Excimer Laser-Assisted Angioplasty in Severe Infrapopliteal Disease and CLI:

The CIS "LACI Equivalent" Experience

David E. Allie, MD, Director of Cardiothoracic and Endovascular Surgery; Director of Noninvasive Vascular Labs, Chris J. Hebert, RT, RCIS, Director of Cardiovascular Services, Craig M. Walker, MD, Founder, President and Medical Director,
Cardiovascular Institute of the South/Lafayette, Lafayette, Louisiana

Abstract

Background: 12-month major amputation rates in "true limb salvage" (Rutherford class 5-6 with established tissue loss) are reported as > 90% if non-revascularable and 25% if revascularable. Twenty-four month mortality rates of > 40-50% are reported post amputation and < 50% will ambulate with a prosthesis. The encouraging Laser Angioplasty for Critical Limb Ischemia (LACI) 6-month limb salvage (LS) rate of 93% prompted adoption of excimer laser assisted angioplasty as one of our primary infrapopliteal treatments for "TLS."

Methods: Between October 2001 – October 2003, 62 patients (62 limbs) with Rutherford class 5-6 symptoms presented with severe infrapopliteal disease without single vessel "straight line flow" to the foot. Seventy infrapopliteal arteries (IA) were treated, including posterior tibial 21/70 (30%), peroneal 16/70 (23%), anterior tibial 8/70 (11%), tibioperoneal trunk 14/70 (20%), and multiple 11/70 (16%). Thirty out of 62 (48%) and 22/62 (35%) required superficial femoral artery (SFA) and popliteal artery (PA) laser assisted angioplasty respectively. Five out of 62 (8%) patients required the "step-by-step" technique.

Results: Procedural success 59/62 (95.2%) with 9/62 (14.5%) requiring a secondary reintervention [bypass 2/62 (3.2%) and repeat laser angioplasty 7/62 (11.2%)] at mean 7 months (range 1-23 months). No periprocedural deaths or major surgical vascular complications. Four out of 62 (6.4%) had minor (< 3cm) hematomas. Six- and 12-month mortality rates were 3/37 (8.1%) and 4/24 (16.6%) respectively. Six- and 12-month LS rates were 34/37 (91.8%) and 20/24 (83.3%) respectively. Arteries stented included SFA 15/23 (65%), PA 4/12 (33%), and IA 7/62 (11.2%).

Conclusion: Excimer laser assisted angioplasty is safe and effective in achieving 6- and 12-month LS in patients with severe infrapopliteal disease and advanced limb ischemia, therefore warranting further investigation.

Critical limb ischemia (CLI) has only recently been characterized in the clinical literature; therefore knowledge of the clinical impact of CLI is still rudimentary at best. The TransAtlantic Inter-Societal Consensus (TASC) committee and document on the management of peripheral arterial occlusive disease (PAOD) have recently attempted to unify and clarify CLI with the following recommendations:[1]

1. **Recommendation 73: Clinical definition of critical limb ischemia:**

The term critical limb ischemia should be used for all patients with chronic ischemic rest pain, ulcers, or gangrene attributable to objectively proven arterial occlusive disease. The term critical limb ischemia implies chronicity and is to be distinguished from acute limb ischemia.

2. **Recommendation 74: Trials and reporting standards definition of critical limb ischemia:**

A relatively inclusive entry criterion is favored, the aim being to ensure that the ulceration, gangrene, or rest pain is indeed caused by peripheral arterial disease and that most would be expected to require a major amputation within the next 6-months to a year in the absence of a significant hemodynamic improvement. To achieve this, it is suggested to use absolute pressures of either ankle pressure < 50-70 mm Hg or reduced toe pressure (< 30-50 mm Hg) or reduced $TCPO_2$ (< 30-50 mm Hg).

Wolfe et al classically described the natural history of CLI in a collation of 20 publications on 6118 patients by stratifying them into a low-risk cohort of 4089 patients (rest pain only and ankle pressure > 40mmHg) and a high-risk cohort of 2029 patients (rest pain and tissue loss with or without ankle pressure < 40mmHg).[2] At 1 year, 95% of the high-risk group and 73% of the low-risk group required a major amputation without revascularization. A 75% limb salvage rate was achieved at 1 year in the high-risk group with revascularization. The cumulative probability of survival for the entire group was 74% at 1 year, 58% at 2 years, 56% at 3 years, 48% at 4 years, and 44% at 5 years.

