Limb Salvage: Early Identification Through Risk Assessment

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What is an Interventionalist?

- Interventional Cardiologist: a specialist who treats coronary artery disease, peripheral artery disease and all aspects of atherosclerosis
- Vascular Surgeon: a specialist of surgical interventions of arteries and veins and of therapies for the peripheral vascular system
- Interventional Radiologist: a sub-specialist of radiology who performs minimally invasive procedures using image guidance
- All have similar skill sets to perform peripheral interventions

Treating PVD

Treatment for severe PVD in the 1800's

Video Clip
Treating PVD

- Despite advanced interventional techniques to restore straight-line flow, amputation continues to be a common “therapy” for CLI
- 200,000 amputations estimated in Europe and the USA annually
Igantz Simmelweis
1849

“I marvel that a society would pay a surgeon a large sum of money to remove a patient’s leg…but nothing to save it.”

George Bernard Shaw

Louis Pasteur

Actual Operative Report

Date of Procedure:
08/24/04

RECOMMENDATIONS: Based upon this angiogram, a revascularization procedure is not an option in this patient. Certainly, if he has progressive pain or tissue loss, he would best be served with a below knee amputation.
“There is no patient that would not intervene on that was scheduled for an amputation”

Craig M. Walker, M.D.
Medical Director
Cardiovascular Institute of the South

Darwin’s Survival of the Fittest

PAD Amputations
- Less than half of amputees ever walk again
- Less than 25% if it is an above the knee amputation
- 5 – 9% die in the hospital
- 25% require nursing home placement
- One third of amputees lose the remaining leg within 18 mos.
- In the United States, the amputation rate is increasing.
“You See What You Look for and You Recognize What You Know”
Lawrence Harkless, DPM

Amputation Impact!!

- 20%-25% (1/4) all diabetics-lifetime
- 30 Day perioperative mortality
  ✓ BKA - 5-8%
  ✓ AKA - 8-12%
- 18 - 24 month overall mortality - 40-50%
- Amputations are NOT benign!

FoxHollow SilverHawk Plaque Excision

Totally occluded Dorsalis Pedis Artery is choking off the blood supply to Jamie’s foot, creating a non healing foot ulcer.

Plaque excised from Jamie’s occluded Dorsalis Pedis Artery using the FoxHollow SilverHawk plaque excision system.

Restored blood flow to Jamie’s foot after plaque was excised from occluded Dorsalis Pedis Artery.

ABI 0.2
ABI .75
Thomas’ Super Femoral Artery is occluded, limiting blood flow to his entire leg and creating an ischemic foot.

Large quantities of plaque were excised from Thomas’ peripheral arteries using the FoxHollow SilverHawk.

Blood flow restored to Thomas’ Super Femoral Artery after FoxHollow SilverHawk plaque excision.

Pre-Procedure Angiogram reveals a totally occluded Popliteal Artery and Below the Knee Arteries, preventing blood flow to Robert’s foot.

Post-Procedure Angiogram reveals a widely patent Popliteal Artery and Below the Knee Arteries, providing blood flow to Robert’s foot!

Percutaneous vs Surgical: Which Would You Rather?

The SFA is Unique

Knee Extension

Knee Flexion
Forces Exerted On Stents In SFA

1. Extension / Contraction
2. Torsion
3. Compression
4. Flexion

Table For Four

Distal PT/Calcaneal

Pre  Peri  Post

Device used On the wire

Darwins Theory of Evolution???
Amputations

- Less than 20% get an angiogram
- Only 50% get an ABI
- Most of these patients do have limb salvage options
- It is not conservative treatment to amputate!

Boxing Video Clip


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<th>ABI’S</th>
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<tr>
<td><img src="image1.png" alt="Image 1" /></td>
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<td><img src="image2.png" alt="Image 2" /></td>
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**“For some reason, it is considered conservative treatment to chop someone’s leg off and aggressive treatment to even do an angiogram”**

“Craig M. Walker, M.D.”
Medical Director
Cardiovascular Institute of the South
American Diabetes Association

• Of 85% of primary care physicians that treat the diabetic, only 15% ask the patient to remove socks and shoes for foot exams.

However...

• Remember 50-75% patients are asymptomatic, or present with atypical symptoms.

Mortality in Patients With Severe* PAD

<table>
<thead>
<tr>
<th>Patients (%)</th>
<th>Breast Cancer(^1)</th>
<th>Colon/Rectal Cancer(^2)</th>
<th>Non-Hodgkin’s Lymphoma(^3)</th>
<th>PAD(^*)</th>
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<tr>
<td>0</td>
<td>14</td>
<td>38</td>
<td>47</td>
<td>56</td>
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* Ankle Brachial Index <0.4
\(^1\)McKenna M et al. Atherosclerosis. 1991;87:119-126.

