2017 European Peripheral Artery Disease Interventions Technology Innovation Award
Contents
Background and Company Performance .................................................................3
  Industry Challenges ..............................................................................................3
  Technology Attributes and Future Business Value of PQ Bypass .........................4
  Conclusion .............................................................................................................6
Significance of Technology Innovation ......................................................................7
Understanding Technology Innovation ....................................................................8
  Key Benchmarking Criteria ..................................................................................8
The Intersection between 360-Degree Research and Best Practices Awards ..........10
  Research Methodology .........................................................................................10
About Frost & Sullivan .............................................................................................10
Background and Company Performance

Industry Challenges

Peripheral Artery Disease: An Overview

Peripheral artery disease (PAD) is the narrowing (stenosis) and blockage of the arteries that supply oxygen-rich blood to the extremities due to atherosclerosis (plaque build-up along the artery walls). Most commonly associated with the legs, PAD progresses from mild discomfort to varying degrees of debilitating leg pain during exercise and even at rest (intermittent claudication) with the potential to impact physical activity, functional capacity, and overall quality of life. According to the American Heart Association, untreated PAD can lead to gangrene or amputation. In addition, people with PAD have a higher risk of coronary artery disease, heart attack, and stroke.¹

Lower extremity PAD is the third-leading cause of atherosclerotic cardiovascular morbidity, following coronary artery disease and stroke.² Systematic reviews indicate that PAD affects over 200 million people worldwide—and the prevalence of PAD is increasing as baby boomers enter high-risk age groups.³ With estimates of more than 20% of the population projected to age into the 65-and-over cohort by the year 2050, PAD is a growing epidemic with staggering social and economic costs.⁴

Treatment Strategies for Advanced Peripheral Arterial Disease

Peripheral artery disease of the femoropopliteal artery is the most common cause of intermittent claudication (pain which interferes with a patient’s ability to function).⁵ Once PAD progresses to lifestyle-limiting claudication or, even further, to critical limb ischemia (ulcers or tissue loss/gangrene), physicians will consider performing either an open surgical or endovascular procedure to increase blood flow to the lower extremities. Depending on the length, severity, and type of femoropopliteal lesion/blockage, physicians will either open the blockage with a minimally invasive procedure or bypass the blockage with an open surgical procedure.

Short lesions (<10 centimeters) can be treated with minimally invasive endovascular technologies such as angioplasty balloons, drug-coated balloons, and stents, which open the narrowed artery. In clinical trials, these technologies have proven safe and effective for restoring blood flow in short, diseased arteries. For long blockages, especially those greater than 20 centimeters, additional challenges remain.

---

¹ http://www.heart.org/HEARTORG/Conditions/VascularHealth/PeripheralArteryDisease/About-Peripheral-Artery-Disease-PAD_UCM_301301_Article.jsp#.WaWgSZOGOV4
³ Overview of Classification Systems in Peripheral Artery Disease Semin Intervent Radiol 2014;31:378–388
Long lesions have historically been treated with open femoropopliteal bypass surgery (fem-pop bypass). Through a large incision in the upper leg, a natural or synthetic vein is attached from a healthy section of the artery above the blockage to a healthy section of artery below the blockage. The attached vein bypasses the blockage to restore blood flow to the legs. Open fem-pop bypass surgery has the benefit of long-term durability/patency (maintaining restored blood flow for a longer period); however, open fem-pop bypass is associated with complications that contribute to a 30-day morbidity rate of 37%.

More recently, minimally invasive technologies (which work well for shorter lesions) are being used to open longer lesions; however, they have yet to demonstrate the same durability as open surgery. These procedures are also time-consuming, resource-intensive, and plagued with re-treatments, generating a financial burden for the health system and frustration for the patient and treating physician. Ultimately, many of these patients progress to open bypass surgery or amputation.

For patients with long-segment femoropopliteal disease, the optimal treatment path remains unclear.

**Technology Attributes and Future Business Value of PQ Bypass**

PQ Bypass, a Silicon Valley-based medical technology company, developed the DETOUR System for percutaneous bypass. The DETOUR System is a minimally invasive technology that enables physicians to re-direct, or detour, blood flow around extremely long blockages in the upper leg arteries to restore blood flow to the lower leg and foot.

