The revolutionary idea of anastomosing a segment of vein directly into the arterial circulation was conceived by Carrel in 1901, at the University of Lyon. It was brought to fruition through his collaboration with Charles Guthrie at the Hull Physiological Laboratory in Chicago (Figure 1).²

The use of metal prostheses by Exner invariably resulted in thrombosis, leading him to conclude that veins could not be used as arterial substitutes. The experiments of Carrel and Guthrie were successful due to their meticulous aseptic technique and the use of a method that did not require a foreign body.
Atherectomy...

other than suture material.

The first clinical anastomosis of a venous graft into the arterial circulation was performed by Jose Goyanes of Madrid. Goyanes had studied the work of Carrel, and Murphy in the United States, and he had experimented with transplantation of canine vena cava grafts into the aorta. In 1906, he was asked to examine a 41-year-old candy maker who had developed a syphilitic popliteal aneurysm. On June 12 of that year, Goyanes excised the aneurysm and, unable to repair the popliteal artery primarily, used an adjacent segment of popliteal vein to bridge the defect. The patient made an excellent recovery after a post-operative wound infection, and Goyanes reported this case in El Siglo Medico, an obscure Spanish weekly medical bulletin.

In 1913, Hogarth Pringle reported two cases of reversed saphenous vein grafts to maintain arterial circulation. His cases involved aneurysms of the popliteal and brachial arteries and were performed at the Royal Infirmary of Glasgow. Both operations were successful.

In 1924, Barney Brooks used injections of sodium iodide to study the arterial anatomy of the lower extremity (Figure 2). Great progress in arteriography was also made in Portugal, where the technique of cerebral angiography was introduced in 1927 by Egas Moniz (Figure 3). Two years later, Reynaldo Dos Santos reported angiography of the abdominal aorta, its branches, and the lower extremities. An accurate diagnostic procedure for vascular lesions was now available.

Jean Kunlin stimulated international interest in leg bypass grafting in 1948. His patient was a 54-year-old man, who despite a lumbar sympathectomy, a femoral arterectomy, and a great toe amputation, was still suffering with painful gangrenous ulcers. On June 3, Kunlin harvested a 26-centimeter length of greater saphenous vein and because of scarring from prior surgery, performed proximal and distal end-to-end anastomoses between the femoral and popliteal arteries. The concept of an end-to-side anastomosis was a new and important one, as side branches between the anastomoses could now be preserved. The results were dramatic, with healing of the ulcers and resumption of painless walking by the patient. In 1951, Kunlin reported 17 cases of autogenous venous bypass grafts.

This procedure was favorably received in the United States and in 1952 Julian reported 19 cases of bypass grafts with success in 12. Other early series included those of Lord and Stone, who reported 21 autogenous vein grafts in 1957, Dale and DeWeese, who analyzed 31 cases in 1959, and the report by Linton and Darling of 76 consecutive saphenous vein bypass grafts in 1962. Until recently, leg bypass grafts remained the primary treatment of limb-threatening ischemia.

Amputations

Despite the tremendous advances in medicine and surgery during recent decades, there has been no decline in the national amputation rate. Each year there are 150,000 lower extremity amputations, with a $270 million price tag. Almost half of these occur in diabetics and it should be possible to reduce this rate. A strategy to reduce amputations in diabetics would be valuable because this disease affects 6% of the U.S. population. Greater than one million diabetics have lower limb ulcers and 20% of diabetic hospital admissions are for leg ulcers. The annual cost for this care exceeds $20 billion.

If a diabetic requires an amputation, his life is likely headed for a downward spiral. In 30% of cases, an above-knee amputation is required. An equal proportion of below-knee amputations are performed, and 10% of amputations comprise a portion of the foot.

It gets worse: The mortality for these procedures hovers around 10 percent. The one-year mortality rate is about 20%, and the chances of a diabetic remaining alive five years after a leg amputation are only about 30-35%. If one does survive, there is a 22% chance of requiring an ipsilateral higher amputation, a 10-15% chance of requiring a contralateral amputation, and only a 50% chance of successful rehabilitation.