I’m Dead Sexy
Vascular Disease and Neuropathy

- Leg/foot cramps
- Numbness feet/legs/toes
- Decrease skin temp.
- Sores that don’t heal

Amputation Impact

- International Diabetes Federation estimates that somewhere in the world, a leg is lost to diabetes every 30 seconds.¹
- In a 2001 study, only 49% of those receiving amputations had any diagnostic vascular evaluation prior to amputation.²
- Each year there are 150,000 lower extremity amputations with a $270 million price tag.³
- Comprehensive foot care programs can reduce amputation rates by 45-85%.⁴

¹ International Diabetes Federation. Time to Act: diabetes and foot care. International Diabetes Federation; 2005
⁴ Complications of diabetes in the U.S. diabetes.org

Video Clip

Risk Factors for Atherosclerosis

- PVD
  - Smoking
  - Diabetes
  - Hypertension
  - Dyslipidemia
  - Sedentary life style
  - Age >50
  - Obesity
  - PVD (carotid stenosis, AAA)
- African Americans, Hispanics, and diabetics have the highest prevalence of PVD

- CAD
  - Smoking
  - Diabetes
  - Hypertension
  - Dyslipidemia
  - Sedentary life style
  - Age >50
  - Obesity
  - PVD (carotid stenosis, AAA)
Analysis of Plaque Gene Expression

Patient → Plaque Excision → Plaque → Microarray Analysis

ACC/AHA Guidelines for the Management of PAD

• The high prevalence of atherosclerotic risk factors place these patients at a "markedly" increased risk of atherosclerotic ischemic events, including MI and stroke

• All patients with lower extremity PAD should achieve risk reduction and specific treatment targets comparable to those of individuals with established coronary artery disease.
**Patient Background - #1**

80 yr old male
- Coronary Artery Disease
- Hypercholesterolemia
- Former smoker
- No rest pain
- Claudication
- Tissue loss – great toe nail, slightly gangrenous, painful to touch
- Left ABI – 0.61

**Results**

- Patient’s foot warm on follow-up
- Patient walking daily without leg pain
- Healing of great toe wound – nail regrowth

**Plaque Excision Procedure**

- Multiple passes in SFA with SilverHawk™ LS catheter
- Multiple passes in TPT with SilverHawk SS catheter

**Patient Background - #7**

90 yr old female
- Non-healing toe wound
- Rest pain
- Claudication
- Left ABI – 0.34
Plaque Excision Procedure

- Roadrunner wire, Bernstein catheter, Mailman wire, and Microglide catheters used to cross total occlusion in popliteal
- Plaque excised in popliteal with SilverHawk™ SS catheter
- Plaque excised in SFA with SilverHawk™ LS catheter

Performed By: Dr. Lakshmikumar Pillai, West Virginia University Medical Center, Ruby Memorial Hospital, Morgantown, WV

Patient Background - #6

83 yr old female
- Non-healing toe wound, tissue loss, gangrenous
- Rest pain
- Smoker
- Left ABI – 0.40
- Stent in renal artery

Performing By: Dr. Mark Picone, Heart Hospital of Austin, Austin, TX

Results

Good distal flow to toes, resulting in healing of toe ulcer
Patient reports left toe pain resolved completely

Performing By: Dr. Lakshmikumar Pillai, West Virginia University Medical Center, Ruby Memorial Hospital, Morgantown, WV

Plaque Excision Procedure

- Plaque excision using SilverHawk™ catheters from left SFA, popliteal, and TPT vessels
- Post SilverHawk™ procedure: Good flow through prior SFA occlusion, into popliteal and TPT
- SFA: Occluded → 20% residual stenosis
- TPT: Occluded → 25% residual stenosis

Performing By: Dr. Mark Picone, Heart Hospital of Austin, Austin, TX
Good distal flow to toes, resulting in healing of toe ulcer

Performing By: Dr. Roger Gammon, Austin Heart Hospital, Austin, TX

## Results

### PAD Treatment Options

- **Medical**
  - Risk Factor Modification*
  - Exercise Therapy*
  - Drug Therapy*

- **Endovascular Therapy**
  - Peripheral Transluminal Angioplasty*
  - Peripheral Stenting*
  - Atherectomy
    - SilverHawk Plaque Excision System™ – An Innovative Approach
  - Thrombolytic Therapy (adjunctive)

- **Surgery**
  - Bypass Grafts*
  - Amputation*
  - Endarterectomy*

*Rosenfield K, Isner JM, Chap. 97 Textbook of Cardiovascular Medicine 1998

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## SilverHawk in Action

**Pre-Procedure**

**Post-Procedure**
“THERE ARE NO MORE – NO OPTION PATIENTS”
Peter Sheehan, MD
September 2006

……when there is a problem that threatens the security of the masses, those that have the ability, have the responsibility, to do something about it……..

A Hawk by any other Name

Contact information

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<table>
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<th>Who’s at risk?</th>
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<th>Early warning system of the heart</th>
<th>Looks like this</th>
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**Peripheral Arterial Disease**

**Peripheral Vascular Disease**

Long before it looks like this!