report combining subintimal angioplasty and nitinol stenting for limb salvage has shown acceptable limb salvage rates despite poor late patency rates.[4] We report our results of subintimal angioplasty and nitinol stenting for limb salvage in patients who were not candidates for distal bypass.

METHODS

From February 2004 to January 2006, 22 of 26 patients with critical limb ischemia underwent successful subintimal angioplasty and nitinol stent placement for limb salvage (Figure 1, Table 1). Failure to achieve luminal re-entry was the sole factor in the four technical failures. In 18 of 22 cases, recanalization of an occluded superficial femoral artery was the sole intervention. In two cases, angioplasty of the tibioperoneal trunk was performed, and in two cases, intraluminal popliteal angioplasty was performed. Patients were heparinized with 100 U/kg and maintained at an ACT >250 seconds throughout the procedure. Once luminal re-entry was confirmed, a limited angioplasty with a 2-mm to 3-mm balloon was performed to ensure passage of the nitinol stent through the previously occluded arterial segment. The entire recanalized segment was then stented using nitinol self-expanding stents oversized by 1 mm. Average occlusion length was 52±12 mm.

Angioplasty was performed after stent placement to the measured size of the target vessel. All patients were loaded after the procedure with clopidogrel (300 mg/kg) and maintained on a daily dose (75 mg/d) for 6 weeks, which was then replaced by aspirin (325 mg/d). Duplex ultrasound and ankle-brachial indices (ABIs) were performed after the procedure, at 3-month intervals for the first year, and yearly thereafter.

RESULTS

Of the 22 patients, distal bypass was not offered because of cardiac dysfunction (10 of 22), inadequate target vessel (six of 22), minimally or nonambulatory status (four of 22), and ischemic tissue loss in the region of the operative site (two of 22). The average patient age was 69.5±5 years. Twenty-four–month mortality was 23% (five of 22). Of these patients, there was one stent occlusion, yet all patents died with intact limbs. The resulting 24-month stent primary assisted patency rate was 72% (16 of 22). There was one stent occlusion resulting in ischemia progression and amputation. One stent

TABLE 1. NITINOL STENTS UTILIZED

Stent	No. of Cases
Lifestent *(Edwards Lifesciences, Irvine, CA)*	13
Precise *(Cordis Corporation, a Johnson & Johnson company, Miami, FL)*	5
Smart *(Johnson & Johnson, New Brunswick, NJ)*	3
Luminexx *(Bard Peripheral Vascular, Tempe, AZ)*	1

