PQ Bypass: A Paradigm Shift in Complex Femoral Popliteal Disease

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Presenter Disclosure Information

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

• PQ ByPass, Founder, Equity, Multiple Patents and Major Stock Holder;

  **Patents** -- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure, Vascular Access Patents
Not FDA cleared or approved.

Not available in the United States.
Background

Limitations in the Treatment of Long, Complex SFA Occlusions

- Revascularization of long, complex SFA occlusions has traditionally required open surgical bypass for long-term success.
- Endovascular techniques and technologies have matured; however, a durable solution for these severe lesions is still lacking.
- Percutaneous bypass may provide the durability associated with open surgery while reducing morbidity and mortality associated with more invasive interventions.

The Solution

Calcium  I.S.R.

The solution combine the best of both worlds:

- Patency of fem-pop bypass and
- Endovascular approach
Who is it for?

The first frontier is still the last frontier?

Bypassing calcium instead of crossing it?
Results of PQB at 5yrs
Proof of Concept

K/P Curve – Primary Patency

- El Camino Hospital, off-the-shelf devices
- 25 limbs in 21 subjects treated
- Primary patency @ 1 year: 82%
- Secondary patency @ 4 years: 91%
- **No objective venous morbidity**
- 78% discharged same or next day

Patency results reported using PSVR>2.0

Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion Length (cm)</th>
<th>31.2 ± 9.7</th>
</tr>
</thead>
<tbody>
<tr>
<td>TASC D</td>
<td>88.0%</td>
</tr>
<tr>
<td>Rutherford 3 - Severe</td>
<td>42.9%</td>
</tr>
<tr>
<td>Rutherford 4 - Ischemic</td>
<td>28.6%</td>
</tr>
<tr>
<td>Rutherford 5 - Tissue loss</td>
<td>28.6%</td>
</tr>
</tbody>
</table>
Intellectual Property

(10) United States Patent
(11) No.: US 6,464,065 B1
(12) Date of Patent: Oct. 15, 2002

(54) CAHETEEH APPARATUS AND METHOD FOR AUGMENTING A VENUS
(75) Inventor: Richard R. Hoener, 26th Ave., Athens, VA 24005
(72) Filed: Jan. 21, 2002
(62) Prior Publication Data
(63) Primary Examiner: L. Thomas Higbee
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 8,062,321 B2
(12) Date of Patent: Nov. 22, 2011

(54) STENT SYSTEM
(75) Inventor: Richard R. Hoener, 252 N. 26th St., Suite 700, Phoenix, AZ 85004
(72) Filed: Jan. 21, 2002
(62) Prior Publication Data
(63) Primary Examiner: L. Thomas Higbee
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 7,402,141 B2

(54) CATHETER GUIDING SYSTEM USING CONCENTRIC WIRES
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Mar. 22, 2006
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 7,347,567 B2
(12) Date of Patent: Mar. 20, 2008

(54) CATHERER SYSTEM FOR CONNECTING ADJACENT BLOOD VESSELS
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Mar. 22, 2006
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 7,023,931 B2
(12) Date of Patent: Nov. 29, 2001

(54) BOMEMETER GUIDING SYSTEM USING CONCENTRIC WIRES
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Mar. 22, 2006
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 7,074,004 B2
(12) Date of Patent: Feb. 21, 2006

(54) STENT SYSTEM
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Jul. 25, 2005
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 6,988,646 B2
(12) Date of Patent: Feb. 21, 2006

(54) STENT SYSTEM
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Jul. 25, 2005
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 6,976,887 B2
(12) Date of Patent: Feb. 21, 2006

(54) STENT SYSTEM
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Jul. 25, 2005
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 6,954,887 B2
(12) Date of Patent: Feb. 21, 2006

(54) STENT SYSTEM
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Jul. 25, 2005
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 6,949,958 B2
(12) Date of Patent: Feb. 21, 2006

(54) STENT SYSTEM
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Jul. 25, 2005
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets

(10) United States Patent
(11) No.: US 6,944,506 B2
(12) Date of Patent: Feb. 21, 2006

(54) STENT SYSTEM
(75) Inventor: Richard R. Hoener, 500 W. Thorne St., Suite 100, Phoenix, AZ (US 85013)
(72) Filed: Jul. 25, 2005
(62) Prior Publication Data
(63) Primary Examiner: David W. Hamblen
(71) Applicant: Richard R. Hoener
(56) References Cited
U.S. PATENT DOCUMENTS

24 Claims, 7 Drawing Sheets
The DETOUR Percutaneous Bypass Procedure

- Designed to achieve the same end-result as open bypass surgery
- Revascularization via modular stent graft bypass
- Utilizes the femoral vein as a conduit

