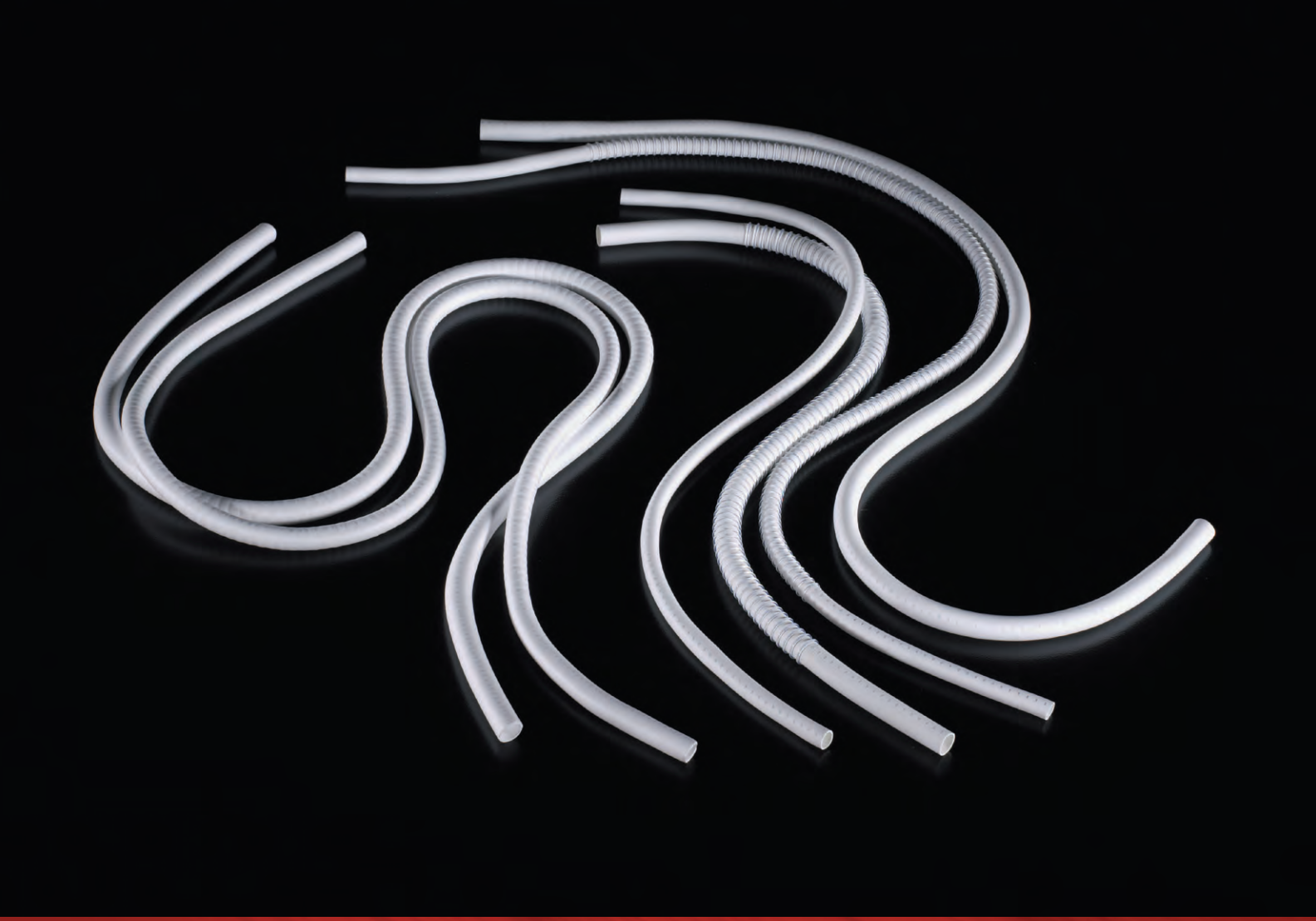
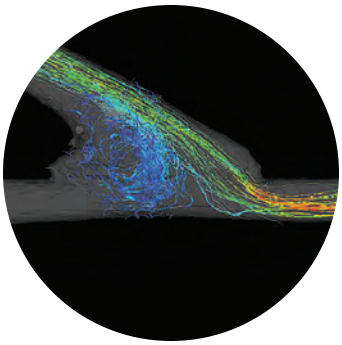
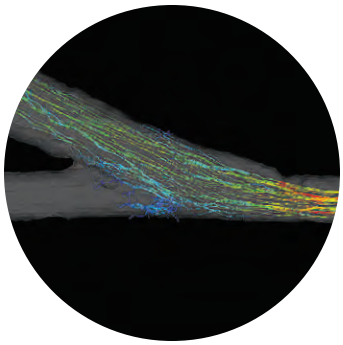