Risk Factors for Amputation

There are many risk factors for leg amputation in the diabetic, but the two most important are absence of protective sensation due to...
Atherectomy...

Peripheral neuropathy, and arterial insufficiency. In cases of both neuropathy and ischemia, elevated glucose levels are the underlying cause of these complications. Sorbitol excess results from hyperglycemia, leading to myoinositol depletion. The consequences of these metabolic derangements include decreased nerve conduction velocities, intraneuronal edema, and a diminished capacity for myelin sheath maintenance. The result is diabetic peripheral neuropathy.

Hyperglycemia also causes irreversible microvascular and macrovascular complications, including retinopathy, neuropathy, nephropathy, atherosclerosis and cerebral-vascular disease.

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Figure 4—Plantar sites for Semmes-Weinstein nylon monofilament testing

Hyperglycemia also causes irreversible microvascular and macrovascular complications, including retinopathy, neuropathy, nephropathy, atherosclerosis and cerebral-vascular disease.

Figure 5—SilverHawk catheter

Figure 6—Plaque removed with SilverHawk catheter

Reducing Amputations

Little progress has been made in reducing the national limb amputation rate during the last decade. Podiatrists are often on the front line of treatment of diabetics with leg ulcers, as well as non-diabetics with peripheral vascular disease and leg ischemia. Vigilance in detecting the two main risk factors for amputation—peripheral neuropathy and arterial insufficiency—remain the best hope for reducing amputation rates.

Since diabetic neuropathy becomes manifest by a wide variety of sensory, motor, and autonomic symptoms, a structured list of symptoms should be used to question the patient. Sensory symptoms are often described as negative or positive, and diffuse or focal. Negative sensory symptoms include numbness, a feeling of wearing gloves or walking on stilts, loss of balance (especially with the eyes closed), and painless injuries. Positive symptoms include burning, a pricking pain, sensations like electric shocks, tightness, and hyper-sensitivity to touch.

Motor symptoms can cause distal, proximal, or focal weakness. Distal motor symptoms include impaired fine coordination of the hand, inability to open jars or turn...
to detect patients with peripheral neuropathy. If individuals with reduced vibration detection can be identified, then preventative care could be concentrated on those patients, potentially saving valuable resources and improving health outcomes. The Semmes-Weinstein nylon monofilaments are used for pressure threshold assessment and provide an ideal modality for testing patients at risk of ulceration and amputation, since unperceived pressure is the mechanism of injury to the foot. The Semmes-Weinstein nylon monofilament 5.04 gauge buckles at a pressure of 10 grams and it has been shown that a patient who can feel this filament in certain selected sites will not develop ulcers. The sites on the dorsal and plantar surface of the foot are illustrated in Figure 4.

Peripheral vascular disease is also initially diagnosed with a simple test: examination of the pulses. The easiest and initial objective test for vascular insufficiency is the ankle-brachial index. This index is a comparison of the blood pressure in the arms to that in the feet and is obtained with an inexpensive ultrasound device. The normal ankle-arm index is 1.0 because the blood pressure at the ankle should be the same, or slightly higher due to the mechanics of blood flow, as the pressure in the arm. If this ratio falls to below 1.0, patients are not only at risk for complications of peripheral vascular disease, but coronary artery disease as well. Abnormalities of this index, as well as the nylon monofilament test, may be important harbingers of leg and foot ulcers, and should be a core component of the podiatrist’s armamentarium.

Atherectomy

The SilverHawk System received FDA approval in June 2003 for the treatment of peripheral arteries, including the femoral, popliteal and tibial vessels (Figure 5). It provides a unique approach to removing plaque from de novo or re-stenotic lesions of any length. Calcified and non-calcified lesions are treatable with the device. Because the cutter is apposed to the plaque mechanically, the catheter excises large amounts of plaque without causing trauma to the arterial wall (Figure 6). The SilverHawk can also remove eccentric plaque and create a more optimal environment for laminar flow. By excising plaque and avoiding stretching of the arteries, the

Plaque excision from leg arteries appears to be an effective and minimally invasive way to treat claudication as well as more serious forms of circulation impairment, such as ulcers and gangrene.