Addresses current SFA treatment limitations with a novel endovascular approach
The DETOUR Percutaneous Bypass Technology
Trio of proprietary devices designed specifically for the DETOUR procedure

**Torus Stent Graft**
- Self-expanding nitinol wire frame encapsulated in ePTFE
- High radial force
- Elongated, exposed end rings to prevent edge stenosis

**PQ Snare**
- Over-the-wire dual-caged scaffold
- Captures and extracts guidewires through the tibial vein

**PQ Crossing Device**
- Spring-loaded guidewire support and delivery system
- Creates initial artery-vein-artery communication
Who is eligible?

- SFA occlusion up to 30 cm
- 1 cm proximal SFA stump
- SFA reconstitution 3 cm above patella
Background

• We report the results of a prospective, multi-center single-arm study of the DETOUR Technique for Percutaneous Femoral-Popliteal Bypass in patients with occlusive long-segment superficial femoral artery disease
  • Included is the one of the largest prospective series evaluating the percutaneous treatment of SFA occlusions ≥ 25cm
The DETOUR I Trial

A Prospective, Multi-Center, Independently Reviewed Single-Arm Trial to Evaluate the Safety and Performance of the PQ Bypass DETOUR Technology and Technique for Percutaneous Femoral-Popliteal Bypass – 6-Month Outcomes

Dainis Krievins, MD
Grzegorz Halena, MD
Piotr Szopinski, MD
Albert Kramer, MD
Grzegorz Oszkinis, MD
Dierk Scheinert, MD
Andrew Holden, MD
Proximal Anastomosis

SFA Vein

Crossing device creates anastomosis
Entry to cage

0.014” wire passing to vein
Distal Anastomosis

Crossing device creates anastomosis
Re-entry to artery

Popliteal a.  Vein

~28 cm
Graft Deployments

Anastomoses PTA

Graft deployment
OBJECTIVE
To assess the safety and performance of the PQ Bypass DETOUR technology and technique for the treatment of long-segment superficial femoral artery occlusions

PRIMARY ENDPOINTS:
- 30D MAE
- 6M Patency (OPG >70%)

DETOUR I Trial Overview
- 60 patients treated at 7 international sites from Jan 2015 to May 2016
- Clinical, lab, and DUS follow-up at 1, 3, 6, 12, 18, and 24M
- Venous Clinical Severity Score (VCCS) Villalta Scale 1, 3, 6, 12, 18, and 24M

MAE: Death, TVR (Target Vessel Revascularization), Target Limb Amputation
## Key Endpoints

<table>
<thead>
<tr>
<th>Primary Safety Endpoint</th>
<th>MAE at 30 days defined as Death, TVR (Target Vessel Revascularization), and Target Limb Amputation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Efficacy Endpoint</td>
<td>Primary patency at 6 months, defined as: no evidence of clinically significant stenosis (≥50%) within, immediately above, or below the treated arterial segment based on duplex ultrasound (PSV&gt;2.5)</td>
</tr>
</tbody>
</table>
| Key Secondary Endpoints | • MAVE  
• Deep Vein Thrombosis (DVT) on ipsilateral limb  
• Venous Clinical Severity Score (VCSS) through 24 months  
• Villalta Scale through 24 months  
• RB improvement by ≥1 |
Stradins University Hospital, Riga, Latvia (n=24), Universidad Católica de, Santiago, Chile (n=7), Poznan University of Medical Sciences, Poznań, Poland (n=4), Institute of Hematology Medicine, Warsaw, Poland (n=7), University Leipzig Medical Centre, Leipzig, Germany (n=3), Gdańsk Medical University, Gdańsk, Poland (n=14), Auckland, New Zealand (n=1)
Key Inclusion Criteria

• Femoro-popliteal lesions ≥10 cm in length considered to be:
  • Chronic total occlusion (100% stenosis);
  • Diffuse stenosis (>50% stenosis) with moderate to heavy calcification;
  < OR >
  • In-stent restenosis (>50% stenosis)
• ≥1 patent tibial artery to the foot
• Patent femoral vein ≥10 mm in diameter or duplicate femoral vein