It is estimated that between 150,000 – 200,000 major and minor lower extremity amputations are performed in the United States (US) and Europe yearly for CLI.[3-4] In the US, the amputation rate has increased from 19 to 30 per 100,000 persons over the last two decades primarily due to an increase in diabetes and an advancing age population.[5-6] Despite advances in cardiovascular treatment and revascularization technology, in patients over 85 years of age, an amputation rate of 140 per 100,000 persons/year has been reported, with a primary amputation (PA) still carrying an excessively high mortality rate of 13-17%.[6-8] Successful rehabilitation after below-knee amputation (BKA) is achieved in less than two-thirds of patients and in less than one half of patients after above-the-knee amputations (AKA).[9-11]

Multiple reports have repeatedly documented the poor overall prognosis for the CLI patient, but recent reports by Panayiotopoulos et al and Kalra et al have shown significantly improved long-term survival after revascularization and limb salvage as compared to CLI patients following revascularization failure and amputation.[6,12] Kalra et al reported the long-term survival after infrainguinal bypass surgery (IBS) (pedal bypass) in 256 CLI patients. Amputation and ESRD predicted higher mortality (p = 0.014, p = 0.0001, respectively) and overall 5-year survival rates were 60%.[6] The 5-year survival rate after an amputation was 26%, therefore documenting significantly worse long-term survival for patients suffering an amputation versus those CLI patients achieving limb salvage.[6].

Clearly, the clinical costs to the CLI patient are extremely high, underscoring the need for a better understanding of the entire scope of this major problem as well as the development of new technologies involved in treating this CLI patient population in which the incidence is expected to increase yearly. Therefore, any treatment strategy aimed at decreasing amputations would have a significant impact on both short- and long-term clinical outcomes. Laird et al in 2003 reported the encouraging results of the Laser Angioplasty for Critical Ischemia (LACI) phase II pivotal trial results.[13] This prompted a retrospective analysis of our group's (the Cardiovascular Institute of the South [CIS]) 24-month excimer laser atherectomy (ELA) experience in a similar patient population; therefore, we report our CIS "LACI Equivalent" results.

LACI Pivotal Trial

The LACI pivotal multi-center trial (15 US and German sites) enrolled 145 CLI patients with 155 ischemic limbs with Rutherford Class [4-6] (rest pain and early tissue loss-ulceration) who were poor or nonsurgical bypass candidates. These patients were considered very fragile with significant cardiopulmonary comorbidities and at high-risk for major amputation. ELA was delivered in 96% of the cases, including 8% who had failed guidewire crossing and required the "step-by-step" technique developed and championed by Professor Giancarlo Biamino. This technique utilizes methodical laser advancements through chronic total occlusions (CTO) uncrossable by traditional guidewire techniques. Of the 423 lesions treated, 41% were superficial femoral artery (SFA), 15% were popliteal artery (PA), and 41% were infrapopliteal arteries (IA). Forty-five percent of the overall lesions treated with ELA required a stent with 61% in the SFA, 38% in the PA, and 16% in the IA.[13]

The LACI results achieved an excellent 93% 6-month limb salvage rate with only 2 patients requiring IBS during follow-up. The in-hospital serious adverse event rate was extremely low,

with a mean hospital stay of 3 days. "Straight line flow" to the foot was achieved in 89% of patients and at 6 months, only 16% required a secondary reintervention, with 69% achieving improvement in Rutherford category. The LACI trial is one of the only scientific-based attempts at evaluating any treatment in this CLI patient population at high-risk for amputation.

CIS "LACI Equivalent"

Patients:

Between October 2001 — October 2003, 62 patients (62 limbs) with Rutherford Class 5-6 symptoms and CLI presented with severe infrainguinal disease without single vessel "straight line flow" to the foot. Seventy IA were treated, including posterior tibial (PTA) 21/70 (30%), peroneal 16/70 (23%), anterior tibial (ATA) 8/70 (11%), tibioperoneal trunk 14/70 (20%), and multiple 11/70 (16%). 28/62 (45.1%) and 19/62 (30.6%) of the CLI cases required SFA and PA ELA respectively. 5/62 (8%) patients required the "step-by-step" technique. Significant cardiopulmonary co-morbidities included coronary artery disease 56/62 (90.3%), congestive heart failure 38/62 (61.2%), chronic obstructive pulmonary disease 29/62 (46.7%), chronic renal insufficiency 24/62 (38.7%), and diabetes 51/62 (82.2%). The treatment group included 42 men and 20 women with a mean age of 73.4 years.

