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Introduction to the use of the PercuSurge GuardWire System in the SAFER Randomized Trial

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Personal Financial Disclosure

From the inception of the SAFER trial in September 1998 to the current date, I have not had any equity interest, either in stock-options or stock ownership, in PercuSurge, Inc.

SVG Intervention: Why is it important?

Natural attrition of SVGs post surgery

- 15-20% in first year
- 1-2% per year between 1-6 yrs
- 4% per year between 6-10 yrs
- 40-50% of grafts closed 10 yrs post surgery

Re-operation is technically difficult

- In Hospital Mortality 3-7%
- Perioperative MI rate 12%
- Difficult recuperation

Percutaneous SVG Intervention Technical Considerations

- During intervention, SVG lesions are known to have a high incidence of slow or "no reflow" due to distal embolization and associated microvascular spasm
- While the risk may be increased with bulky, fragmented, or thrombus associated lesions, the potential for "no reflow" is difficult to predict

SVG Intervention
Historical Outcomes

MACE events

- Device dependent: atherectomy devices > stents > balloon angioplasty

MACE events following stent deployment

- Mortality: 3-4%
- Q-wave MI: 2-3%
- Non Q-wave MI: 15-25% (CPK >3x upper limit of normal)

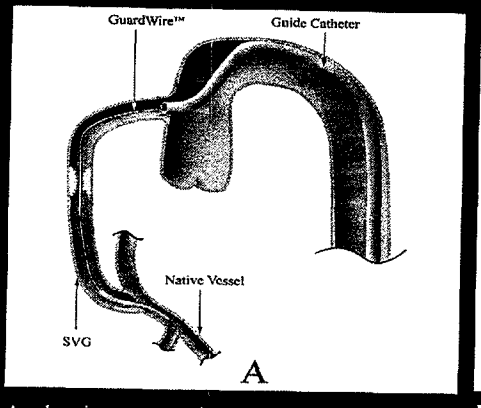
CPK rises correspond with decreased long term survival: "Walking Wounded"

Summary

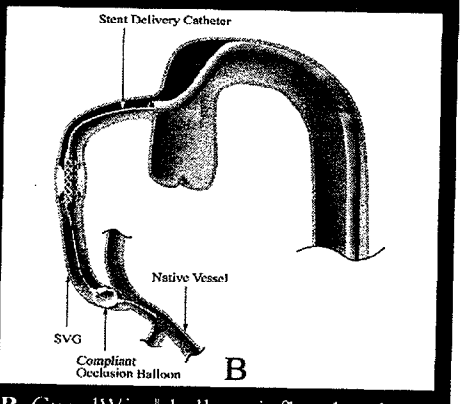
The historical inability of interventional cardiologists to treat saphenous vein disease with a low complication rate represents an important Unmet Clinical Need

.....until the SAFER Trial

PercuSurge GuardWire System

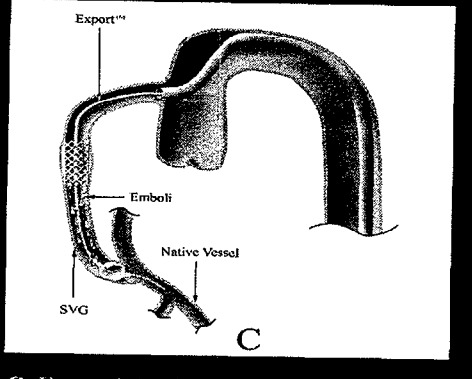


A. Lesion crossed with GuardWire®

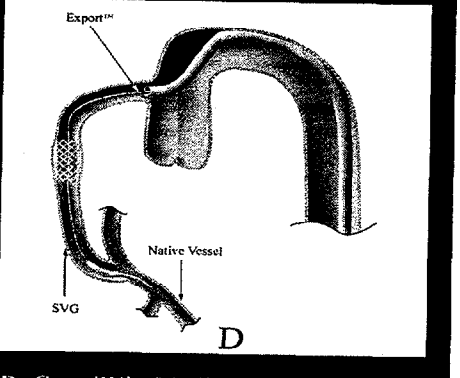


B. GuardWire® balloon inflated and intervention performed under protection. Stent placed with single wire technique

PercuSurge GuardWire System

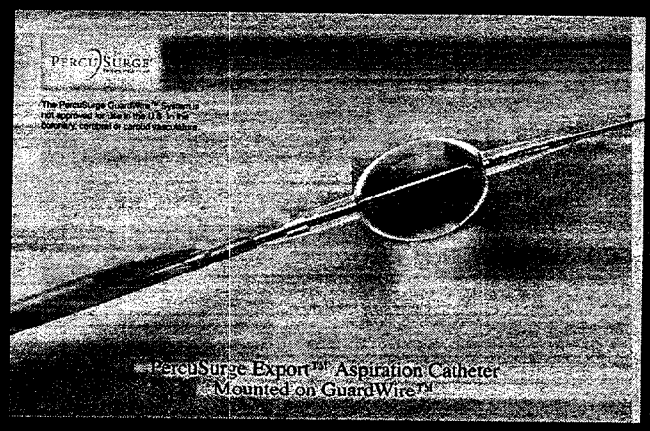


C. Export® Aspiration catheter removes emboli & thrombus with slow distal to proximal pullback

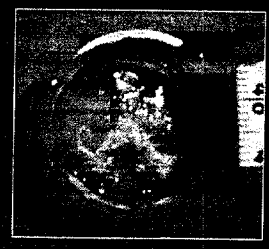


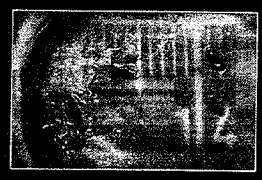
D. GuardWire® balloon deflated

PercuSurge GuardWire System



PercuSurge Export™ Aspiration Catheter
Mounted on GuardWire™





Videos

SVG Intervention: Personal Observation and Perspective

- Difficult to predict which patients will have "no reflow"
- There was no balloon intolerance @ Michigan Heart (42 cases)
- It has become progressively more difficult to treat patients with SVG disease when GuardWire distal protection is not available.