Abbott

ENGINEERING INSIGHTS

PORTICO™ WITH FLEXNAV™ TAVI SYSTEM

Hydrophilic Coating Reduces Insertion and Tracking Forces to Improve Deliverability*[1]

Compared to Evolut‡ PRO valve with EnVeo‡ PRO, the Portico™ with FlexNav™ TAVI System demonstrated:*[1]

- 76% reduction in average insertion force
- 97% lower frictional force on the distal capsule
- 96% reduction in frictional force on the integrated sheath

BACKGROUND

The Portico with FlexNav TAVI System utilizes a hydrophilic coating on three key components including the nosecone, the distal capsule, and the integrated sheath. Applied as a single coat, this added feature can lower insertion forces, reduce vascular friction, and provide improved trackability.[2] Measuring these factors in the clinical setting presents significant barriers that may be overcome through *in-vitro* testing. Abbott conducted a series of internal tests to compare TAVI systems.

OBJECTIVE

To compare the force and friction associated with insertion and tracking of the Portico with FlexNav TAVI System to the Evolut‡ PRO valve with EnVeo‡ PRO.[1,3]

METHODS: INSERTION TEST

The insertion test measured the force required to insert a loaded delivery system through a seal (see Figure 1) and simulated percutaneous insertion of the device into a femoral artery. Peak and average insertion force were captured for both systems. (Portico with FlexNav TAVI System, n=3; Evolut‡ PRO valve with EnVeo‡ PRO, n=3)[3]

RESULTS: INSERTION TEST

Figure 2 shows the force as each device was inserted into the seal. The Portico with FlexNav TAVI System had a 69% reduction in peak insertion force and a 76% reduction in average insertion force relative to the Evolut‡ PRO valve with EnVeo‡ PRO (see Table 1).[1]

* Based on insertion through a seal to simulate femoral artery, and silicone padded grips testing by Abbott.

See Important Safety Information referenced within.

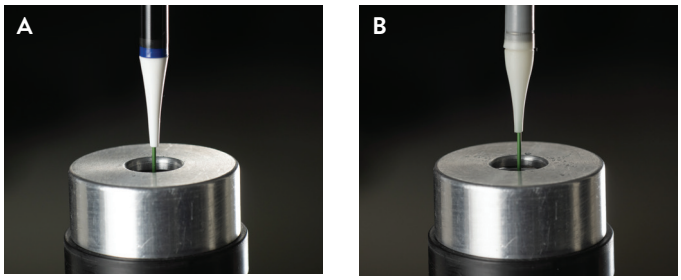


Figure 1. The insertion test measured the force required to insert the loaded delivery systems, A) Portico™ with FlexNav™ TAVI System and B) the Evolut‡ PRO valve with EnVeo‡ PRO, through a seal.[1]

Figure 2. Insertion test A) all results and B) average (lbf = pound-force)[1]

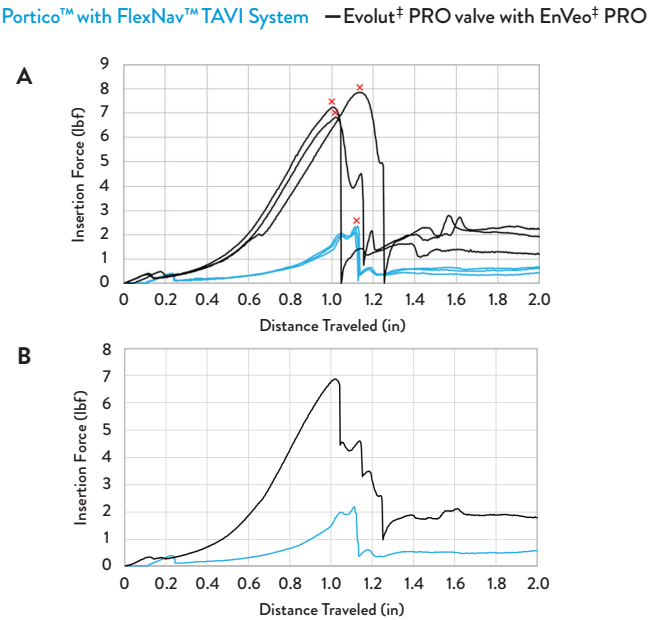


Table 1. Insertion Force Results (lbf = pound-force)[1]

Force, lbf	Portico™ with FlexNav™ TAVI System	Evolut‡ PRO valve with EnVeo‡ PRO
Peak	2.26	7.30
Average	0.55	2.27