Key exclusion criteria: history of DVT, known hypersensitivities to nitinol, PTFE; aspirin, heparin, antiplatelet, anticoagulant or thrombolytic therapy; or anticoagulation or contrast media
## Baseline Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, Y ± SD</strong></td>
<td>64 ± 9</td>
</tr>
<tr>
<td><strong>Male, % (n)</strong></td>
<td>83.3% (50/60)</td>
</tr>
<tr>
<td><strong>Diabetes, % (n)</strong></td>
<td>20% (12/60)</td>
</tr>
<tr>
<td><strong>Smoking Hx, % (n)</strong></td>
<td>92% (55/60)</td>
</tr>
<tr>
<td><strong>Previous Peripheral Intervention, % (n)</strong></td>
<td>33.3% (20/60)</td>
</tr>
<tr>
<td><strong>Duplicate Femoral Vein, % (n)</strong></td>
<td>20% (12/60)</td>
</tr>
<tr>
<td><strong>Rutherford Class, % (n)</strong></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>96.6% (58/60)</td>
</tr>
<tr>
<td>4</td>
<td>1.7% (1/60)</td>
</tr>
<tr>
<td>5</td>
<td>1.7% (1/60)</td>
</tr>
<tr>
<td><strong>ABI ± SD</strong></td>
<td>0.65 ± 0.19</td>
</tr>
<tr>
<td><strong>Range (n)</strong></td>
<td>0.34 – 1.50 (59)</td>
</tr>
</tbody>
</table>
Baseline Lesion Characteristics

n=60 Lesions

<table>
<thead>
<tr>
<th>Lesion length (cm ± SD)</th>
<th>28.6 ± 5.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range (cm)</td>
<td>13.4 – 43.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Occlusions, % (n)</th>
<th>96.7% (58/60)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Calcification at Landing Zone, % (n)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>56.7 % (34/60)</td>
</tr>
<tr>
<td>Moderate to Severe</td>
<td>43.3% (26/60)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Run-off vessels, % (n)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1.7% (1/60)</td>
</tr>
<tr>
<td>1</td>
<td>15.0% (9/60)</td>
</tr>
<tr>
<td>2</td>
<td>36.7% (22/60)</td>
</tr>
<tr>
<td>3</td>
<td>46.6% (28/60)</td>
</tr>
</tbody>
</table>

TASC II Lesion Type

- TASC B: 1.7% (1/60)
- TASC C: 5.0% (3/60)
- TASC D: 93.3% (56/60)

1 As assessed by Independent Medical Review
## Procedural and Clinical Success

### n=60 Subjects

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>Successful delivery of the investigational devices to the identified area and removal of delivery system</td>
<td>98.3% (59/60)</td>
</tr>
<tr>
<td>Procedural Success</td>
<td>Successful delivery of the investigational devices to the identified area and removal of delivery system in the absence of in-hospital MAEs</td>
<td>96.7% (58/60)</td>
</tr>
<tr>
<td>Clinical Success</td>
<td>≥1 Grade Improvement in Rutherford Class at 6 months</td>
<td>94.7% (54/57)</td>
</tr>
</tbody>
</table>
DETOUR Trial Met the Primary Safety and Efficacy Endpoints

Results

- **N = 59 patients**
- 30 Day MAE Rate: 3.4%
- 6 Month Primary Patency Rate (PSVR > 2.5): 84.7%

*One patient withdrew post-discharge from the index procedure (no device implanted due to technical failure).*
## Low 30D and 6M MAVE Rate

<table>
<thead>
<tr>
<th>MAVE¹</th>
<th>MAVE through 30 Days</th>
<th>MAVE through 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 59 Subjects</td>
<td>N = 59 Subjects</td>
</tr>
<tr>
<td>Major Amputation of Ipsilateral Target Limb</td>
<td>0% (0/59)</td>
<td>0% (0/59)</td>
</tr>
<tr>
<td>Clinically Apparent Distal Embolization</td>
<td>0% (0/59)</td>
<td>0% (0/59)</td>
</tr>
<tr>
<td>Procedure Related Arterial Rupture</td>
<td>0% (0/59)</td>
<td>0% (0/59)</td>
</tr>
<tr>
<td>Bleeding Event Requiring Transfusion &gt;2 Units of Packed Red Blood Cells</td>
<td>0% (0/59)</td>
<td>0% (0/59)</td>
</tr>
<tr>
<td>Acute Limb Ischemia</td>
<td>1.7% (1/59)</td>
<td>1.7% (1/59)</td>
</tr>
<tr>
<td>Stent Thrombosis</td>
<td>3.4% (2/59)</td>
<td>10.2% (6/59)</td>
</tr>
<tr>
<td>Total Patients with MAVE</td>
<td>5.1% (3/59)</td>
<td>11.9% (6/59)</td>
</tr>
</tbody>
</table>

¹Includes stent thrombosis, target limb amputation, clinically apparent distal embolization, defined as causing end-organ damage (e.g. lower extremity ulceration, tissue necrosis, or gangrene), procedure related arterial rupture, acute limb ischemia or bleeding event requiring transfusion >2 units of packed red blood cells.
What happens to the vein?