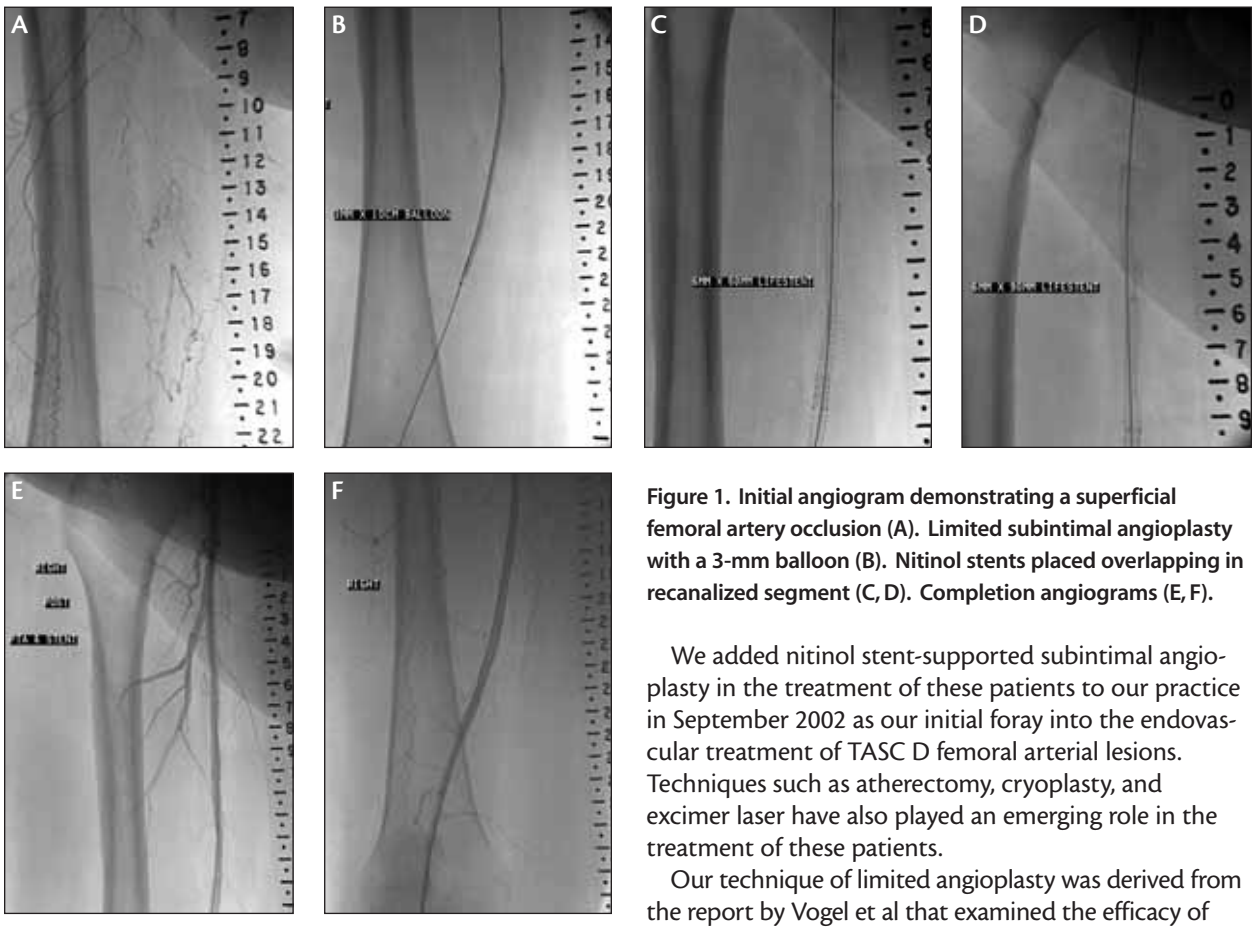

Figure 1. Initial angiogram demonstrating a superficial femoral artery occlusion (A). Limited subintimal angioplasty with a 3-mm balloon (B). Nitinol stents placed overlapping in recanalized segment (C, D). Completion angiograms (E, F).

occlusion did not result in amputation. Three patients required reintervention due to hemodynamically significant velocity increases seen on surveillance duplex examination. Of these, two required additional stent placement due to disease progression in adjacent areas.

There were four in-stent restenoses; one was treated with angioplasty, and three were treated with atherectomy. Two patients with patent stents failed to achieve limb salvage. Pre- and post-ABI and first digit pressures were 0.49±0.17 mm Hg and 27±5 mm Hg; and 0.83±0.09 mm Hg and 57±12 mm Hg, respectively. The total limb salvage rate was 86% (19/22). Limb salvage of surviving patients was 94% (16 of 17), with a mean follow-up of 18±7 months.

DISCUSSION

Limb salvage in individuals who are not candidates for distal bypass remains a challenging clinical problem for the vascular specialist. These patients often have limited ability to ambulate as a result of severe deconditioning and comorbid medical conditions. Emotional obstacles must also be addressed when treating these individuals and their families who are often extremely resistant to limb amputation.

We added nitinol stent-supported subintimal angioplasty in the treatment of these patients to our practice in September 2002 as our initial foray into the endovascular treatment of TASC D femoral arterial lesions. Techniques such as atherectomy, cryoplasty, and excimer laser have also played an emerging role in the treatment of these patients.

Our technique of limited angioplasty was derived from the report by Vogel et al that examined the efficacy of nitinol stenting of nonocclusive femoral lesions.[5] They hypothesize their stent patency of 84% at 24 months to be related to their technique of primary stenting that may result in less intimal injury and thus less risk of in-stent restenosis. Although encouraging, our high stent patency rates utilizing minimal angioplasty and stenting must be tempered by the combination of high mortality in this series and the relatively short mean follow-up. More important, however, is the limb salvage rate of 94% achieved in surviving patients. The utilization of duplex ultrasound surveillance combined with ABI measurements cannot be overestimated and greatly impacts limb salvage. We intervene if there is an ABI decrease >0.15, or an in-stent velocity elevation suggesting a significant stenosis.

Recent investigators have examined the role of stent fracture in long-segment femoral artery occlusions. In one series, fractures were observed in 37% of treated arteries and led to a higher rate of stent stenosis and occlusion.[6] This is thought to be due to the forces of compression, torsion, and elongation unique to the femoral artery, resulting in stent kinking and compression. For these reasons, stents composed of laser-cut,

electropolished nitinol combined with designs allowing for a greater degree of stent flexibility may be advantageous. Although unproven, based on this small clinical series, we believe that nitinol stents providing these characteristics will positively impact stent patency and thus limb salvage.

CONCLUSION

Subintimal angioplasty and nitinol stenting for limb salvage should be considered in patients not suitable for distal bypass. Combined with serial surveillance, limb salvage rates may be improved in this population of patients with "end-stage" peripheral artery disease. ■

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