# Why Gore Does Not Offer a Pre-Cuffed Graft:
## The Science Behind Cuff Technology





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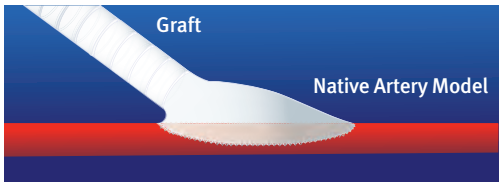
## *In Vitro* Experiments Shed New Light on the Hemodynamics of Distal Bypass Anastomoses

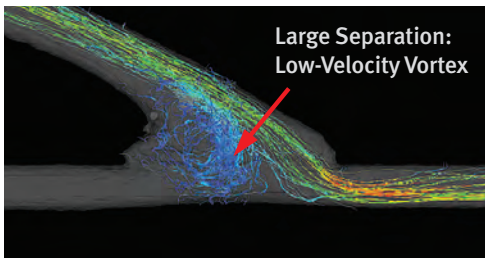
MRI-based 3-Dimensional Flow Velocity Measurement of Pre-cuffed Graft and Standard End-to-Side Anastomoses[1,2]



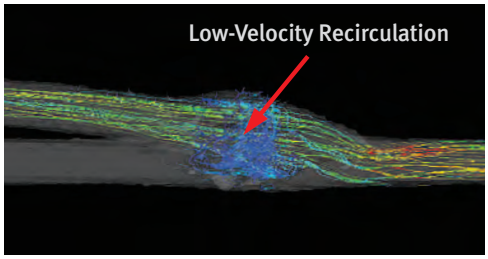

**Pre-cuffed Graft**


**Standard End-to-Side**

### Low-Velocity Vortex

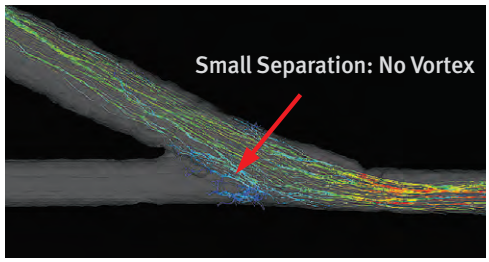



Lateral view

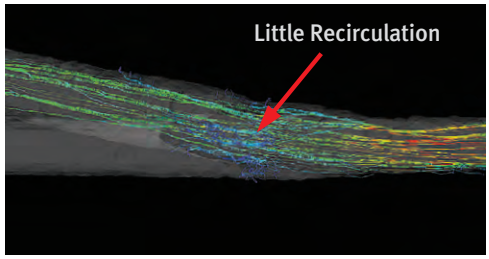



Bottom view

### Smooth Flow Transition

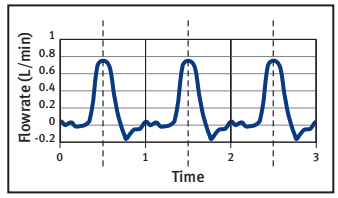



Lateral view

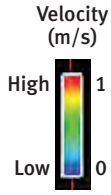



Bottom view

*3-D Flow Streamlines at Peak Systole*




*Pulsatile Flow Rate Waveform*




### Low-Velocity Vortex Results In:

- Inertial energy losses
- Low-velocity recirculation
- Low wall shear stress conditions

### Smooth Flow Transition Results In:

- Undisturbed flow
- Little recirculation
- Favorable wall shear stress conditions

> *"These areas of increased flow separation and vortex formation [in the pre-cuffed graft] would seem to be disadvantageous, and correlate with the areas of intimal hyperplasia formation. Velocity vectors in the heel vortex demonstrate low velocity and disordered flow patterns. There was no evidence of the high velocity, uniform flow that would maintain an advantageous high shear stress environment."*[2]
>
> – R. Neville, *et al. Journal of Surgical Research*, In Press.