Technique:

The contralateral common femoral artery is always our access of choice unless contraindicated, and standard guidewire techniques were used to place a 7 or 8-French sheath over the aortic bifurcation. Excimer laser atherectomy, using a variety of laser catheters ranging from 0.9 mm to 2.0 mm in diameter (CVX-300, Spectranetics Corporation, Colorado Springs, CO) was used to laser debulk the lesions as previously described.[14] The concentric Extreme 0.9 mm (0.014-inch and 0.018-inch wire, over-the-wire) catheter is the most frequently used catheter to begin laser atherectomy, especially in the IA, and we recommend starting with smaller size catheters. Excimer laser therapeutic energy density (fluence) is between 30 mJ/mm^2 and 80 mJ/mm^2, with 45 mJ/mm^2 being a common starting level. Pulse repetition rates are from 25 pulses/s to 40 pulses/s, with calcium-cutting, 0.9 mm catheters being able to deliver 80 mJ/mm^2 and 80 pulse repetitions/s.

Adjuvant percutaneous transluminal balloon angioplasty (BA) was used post ELA frequently in the first 12 months of our experience, but less frequently in the second 12 months, as we learned to accept post laser atherectomy-only angiographic results in an effort to avoid barotrauma and stent deployment, especially in an IA. Optional stenting was reserved for flow-limiting residual stenosis or significant dissections. The goal was to achieve "straight line flow" to the foot in at least one IA. Anticoagulation was provided by direct thrombin inhibition with bivalirudin (Angiomax, The Medicines Company, Parsippany, NJ) with the recommended coronary dose of 0.75 mg/kg bolus with 1.75 µg/kg/hour periprocedural infusion. Further platelet inhibition was provided by glycoprotein IIb/IIIa inhibition with tirofiban (Aggrastat, Guilford Pharmaceuticals, Baltimore, MD) with a 0.4 ug/kg/min 30-minute bolus with 8-12 hour peri and postprocedural 0.1 µg/kg/min continuous infusion in every case. The recognition of severe heparin limitations has prompted the adoption of direct thrombin inhibition on all of our PVD cases since bivalirudin became available. We believe this has significantly decreased our bleeding complications and optimized anticoagulation in this patient population at high risk for both bleeding and thrombotic complications.[15]

continued on page 16

Continued from page 15

"LACI Equivalent"

Definitions and Follow-Up:

Procedural success was defined as a patent vessel with < 30% postprocedural residual stenosis. A baseline and 1-month ABI was obtained in all 62 patients. Clinical exams were obtained at 1 month and every 3 months for the duration of follow-up. Duplex ultrasounds were not consistently available pre or post procedure, therefore were not analyzed. The status of Rutherford classification was documented at each visit.

Results:

We obtained procedural success in 59/62 (95.2%), with all successful cases resulting in "straight-line flow" to the foot. 9/62 (14.5%) required a secondary reintervention [bypass 2/62 (3.2%) and repeat ELA 7/62 (11.2%)] at mean 7 months (range 1-21 months). There were no periprocedural deaths or major vascular or bleeding complications requiring surgery. There were 4/62 (6.4%) minor (< 3 cm) hematomas. The 6 and 12 month mortality rates were 3/37 (8.1%) and 4/24 (16.6%), respectively. ***The 6- and 12-month LS rates were 34/37 (91.8%) and 20/24 (83.3%), respectively.*** The arteries stented included SFA 15/23 (65%), PA 4/12 (33%), and IA 7/62 (11.2%). There were no clinically evident distal emboli. The mean SFA lesion length was 12.8 cm (4-28 mm).

Case Examples

Case #1:

A 69-year-old diabetic male presented with an ischemic left foot with a black ischemic eschar of the left ankle and heel after being told to "just soak your leg in betadine and it will get better" (Figure 1A, page 18). Angiography revealed a 100% occlusion of the ATA, peroneal artery, and subtotal occlusion of the proximal PTA and 100% occlusion of the mid-PTA with no flow to the foot (Figures 1B-C). A Glidewire and Glidecath (Terumo Medical, Somerset, NJ) were positioned to the mid-PTA and a 0.014" coronary wire was advanced to the tarsal vessel of the foot (Figure 1D). A 0.9 mm Extreme laser was advanced over the wire into the tarsal vessel (Figure 1E). Low-pressure coronary balloons were used for BA with excellent "straight-line flow" provided to the foot (Figures 1F-H). Twenty-four hours later, the eschar was debrided and several Apligraf (Organogenesis, Boston, MA) were applied, all under local anesthesia, in an attempt to provide optimized wound healing (Figures 1I-K). Bioengineered graftskin or Apligraf, is a new bilayered tissue-engineered skin, equivalent FDA-approved for treatment in venous and diabetic ulcers. It is reported to improve wound healing and epithelization by multiple mechanisms, including increasing matrix proteins, cytokines, and growth factors and promoting angiogenesis.[16-17] Apligraf has been recently reported in the *Annals of Thoracic Surgery* to decrease the time to healing in patients with sternal and leg wound complications following coronary artery bypass surgery (CABG). It is reportedly showing promise as an adjuvant in wound healing after revascularization in patients with CLI.[18] The patient achieved complete wound healing at 48 days (1L-M).