**Improving the Patient Journey Through Physician-led Innovation**

A decade ago, Dr. James Joye, an interventional cardiologist and world-renowned specialist in peripheral vascular disease, started seeking therapeutic alternatives to current standards of care in the treatment of long-segment femoropopliteal disease. Tired of referring patients for an invasive surgery or performing an endovascular procedure with less-than-optimal outcomes, Dr. Joye pioneered a new technique to improve care for these patients. Using off-the-shelf devices, he performed a fully percutaneous bypass via circulatory anastomosis between the femoral artery and the femoral vein. Over the course of several years, Dr. Joye successfully treated more than 20 patients using this novel procedure. The technique; nonetheless, required too many instruments and procedure times were taxing.

Out of his desire to improve the procedure, Dr. Joye founded PQ Bypass in 2009. The mission was to develop technology (DETOUR System) specifically for the procedure (DETOUR procedure) that provided physicians the ability to achieve consistent, safe, and durable results during long-lesion treatment.

---


“PQ Bypass is working to improving the patient journey for people with PAD who, today, do not have an optimal treatment solution for extremely long femoropopliteal disease. Our proprietary DETOUR System is designed to combine the durability advantages of surgical bypass with the minimally invasive advantages of a percutaneous procedure. This combination is unlike any existing therapeutic option for treating this type of advanced disease.”

- Heather Simonsen, Vice President of Therapy Development, PQ Bypass, Inc.

A Surgical Result with a Percutaneous Approach

Percutaneous femoropopliteal bypass is a newly developed procedure, enabled through the DETOUR System, which consists of three technologies: TORUS Stent Graft, the DETOUR Crossing Device, and DETOUR Snare. These devices were specifically designed to perform a femoropopliteal bypass via two small punctures in the skin rather than open surgery.

During the DETOUR procedure, a pathway is created by crossing from the superficial femoral artery (SFA) into the femoral vein and back into the artery using the DETOUR Crossing Device and Snare. This pathway allows TORUS Stent Grafts to be placed in a continuous line. The stent grafts redirect the oxygen-rich blood around the blockage and restore blood flow to the lower leg and foot of the patient. The restoration of blood flow has the goal of pain reduction and improvement of patient mobility while limiting the progression of PAD.

Toward a Promising Future: “No Detours”

Frost & Sullivan identifies PQ Bypass as a groundbreaking, innovative medical technology company. Through its proprietary DETOUR System for percutaneous bypass, the company offers a pioneering endovascular procedure for complex, long-segment femoropopliteal disease.

In March 2017, PQ Bypass received CE Mark approval for the three unique devices that comprise the DETOUR System and is planning a pivotal investigational device exemption study to support premarket approval from the United States Food and Drug Administration (FDA). The DETOUR procedure is generating a significant amount of interest from potential end users—particularly those in the vascular surgery community.
“The PQ DETOUR procedure is a new and innovative approach to treating patients with extremely long SFA lesions. The initial safety and effectiveness of the DETOUR procedure, as shown in the DETOUR I trial, is encouraging, and the results demonstrate the potential for this to become a key addition to the treatment armamentarium for patients with complex PAD.”

- Sean Lyden, M.D., Chairman of the Robert and Suzanne Tomsich Department of Vascular Surgery, Cleveland Clinic, Cleveland, Ohio

In the age of value-based, patient-centered care, the DETOUR System and procedure may offer a new, minimally invasive, high-quality, cost-effective revascularization option. Frost & Sullivan anticipates rapid, widespread technology adoption once the system launches commercially. The global market potential for endovascular approaches to extremely long-segment disease is significant, and PQ Bypass has first-mover status in the space. Moreover, the novel technique has the potential to significantly improve patient safety and clinical outcomes.