## A Review of Recent Literature Does Not Demonstrate a Clinical Benefit for Pre-cuffed Grafts Over Conventional ePTFE Grafts

| Average Primary Patency for Below-Knee Bypasses [a] | ePTFE Pre-cuffed Graft [b] | ePTFE Standard End-to-Side (no vein cuffs or patches) [c] | Vein Bypass [c] |
|---|---|---|---|
| One Year | 60% (N = 174 ) | 63% (N = 549) | 81% (N = 9570) |
| Two Year | 50% (N = 87) | 50% (N = 301) | 72% (N = 5062) |

N = total number of bypasses

[a] Weighted average

[b] Includes studies of below-knee popliteal and distal bypasses only. Through July 2010. Data of analysis on file.

[c] Data based on an analysis of current literature: Several Medline searches were performed to identify publications pertaining to ePTFE synthetic vascular graft and vein infragenicular bypasses. Search criteria included (1) articles published from January 2000 to September 2005, (2) key words used were below-knee, polytetrafluoroethylene, prosthetic, bypass, patency, (3) articles in English language, (4) N equal or greater than 30 bypasses, (5) clinical publications, (6) reviews, case reports or meta-analysis articles were excluded, (7) articles containing the key word AV access (including synonyms) were excluded, (8) majority tibial bypasses. Articles that did not meet the above criteria were deemed ineligible for this analysis. Data of analysis on file.

## Frequently Asked Questions

### What was the rationale behind the pre-cuffed graft?

In the worst-case view of end-to-side flow, abnormal shear stress conditions are thought to occur, contributing to the development of intimal hyperplasia.[4] Pre-cuffed grafts were thought to improve these shear conditions[5] by mimicking the hemodynamics of vein cuffs, while eliminating the need to create a vein cuff. As shown by the results on the previous page, the cuffed geometry may instead contribute to poor hemodynamics, while conventional end-to-side anastomoses with an optimal bevel angle can produce favorable flow conditions.

### Do vein cuffs produce better clinical results?

Clinical studies comparing the use of vein cuffs vs. plain ePTFE have had mixed results. Some clinical studies have shown improved primary patency in below-knee bypasses when vein cuffs are used,[6] while other studies have found that clinical outcomes are no better than plain ePTFE.[7]

### If hemodynamics of the cuffed geometry are unfavorable, why do some vein cuffs and patches appear to improve results?

Experimental evidence suggests that the benefits of vein cuffs and patches may be due to biological factors and improved wall compliance matching, rather than hemodynamic changes.[8,9] The superior performance of vein bypasses, which do not have a large cuffed shape, also suggests that a cuffed geometry is not an important factor in improving graft performance.

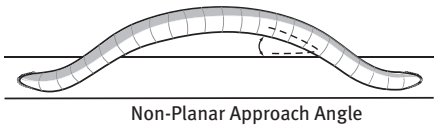
> *"The marked increase in IH [Intimal Hyperplasia] with PCs [ePTFE Cuffs], despite a similar geometric configuration to VCs [Vein Cuffs], suggests that the biologic properties of autogenous tissue dissipate IH development."*[9]
>
> – M. Kissin, *et al. Journal of Vascular Surgery*, 2000.

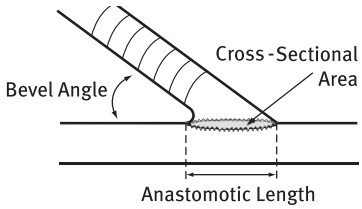
## The Power is In the Surgeon's Hands: Hemodynamics Can be Improved with Anastomotic Technique

The current results of 3-D flow velocity studies suggest: [1,2]

- The pre-cuffed graft does not offer the solution to the problem of poor hemodynamics in an end-to-side anastomosis.
- A standard end-to-side anastomosis using a conventional ePTFE graft does not necessarily have poor flow.

### Flow can be improved by considering these important geometric factors:




- Non-planarity [10,11]
- Bevel angle [12,13]
- Anastomotic length [13,14]
- Cross-sectional area [13,14]

Current results confirm that a 30° bevel angle can produce favorable flow conditions. Investigation of optimal surgical techniques for end-to-side anastomoses will continue to be an active and important area of hemodynamic research.

*Currently, the Best Way to Achieve Improved Hemodynamics is Through Anastomotic Technique –* **Not Pre-Cuffed Grafts**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