Case #2

A 72-year-old black diabetic male presented with left foot rest pain and early gangrenous changes of digits 1-3 (Figure 2A, page 20). Angiography revealed a 100% SFA occlusion and a 100% PTA occlusion with > 90% ATA and peroneal stenosis (Figures 2B-C). ELA with low-pressure BA was performed at the

same setting in the SFA, ATA, and peroneal artery with excellent results (Figures 2D-F). A 0.018" coronary wire was utilized in all areas with "kissing BA" performed in the IAs (Figures 2 G-H). Limb salvage was achieved and the patient remains asymptomatic at 18 months post procedure (Figure 2I).

Discussion

The overall prognosis of the CLI patient remains dismal despite advances in the treatment of many other cardiovascular diseases. As noted earlier, Wolfe et al identified a > 90% 12-month amputation rate in a high-risk CLI patient population if not revascularized and > 25% even if revascularization was provided.[2] CLI is a marker for premature death with mortalities of 21% and 31.6% at 1 and 2 years respectively, after a diagnosis of CLI is made.[19] Within 3 months of diagnosis of CLI, there is a 9% mortality, 1-2% will have a MI or stroke, and 12% will require a major amputation clearly defining this poor prognosis. To confound the problem even more, there occurs no universal consensus and sparse data exists regarding the treatment of CLI. The LACI trial Phase II data provides one of the few published multi-center series regarding the treatment of CLI.

The CIS "LACI Equivalent" results very closely mirror the excellent results of the LACI trial. This is important, considering the overall dismal results of medical therapy (non-revascularizations) once the patient reaches the advanced Rutherford classifications for CLI. No pharmacologic clinical trials have been published demonstrating improved outcome as a sole therapy in patients with CLI without revascularization. Prostanoids (PGE_1 and PGE_2) have had the most investigations, but the data is inconclusive and failure rates of > 80% have been reported.[1, 20-22] The general TASC recommendations for prostanoids and all other pharmacological therapies for CLI are as adjunctive treatments at best and these should be used as sole therapy ***only*** if no revascularization option is available.[1] Ongoing trials with gene-induced therapeutic angiogenesis are promising, but likewise no definitive data exists that this therapy is ready for a primary treatment role in CLI at this time.[1, 23-24]

Tibial bypass surgery has a good proven track record in the CLI patient population and achieves limb salvage rates of > 80-90% at 5 years[25-27] but the procedure has limitations, including: oftentimes requires general anesthesia, requires optimal vein as a conduit, small but ***not*** negligible perioperative cardiovascular mortality and morbidity (2-8%), moderate (10-30%) wound infection rate, requires intense graft surveillance with a 20-30% reintervention rate for optimal secondary patency outcomes, utilizes the vein that still remains the most frequently used conduit for CABG, and the surgery is a technically demanding operation ***not*** performed in every community. Substantial experience over the last decade has demonstrated the safety and, in general, excellent immediate and short-term results in the CLI patient population with infrainguinal BA.[1,28-30] Therefore, the excellent results of the LACI trial and now our "LACI Equivalent" experience should underscore the appropriateness of aggressive endovascular strategies to provide "straight-lined" revascularization to the foot for limb salvage.

Our "LACI Equivalent" results again confirm a very low overall complication rate (< 5%) in this very fragile CLI patient population, with > 90% 6-month limb salvage rates in a patient population with > 90% risk for major amputation within 12 months. The concept of "straight line flow" to the foot was not only defined by the

