



## Heparin Coated (Propaten) PTFE Grafts Versus Autologous Vein Grafts for Bypasses to Targets Above and Below the Knee: Are Heparin Coated Grafts Worth The Cost

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### Disclosures

The literature search and statistical analysis for the meta-analysis were sponsored by WL Gore



### Perspective in today's literature


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE (FREE PREVIEW)

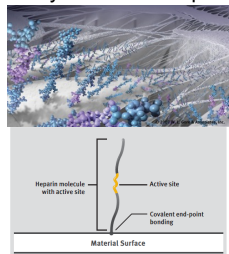
#### Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia

Alik Farber, M.D., Matthew T. Menard, M.D., Michael S. Conte, M.D., John A. Kaufman, M.D., Richard J. Powell, M.D., Nitesh K. Choudhry, M.D., Ph.D., Taya H. Hamza, Ph.D., Susan F. Assmann, Ph.D., Mark A. Creager, M.D., Mark J. Cziraky, Pharm.D., Michael D. Dale, M.D., Michael R. Jaff, D.O., et al., for the BEST-CLI Investigators<sup>1</sup>

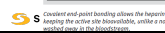
**RESULTS** In cohort 1, after a median follow-up of 2.7 years, a primary-outcome event occurred in 302 of 709 patients (42.6%) in the surgical group and in 408 of 711 patients (57.4%) in the endovascular group (hazard ratio, 0.68; 95% confidence interval [CI], 0.59 to 0.79; P<0.001). In cohort 2, a primary-outcome event occurred in 83 of 194 patients (42.8%) in the surgical group and in 95 of 199 patients (47.7%) in the endovascular group (hazard ratio, 0.79; 95% CI, 0.58 to 1.06; P=0.12) after a median follow-up of 1.6 years. The incidence of adverse events was similar in the two groups in the two cohorts.



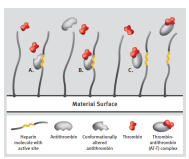
### CBAS Heparin Surface: Proprietary Covalent End-point Bonding




- The anticoagulant function of heparin is dependent on the bioavailability of an active site within the molecule.
- Some methods of covalent heparin bonding damage and/or obstruct the active site.
- The CBAS Heparin Surface consists of a proprietary covalent end-point bond that preserves the active site, thus retaining heparin's anticoagulant activity.



### CBAS Heparin Surface: Mechanism of Action



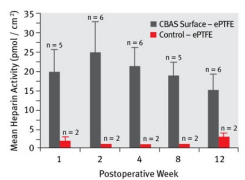
- Bioactive site of heparin molecule enables anti-thrombin to bind thrombin.
- When antithrombin binds to thrombin, a neutral AT-T complex is formed.
- Neutral AT-T complex detaches from the heparin molecule. Active site becomes available to again bind antithrombin.



### How Long Does Heparin Last? (Canines)

In-vivo canine aorto-iliac bypasses  
 15 GORE® PROPATEN® Vascular Grafts and five control ePTFE (6 mm x 12 cm)

In vivo canine carotid artery interposition model  
 GORE® PROPATEN® Vascular Graft



Legend: ■ CBAS Surface - ePTFE, ■ Control - ePTFE

Mean Heparin Activity (pmol / cm<sup>2</sup>)

Postoperative Week: 1, 2, 4, 8, 12


Legend: ■ CBAS Surface - ePTFE, ■ Control - ePTFE

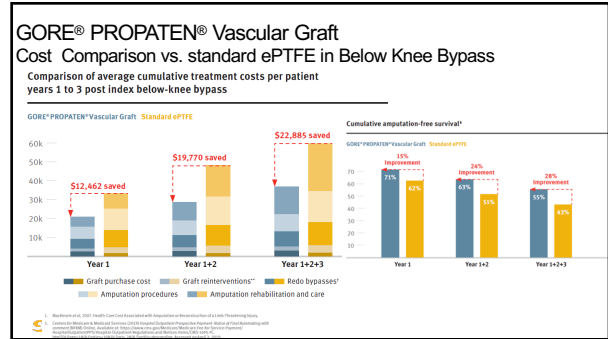
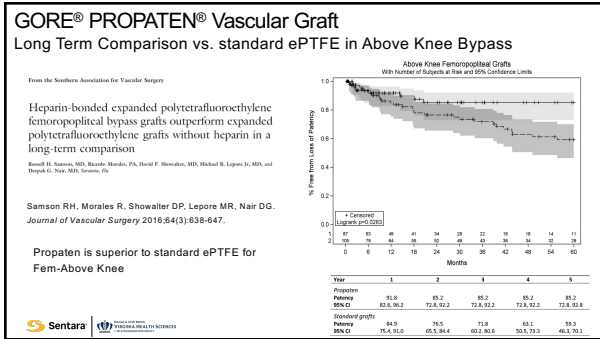
Legend: ■ CBAS Surface - ePTFE, ■ Control - ePTFE