Conclusion

PAD affects over 200 million people worldwide. With PAD prevalence rising and healthcare costs at unprecedented levels, cost-effective revascularization strategies constitute a critical need. Endovascular therapies offer effective revascularization options in patients exhibiting shorter lesions, i.e., less than 10 centimeters (cm), but these approaches are suboptimal in lesions over 20 cm that usually require open surgery.

PQ Bypass has developed groundbreaking endovascular technology, the DETOUR System, which enables physicians to perform minimally invasive procedures on patients with long-segment femoropopliteal blockages. The company offers a novel revascularization strategy that has the potential to become a new standard of care—for a previously underserved patient population.

With its commitment to improving quality care through technological innovation, PQ Bypass earns Frost & Sullivan’s 2017 European Technology Innovation Award in the peripheral artery disease interventions market.
Significance of Technology Innovation

Ultimately, growth in any organization depends upon finding new ways to excite the market and maintaining a long-term commitment to innovation. At its core, technology innovation, or any other type of innovation, can only be sustained with leadership in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.
Understanding Technology Innovation

Technology innovation begins with a spark of creativity that is systematically pursued, developed, and commercialized. That spark can result from a successful partnership, a productive in-house innovation group, or a bright-minded individual. Regardless of the source, the success of any new technology is ultimately determined by its innovativeness and its impact on the business as a whole.

Key Benchmarking Criteria

For the Technology Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—Technology Attributes and Future Business Value—according to the criteria identified below.

Technology Attributes
- Criterion 1: Industry Impact
- Criterion 2: Product Impact
- Criterion 3: Scalability
- Criterion 4: Visionary Innovation
- Criterion 5: Application Diversity

Future Business Value
- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Technology Licensing
- Criterion 4: Brand Loyalty
- Criterion 5: Human Capital
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analyst follow a 10-step process to evaluate Award candidates and assess their fit with select best-practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

<table>
<thead>
<tr>
<th>STEP</th>
<th>OBJECTIVE</th>
<th>KEY ACTIVITIES</th>
<th>OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Monitor, target, and screen</td>
<td>Identify Award recipient candidates from around the globe</td>
<td>Pipeline of candidates who potentially meet all best-practice criteria</td>
</tr>
<tr>
<td>2</td>
<td>Perform 360-degree research</td>
<td>Perform comprehensive, 360-degree research on all candidates in the pipeline</td>
<td>Matrix positioning of all candidates’ performance relative to one another</td>
</tr>
<tr>
<td>3</td>
<td>Invite thought leadership in best practices</td>
<td>Perform in-depth examination of all candidates</td>
<td>Detailed profiles of all ranked candidates</td>
</tr>
<tr>
<td>4</td>
<td>Initiate research director review</td>
<td>Conduct an unbiased evaluation of all candidate profiles</td>
<td>Final prioritization of all eligible candidates and companion best-practice positioning paper</td>
</tr>
<tr>
<td>5</td>
<td>Assemble panel of industry experts</td>
<td>Present findings to an expert panel of industry thought leaders</td>
<td>Refined list of prioritized Award candidates</td>
</tr>
<tr>
<td>6</td>
<td>Conduct global industry review</td>
<td>Build consensus on Award candidates’ eligibility</td>
<td>Final list of eligible Award candidates, representing success stories worldwide</td>
</tr>
<tr>
<td>7</td>
<td>Perform quality check</td>
<td>Develop official Award consideration materials</td>
<td>High-quality, accurate, and creative presentation of nominees’ successes</td>
</tr>
<tr>
<td>8</td>
<td>Reconnect with panel of industry experts</td>
<td>Finalize the selection of the best-practice Award recipient</td>
<td>Decision on which company performs best against all best-practice criteria</td>
</tr>
<tr>
<td>9</td>
<td>Communicate recognition</td>
<td>Inform Award recipient of Award recognition</td>
<td>Announcement of Award and plan for how recipient can use the Award to enhance the brand</td>
</tr>
<tr>
<td>10</td>
<td>Take strategic action</td>
<td>Upon licensing, company is able to share Award news with stakeholders and customers</td>
<td>Widespread awareness of recipient’s Award status among investors, media personnel, and employees</td>
</tr>
</tbody>
</table>
The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best-practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.