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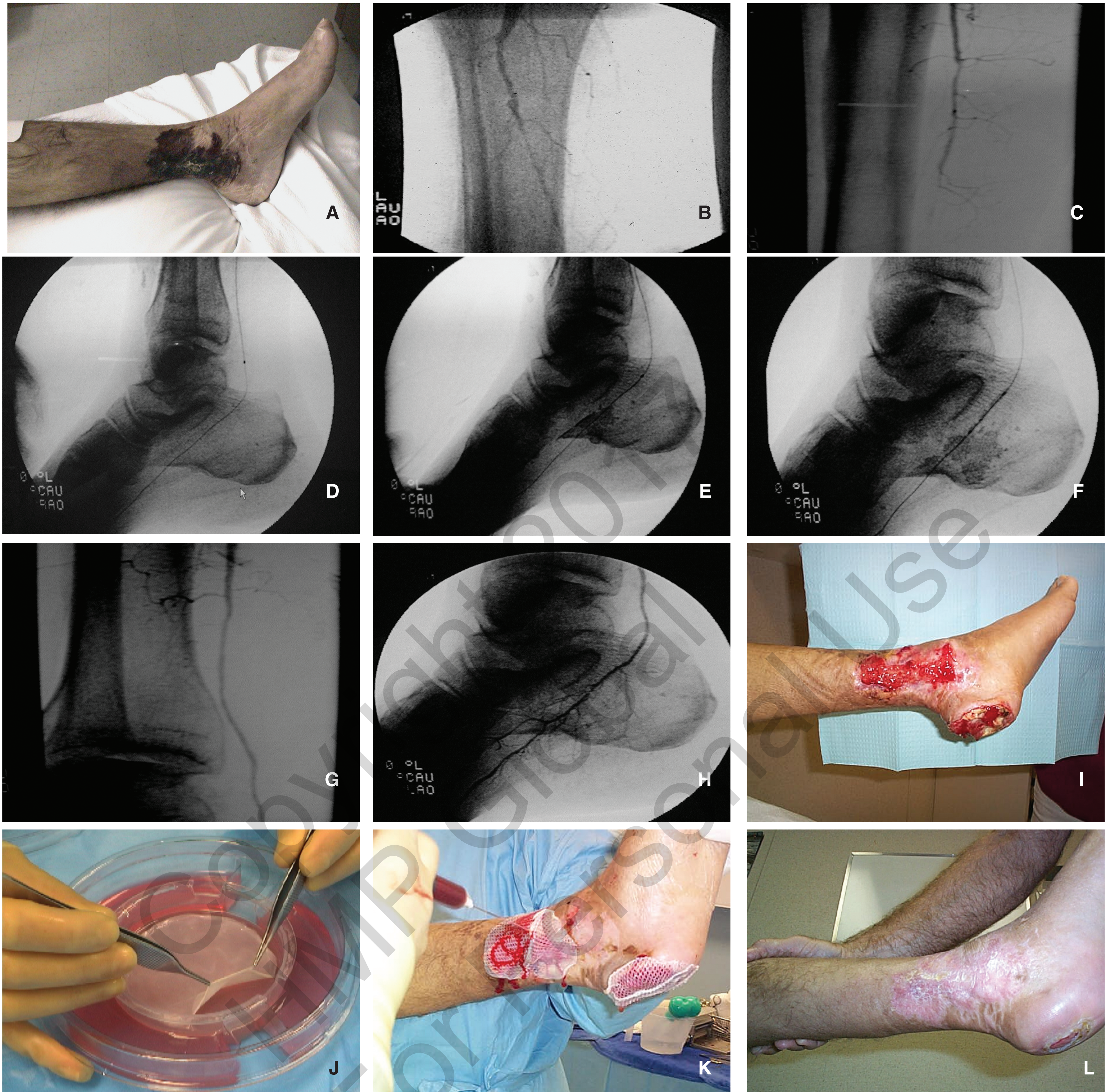

Case #1. Combined ischemic and venous ulcer with betadine-induced eschar (a lateral heel pressure ulceration also occurs) (1A). Angiography reveals severe infrapopliteal disease with no flow to the foot (1B-C). A 0.014' coronary wire is advanced across the occluded PTA and into a tarsal vessel followed by a 0.9 mm laser catheter (1D-E). Low pressure PTA using a 2.0 mm coronary balloon is performed (1F). Excellent "straight-line flow" is restored to the foot (1G-H). The ankle and heel ulcer are debrided (1I). The bioengineered Apligraf is applied to the ischemic wounds (1J-K). The wound appearance at 45-days (1L).

Continued from page 17

"LACI Equivalent"

LACI trial experience. Bakal et al[31] in 1990 reported an 80% limb salvage rate in patients with "straight line flow" to the foot in at least one tibial vessel after BA, versus 0% limb salvage when no flow to the foot could be obtained. The role of tibial stenting and the use of drug-eluting stents in the IA remain undefined, but a recent report by Biamino[32] and a subset analysis of the IA stented cases in the LACI trial have shown improved results versus BA alone, further extending the potentials for improving endovascular outcomes in CLI.

Our favorable experience with ELA in the CLI patient population has significantly improved our overall limb salvage rates, especially in those patients who are poor candidates for IBS or have no available conduit. Additionally, ELA has **not taken away** the surgical IBS option for the patient in those several patients who have required IBS for limb salvage after ELA was chosen as first line therapy. ELA has been shown to have "thromboablative" as well as "atheroablative" benefits in the treatment of coronary artery disease, AMI, and saphenous vein graft disease post CABG.[33-35] Unquestionably, all phases of thrombus play a significant role in CLI and this is likely an added laser benefit in this patient population.