Magnified Cutter View

Figure 7—Plaque excision with SilverHawk catheter

Figure 8—SilverHawk catheter carbide cutter

Figure 9—Histologic analysis of excised plaque

Continued on page 183
Atherectomy...

The chance of dissection is minimized which should theoretically minimize the likelihood of intimal hyperplasia (Figure 7).31,32

The SilverHawk catheter consists of a long catheter with a battery and motor pack on one end, and a nosecone with a carbide cutter on the other. The cutter is 3.5 times stronger than stainless steel and 23 times stronger than calcium; it operates at 8,000 RPM (Figure 8). The operator—not the device design—determines the cut length, and continuous longitudinal plaque shaving enables efficient treatment of long blockages within the arteries of the leg. After delivering the catheter along a guide wire to the proximal end of the target lesion, the cutter is turned on. The device is then advanced through the length of the stenosis or occlusion. After excision of the plaque, the cutting blade extends through the collection chamber to pack the tissue into the nosecone. The cutter is then switched off and retracted to prepare to approach the blockage from a different angle, or to treat another blockage.

All of these maneuvers are observed under fluoroscopy. Atherectomy avoids creating the barotrauma attendant with angioplasty that subsequently leads to intimal hyperplasia and re-stenosis of the artery.

The Talon Registry was begun by the manufacturers of the SilverHawk catheter to evaluate acute and long term outcomes of patients treated for blockages in the arteries of the legs. It aims to correlate patient outcomes, angiographic features, histologic findings and genomic profiles. At this writing, a total of 362 patients have been enrolled. A total of 450 procedures were performed to treat 456 legs and 731 blockages. Most of the patients in this registry were treated for pain after walking a short distance, which interfered with their lifestyle. The procedure success rate was 99%, while the incidence of major complications, such as perforation of a vessel, was approximately 0.5%. After an average follow-up of 6 months, only 11% of the patients needed repeat treatment for recurrence of symptoms. If a patient initially only had one blockage treated, then the need for repeat treatment after 6 months was only 3%.

Plaque excision from leg arteries appears to be an effective and minimally invasive way to treat claudication as well as more serious forms of circulation impairment, such as ulcers and gangrene. The high procedure success rate and low complication rate make atherectomy an appealing alternative to traditional bypass surgery.

Plaque excision may also provide an opportunity to learn more about atherosclerosis. Histologic analysis can identify inflammatory cell infiltration; the presence of thrombus, calcification, or fibrosis; the degree of smooth muscle cell proliferation; and the lipid content of the plaque removed (Figure 9). Genomic and proteomic analysis of the excised tissue may provide further insight into the pathophysiology of re-stenosis and identify predictive markers of re-stenosis and cardiovascular risk.

At a recent National SilverHawk Summit, several conclusions were reached: Adjunctive angioplasty and stenting are usually not required after plaque excision, regardless of location. A “perfect” or “stent-like” angiographic result is not crucial as many operators reported observing positive remodeling after one month. Acute procedural data demonstrate a high safety rate with rare perforations, dissections, or distal embolization.

Participants at this forum focused on determining the optimal applications for the SilverHawk catheter. Summit participants used the SilverHawk in the superficial femoral, common femoral, popliteal, and tibial arteries. The catheter was employed for chronic

**Figure 10—Pre-atherectomy angiogram**

**Figure 11—Post-atherectomy angiogram**

**Figure 12—Excised plaque from case report**

References
4 Brooks, B. Injection of sodium iodide. JAMA. 1903;60:159-66.
5 Pringle, H. Two cases of vein grafting for the maintenance of direct arterial circulation. Lancet. 1913;1:1795.
7 Moniz, E. L’encephalographie arterielle.
1) The first experiments with vein grafts used which material to hold the grafts in place?
A) silk sutures
B) nylon sutures
C) magnesium tubes
D) crazy glue

2) Who conceived the idea of revascularizing limbs with vein grafts?
A) Emil Theodore Kocher
B) Alexis Carrel
C) Frederick Grant Banting
D) Charles Brenton Huggins

3) The ability to perform successful limb revascularization depended upon the development of which of the following?
A) aseptic technique
B) heparin
C) atraumatic clamps
D) all of the above