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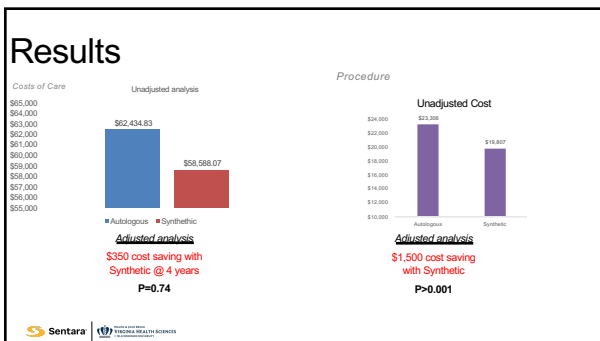
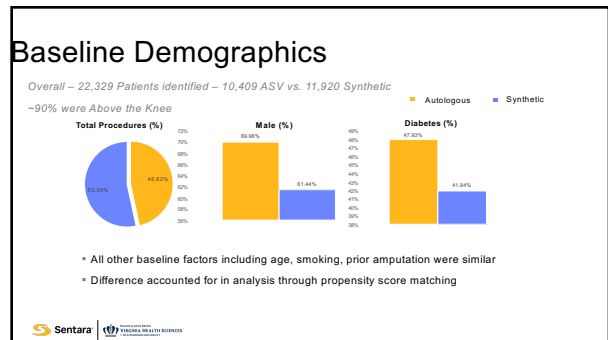
Legend: ■ CBAS Surface - ePTFE, ■ Control - ePTFE

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- ### Overview and Protocol
- Assess the safety, effectiveness and economic impact of synthetic vascular graft to autologous vein
  - Retrospective US real world claims database analysis. Medicare Provider Utilization and Payment Data from 2015-2017
  - ICD-10 diagnosis and procedure codes and followed for up to 4 years.
  - Linkage and longitudinal follow up - identified by in-patient and out-patient procedure codes.
  - Propensity score matching to balance cohorts for comparative statistics.



### Meta-Analysis

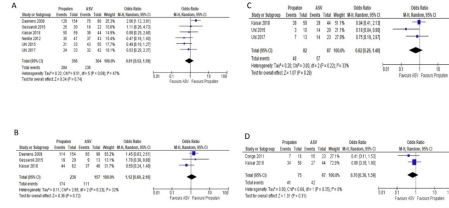
An electronic literature search was conducted in MEDLINE and EMBASE to identify comparative studies in patients undergoing below-the-knee surgical bypass. Studies were screened at abstract and full text review using pre-defined inclusion criteria by two independent reviewers and critically appraised for risk of bias. Meta-analyses were conducted using Review Manager 5 software

### Methods

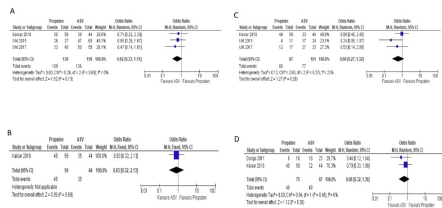
The electronic literature search identified 11,829 citations with an additional 1,696 records identified from grey literature searches  
 After deduplication there were 10,263 records in total. Full text review was conducted on 258 publications, of which 250 were excluded.  
 Eight retrospective cohort studies comparing HePTFE grafts with ASV and including 2158 patients were included in the primary analysis.



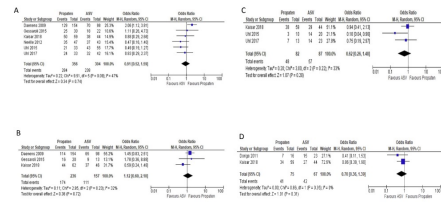
### Primary Patency



### Secondary Patency



### Amputation Free Survival



### Conclusions

- In the absence of vein, Propaten has a clinical and financial advantage over standard ePTFE both above and below the knee
- When compared to autologous vein, Propaten demonstrates similar clinical outcomes above the knee
- When compared to autologous vein, Propaten has similar financial costs to autologous vein above and below the knee
- Tibial Subset analysis is ongoing but underpowered



### Thank You