This "thromboablative" effect may be responsible for our trend towards less BA and stenting post laser atherectomy, especially in the IAs. The often diffuse nature of IA disease makes avoiding the inevitable dissections created by higher pressure BA very attractive. We believe laser therapy has allowed us to avoid barotrauma and stenting in the IAs by creating an acceptable angiographic appearance with flow oftentimes to the

continued on page 20

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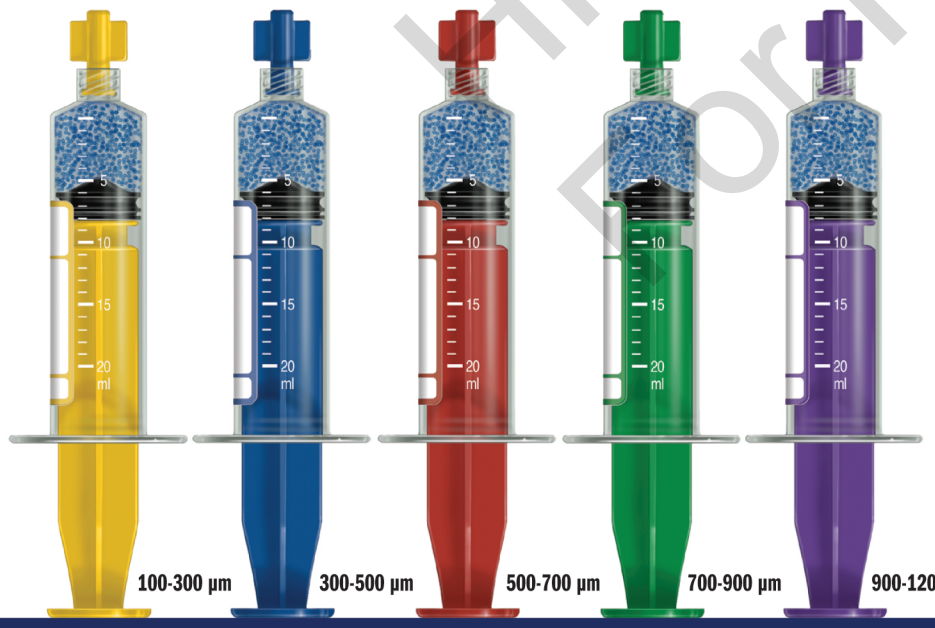

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Continued from page 18

"LACI Equivalent"

foot with laser therapy alone. We are still concerned about placing stents in the infrapopliteal vessels.

Conclusion

In conclusion, our CIS "LACI Equivalent" experience confirms the safety and efficacy of excimer laser-assisted therapy in the treatment of severe infrapopliteal disease and CLI. Our 91.8% 6-month limb salvage rates closely mirror the excellent 93% 6-month limb salvage rate reported in the LACI pivotal multi-center trial, therefore further adding to the accumulating data that laser endovascular therapy is a vital tool when facing limb salvage in the CLI patient.