4) The annual amputation rate in the United States is:
A) 1,500
B) 15,000
C) 150,000
D) 1,500,000

5) Which of the following is true?
A) one half of all amputations occur in diabetics
B) 6% of Americans have diabetes
C) The incidence of diabetes is declining
D) A & B

6) What percent of amputations in diabetics are major limb amputations?
A) 20%
B) 40%
C) 60%
D) 80%

7) The mortality rate for diabetics undergoing limb amputation is approximately:
A) 8%
B) 10%
C) 12%
D) 14%

8) Which of the following statements is true?
A) The one-year mortality rate in a diabetic undergoing limb amputation is 15%.
B) After limb amputation, 50% of diabetics will require another amputation.
C) Only 30% of diabetics remain alive five years after limb amputation.
D) Successful rehabilitation in diabetics with amputations occurs in most cases.

9) An important risk factor for leg amputation in the diabetic is:
A) peripheral neuropathy
B) arterial insufficiency
C) obesity
D) all of the above

10) Metabolic derangements leading to many of the complications of diabetes result from elevated levels of:
A) androstenedione
B) sorbitol
C) mannitol
D) cholesterol

11) Which of the following is true?
A) Sorbitol excess leads to myoinositol depletion.
B) Advanced glycosylation end-product formation results from glycosylation of carbohydrates.
C) Intraneuronal edema accelerates nerve conduction.
D) Hyperglycemia may lead to retinopathy, neuropathy, nephropathy, and coagulopathy.

12) Which of the following is true?
A) The national amputation rate has averaged a 3% annual decline during the past decade.
B) Sensory symptoms of diabetic neuropathy include numbness, burning, and dizziness.
C) Motor symptoms of diabetic neuropathy cause generalized weakness only.
D) Autonomic symptoms of diabetic neuropathy include papillary, sudomotor, and urinary.

13) Semmes and Weinstein
A) were Talmudic scholars
B) discovered insulin
C) studied pressure threshold assessment
D) performed the first renal transplant

14) Which of the following is false?
A) The easiest and initial objective test for vascular insufficiency is the ankle-brachial index.
B) The ankle-brachial index is a comparison of the blood pressure in the arms to that in the feet and is obtained with an inexpensive ultrasound device.
C) The normal ankle-arm index is 1.0 because the blood pressure at the ankle should be the same or slightly higher due to the mechanics of blood flow, as the pressure in the arm.
D) An angiogram should be performed in a diabetic with an abnormally elevated ankle-arm index, as this is a sign of vessel calcification.
15) SilverHawk is the name of
   A) a bird on the endangered species list.
   B) a bird whose nest on a 5th Ave. condo-
      minium was destroyed, then replaced.
   C) an atherectomy catheter.
   D) a predatory bird in the southwest USA.

16) Each of the following are techniques for
    leg revascularization except
    A) bypass with autogenous vein
    B) bypass with prosthetic graft
    C) endarterectomy
    D) sympathectomy

17) The advantages of atherectomy over an-
    gioplasty include
    A) avoidance of barotrauma
    B) the artery is not stretched
    C) the intima is not cracked
    D) all of the above

18) At a recent National SilverHawk Summit,
    several conclusions were reached except
    A) Adjunctive angioplasty and stenting are
        usually not required after plaque excision,
        regardless of location.
    B) A “perfect” or “stent-like” angiographic
        result is not crucial as many operators re-
        ported observing positive remodeling after
        one month.
    C) Acute procedural data demonstrate a
        high safety rate with rare perforations,
        dis-
        sections, or distal embolization.
    D) Calcified plaque is a contraindication to
        atherectomy.

19) The percentage of patients requiring re-
    peat intervention 6 months after a SilverHawk
    atherectomy is
    A) 6%
    B) 8%
    C) 11%
    D) 14%

20) Advantages of atherectomy over conven-
    tional leg bypass include
    A) reduced hospital stay
    B) less chance of injuring important collat-
       eral vessels
    C) lower complication rate

See answer sheet on page 187.
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EXAM #5/05
Atherectomy for Plaque Removal (Friedman)

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20. A B C D

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How much time did it take you to complete the lesson?

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