- No Clinical DVTs at 30 Days
- Femoral veins ≥ 10mm in diameter retain at least 50% of their volume and remain patent
- Duplicate femoral veins are occupied
- No observed impact on venous health
Deep Femoral Vein as a Conduit

- 11 mm femoral vein
- 6-8 mm duplicate veins
- 8 mm vein (marked as 'X')
Venous Compression with DUS

Cine: Vein remains patent around implanted Torus Stent Graft
Duplicate Femoral Vein with the Bypass

Vein Pre

Duplicate Vein 6.8mm

Vein 8.5mm

Vein Post

PQB Stent Graft 6.0mm

Patient 10-014
Anastomotic junctions demonstrate wide lumen with smooth transition and tri-phasic bloodflow.
Post 6-Month Re-interventions

- No occlusions
- 2 stenoses post 6 months
- That stenoses could have been avoided!
- High placement of proximal edge of the graft is critical

Patient 10-029: Pre and Post DEB Re-intervention
Patient 01-AG

- Treated Jan 20\textsuperscript{th}, 2015
- 65 y/o female
- CTO, TASC D lesion
- Lesion length (A-C): 22 cm
- 2 SG deployed
- 6 cm overlap
- Venous Diameter: 11 mm
# Venous Function through 6 Months

Venous Clinical Severity Scale (VCSS) and Villalta Assessments

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**No Clinical DVTs at 30 Days**

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<table>
<thead>
<tr>
<th>VCSS Scale</th>
<th>Baseline N = 60 Subjects</th>
<th>6 Months N = 58 Subjects</th>
<th>6 Month Change from Baseline¹</th>
<th>P-Value Baseline vs. 6 Months³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>0.81 ± 1.37 (59)</td>
<td>0.78 ± 1.30 (58)</td>
<td>-0.05 ± 0.96 (58)</td>
<td>0.68</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Villalta Score</th>
<th>Baseline N = 60 Subjects</th>
<th>6 Months N = 58 Subjects</th>
<th>6 Months Change from Baseline</th>
<th>P-Value Baseline vs. 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>0.81 ± 1.53 (59)</td>
<td>0.50 ± 1.01 (58)</td>
<td>-0.33 ± 1.53 (58)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

---

¹Sample sizes less than 60 subjects at baseline, 59 subjects at 30 days/58 at 6 months reflect unknown data.
²Change from baseline calculated using matched pairs.
³P-values are calculated for absolute change using paired t-test for matched data.
Significant Improvement in Ankle Brachial Index

Ankle Brachial Index (ABI) | Baseline ABI N = 60 Subjects | 6 Month ABI N = 58 Subjects | P-Value Baseline vs. 6 Months
--- | --- | --- | ---
Mean ± Stdev (N) | 0.65 ± 0.19 (59) | 0.93 ± 0.13 (58) | <0.0001

ABI was significantly improved at 6 months compared to baseline (P<0.0001)

1 Sample sizes less than 60 subjects at baseline, 59 subjects at 30 days and 58 subjects at 6 months reflect unknown data.
2 P-values are calculated using paired t-test for matched data.
94% of Subjects Improved ≥1 RB Class at 6M as Compared to Baseline (p<0.0001)

10.5% improved by 2 RB clinical categories | 80.7% improved by 3 categories | 3.5% improved by 4 categories
3.5% had no change in category | 1.8% worsened by 1 category
Conclusions

Primary Patency: 84.7% at 6 Months in nearly 30cm TASC II D lesions

Primary performance endpoint met
No impact on venous health; low MAE rate

High procedural and technical success rates of >95%

Clinical performance in severe lesions (95% CTOs, 93% TASC II D, 28.6 cm mean length) demonstrates this novel therapy’s potential for complex patients without a durable endovascular option

Percutaneous Bypass using the Femoral Vein as a Conduit may Prove to be An Important Step Forward in the Treatment of Long SFA Occlusions
5th Annual Symposium

Cardiovascular Disease Management: A Case-Based Approach

Richard R. Heuser, MD, FACC
Program Director

October 5-6, 2017
Arizona Biltmore, Phoenix, Arizona

Nursing Symposium will take place
October 4, 2017 from 12:00 – 5:00 pm

SAVE THE DATE
For more information, please visit www.promedicacme.com
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Professor of Medicine, Univ. of Arizona
College of Medicine, Phoenix, Arizona

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18th Annual Conference
May 31 - June 02
THE PERIPHERAL EVENT OF THE YEAR