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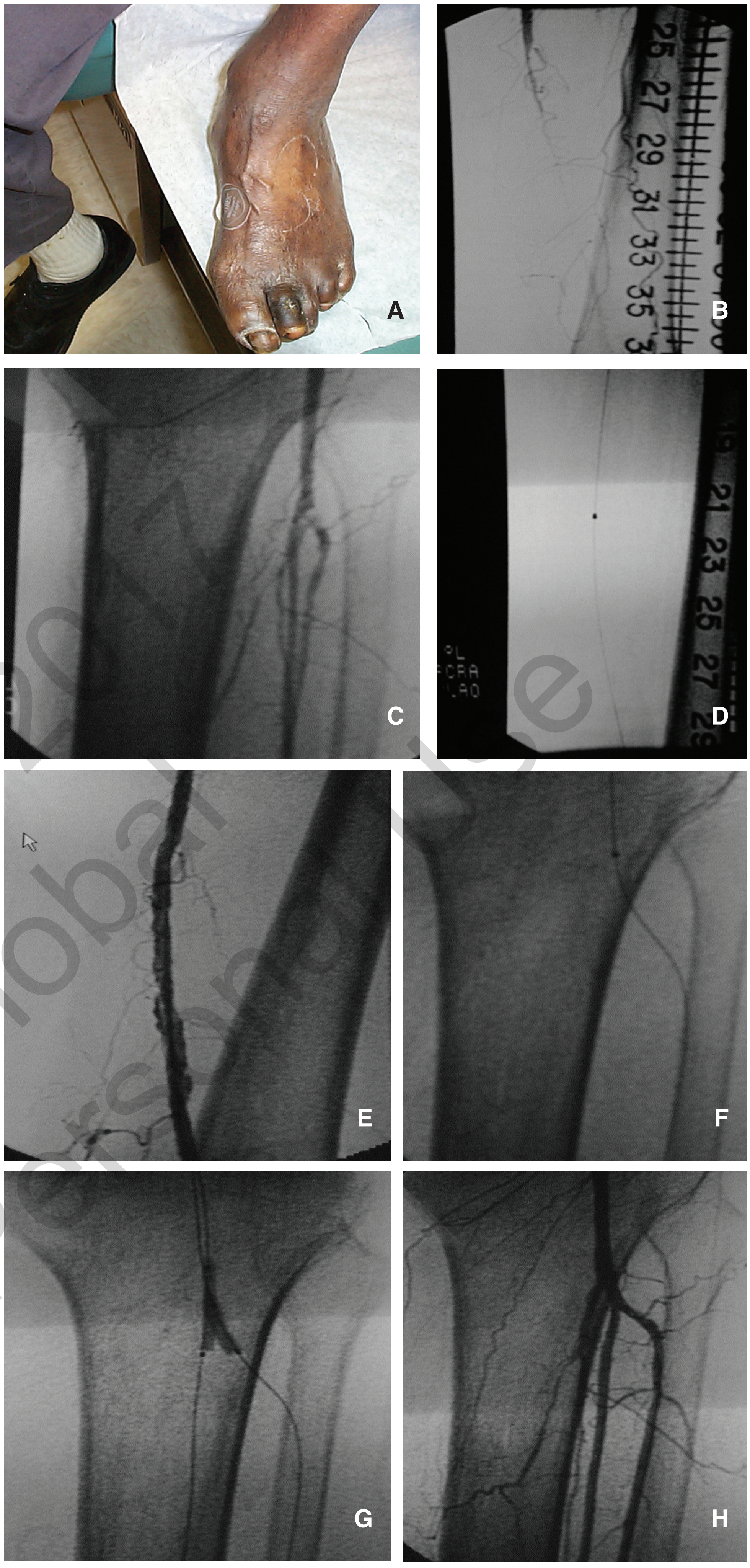
References:

1. Transatlantic Inter-Society Consensus (TASC) on Management of Peripheral Arterial Disease (PAD). *J Vasc Surg* 2000;31:1-296.
2. Wolfe JH, Wyatt MG. Critical and subcritical ischemia. *Eur J Vasc Endovasc Sug* 1997;13:578-582.
3. Fisher RK, Harris PL. Epidemiological and economic considerations in the critically ischemic limb. "Critical Limb Ischemia" 1999;19-25.
4. Anonymous. Second European Consensus Document on Chronic Critical Limb Ischemia. *Eur J Vasc Surg* 1992;6:Suppl A:1-32.
5. Hallett JWJ, Bryne J, Gray DT, et al. Impact of arterial surgery and balloon angioplasty on amputation: a population based study of 1155 procedures between 1973-1992. *J Vasc Surg* 1997;25:29-38.
6. Kalra M, Gloviczki P, Bower TC, et al. Limb salvage after successful pedal bypass grafting is associated with improved long-term survival. *J Vasc Surg* 2000;33:6-16.
7. Hobson RW, Lynch TG, Padberg FTJ, et al. Results of revascularization and amputation in severe lower extremity ischemia: a five year clinical experience. *J Vasc Surg* 1985:2:174-85.
8. Dormandy JA, Ray S. The natural history of peripheral arterial disease. In: Tooke JE, Loew GD, editors. *A textbook of vascular medicine.* London: Arnold;1996.p.162-75.
9. Paaske WP, Lausten J. Femorodistal bypass grafting: quality of life and socioeconomic aspects. *Eur J Vasc Endovasc Surg* 1995;10:226-230.
10. Raviola CA, Nichter LS, Moore WS, et al. Costs of treating advanced leg ischemia. Bypass graft versus primary amputation. *Arch Surg* 1988;123:495-496.
11. Mackey WC, McCullough JI, Callow AD, et al. The costs of surgery for limb-threatening ischemia. *Surgery*1986;99:26-35.
12. Panayiotopoulos YP, Tyrrell MR, Taylor PR, et al. Outcome and cost analysis after femorocrural and femoropedal grafting for critical limb ischaemia. *British J Surg* 1997;84:207-212.
13. Laird JR. Laser angioplasty for critical limb ischemia (LACI); results of the LACI phase 2 clinical trial. Presented at ISET annual meeting, January 2003;www.iset.com.
14. Scheinert D, Laird JR, Schroder M, et al. Eximer-laser assisted recanalization of long, chronic superficial femoral occlusions. *J Endovasc Ther* 2001;8:156-66.
15. Allie DE, et al. Bivalirudin as a foundation coagulant in peripheral vascular disease: a safe and feasible alternative for renal and iliac interventions. *J Invas Cardiol* 2003;15:334-342.
16. Falanga V, Margolis D, Alvarez O, et al. Rapid healing of venous ulcers and lack of clinical rejection with an allogenic cultured human skin equivalent. *Arch Dermatol* 1998;134:293-300.
17. Sabolinski ML, Alvarez O, Aulette M, et al. Cultured skin as a "smart material" for healing wounds: experience in venous ulcers. *Biomaterials* 1996;17:311-20.
18. Allie DE, Hebert CJ, Walker CM, et al. Novel treatment strategy for leg and sternal wound complications after coronary artery bypass graft surgery: A bioengineered Apligraf. *Ann Thoracic Surg* 2004;78:673-678.
19. Fagan A. The LACI Trial: 6-month results. *Endovascular Today* October 2003, 1-3.
20. Vollert B, Junger M. PGE-1 and Iloprots. *Phlebology.* 1999;28:122-125.
21. Dormandy JA. Clinical experience with Iloprost in the treatment of critical limb ischemia. In: Rubanyi GM, ed. *Cardiovascular Significance of Endothelium-derived Vasoactive Factors.* Mount Kisco, NY: Futura Publishing Co, Inc., 1991;335-347.
22. Keller T, Scheinert D. Laser angioplasty for critical limb ischemia. *Endovascular Today* 2004;3:63-65.
23. Baumgartner I, Pieczek A, Manor O, et al. Constitutive expression of phVRGF-165 after intramuscular gene transfer promoted collateral vessel development in patients with critical limb ischemia. *Circulation* 1998;97:1114-1123.
24. Isner JM, Pieczek A, Shainfeld R, et al. Clinical evidence of angiogenesis after arterial gene transfer of phVEGF-165 in patients with an ischaemic limb. *Lancet* 1996;348:370-374.
25. Pomposelli FB, etal. A decade of experience with dorsalis pedis artery bypass:Analysis of outcome in more than 1000 cases. *J Vasc Surg* 2003;37:307-315.
26. Kalra M, et al. Limb salvage after successful pedal bypass grafting is associated with improved long term survival. *J Vasc Surg* 2001;33:6-16.
27. Curi MA, et al. Long-term results of infrageniculate bypass grafting using all-autologous composite vein. *Ann Thoracic Surg* 2002, online publication. DOI: 10.1007/s10016-001-0266-6.
28. Dorros G, Jaff Mr, et al. Tibioperoneal (Outflow Lesion) angioplasty can be used as primary treatment in 235 patients with critical limb ischemia: five year follow-up. *Circulation* 2001;104:2057-2062.
29. Jamsen T. Manninen H, Tulla H, et al. The final outcome of primary infrainguinal percutaneous transluminal angioplasty in 100 consecutive patients with chronic critical limb ischemia. *J Vasc Interven Radiol* 2002:13(5):455-463.
30. Brillu C, Picquest J, Villapadierna F, Papon X, et al. Percutaneous transluminal angioplasty for management of critical limb ischemia in arteries below the knee. *Ann Vasc Surg* 2001;15(2):175-181.
31. Bakal CW, Sprayregen S, Veith FJ, et al. Percutaneous transluminal angioplasty of the infrapopliteal arteries: results in 53 patients. *AJR* 1990;154:171-174.
32. Biamino G. Tibioperoneal stenting. *Endovascular Today* 2004;3:58-62.
33. Ebersole, M.D., Dahm, J.B., Das, T., et.al. (2004). Excimer laser revascularization of saphenous vein grafts in acute myocardial infarction. *J Invas Cardiol*;16:177-180.
34. Topaz, O., Ebersole, D., Das, T., et.al. (2004). Excimer laser angioplasty in acute myocardial infarction: The CARMEL multicenter trial. *Am J Cardiol*;93:694-701.
35. Topaz, O., Minisi, A., Bernardo, N., et.al. (2001). Alterations of platelet aggregation kinetics with ultraviolet laser emission: The stunned platelet phenomenon. *Thromb Haemost*;86:1087-1093.

Dr. Allie, Chris Hebert, and Dr. Walker have disclosed that they have no significant financial relationship with any organization that could be perceived as a real or apparent conflict of interest in the contexts of the subject of this article.

The authors can be contacted at David.Allie@cardio.com. ■



Case #2.
Ischemic left foot with gangrenous digits 1-3 (2A). Angiography revealed 100% left SFA and PTA occlusions with > 90% ATA and peroneal artery stenosis (2B-C). 2.0 mm ELA/BA performed in left SFA with results (2D-E). 1.4 mm ELA/BA in the IAs with results low-pressure "kissing BA" (2F) using coronary balloons at the ATA and tibioperoneal trunk (2G-H). Limb salvage and wound healing at 6-months (2I).