METHODS: LUBRICITY TEST

The lubricity test measured the frictional force required to pull the distal capsule and integrated sheath of the Portico™ with FlexNav™ TAVI System (n=30) and the Evolut‡ PRO valve with EnVeo‡ PRO (n=3) through the silicone padded grips at a specific grip pressure, speed, and distance. This procedure assessed the frictional characteristics of the devices when they are inserted and tracked through the anatomy. Measured outputs included maximum frictional forces on the distal capsule and the integrated sheath (see Figure 3).[3]

RESULTS: LUBRICITY TEST

When compared to the Evolut‡ PRO valve with EnVeo‡ PRO, the Portico with FlexNav TAVI System demonstrated a:

- 97% reduction in maximum frictional force (23 g vs 754 g) on the distal capsule (see Figure 4)[1]
- 96% reduction in maximum frictional force on the integrated sheath (38 g vs 904 g)[1]

CONCLUSIONS

In this testing the Portico with FlexNav TAVI System demonstrated low insertion and frictional forces that may improve patient safety by reducing complications in tortuous, calcified anatomies. These results are due in part to the application of hydrophilic coating on the nosecone, distal capsule, and integrated sheath.[1] This bench testing supports earlier findings,[2] quantifies delivery forces, and reinforces physician implanter feedback regarding the smooth delivery of the Portico with FlexNav TAVI System.

Figure 3. The lubricity test measured the frictional force required to pull the Portico™ with FlexNav™ TAVI System A) distal capsule and B) integrated sheath, through silicone padded grips at a specific grip pressure, speed, and distance.[1]

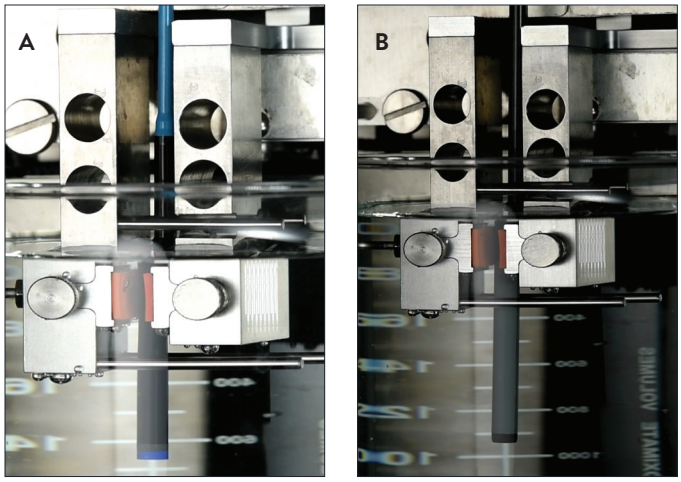
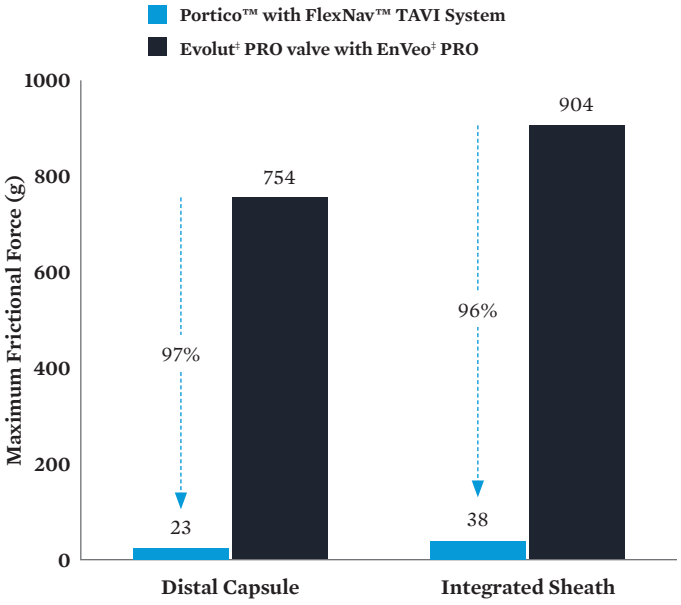


Figure 4. Distal capsule and integrated sheath lubricity tests for the Portico™ with FlexNav™ TAVI System, and the Evolut‡ PRO valve with EnVeo‡ PRO.** [1]



** Portico™ with FlexNav™ TAVI System data from Abbott commercial design verification testing of 30 sample devices compared to data from Abbott testing of 3 Evolut‡ PRO units.

REFERENCES

1. Abbott data on file 90598280.
2. Abbott data on file 90346620.
3. Abbott data on file 90584162.

See Important Safety Information referenced within.

PORTICO™ TRANSCATHETER AORTIC VALVE IMPLANTATION SYSTEM

IMPORTANT SAFETY INFORMATION

℞ ONLY

INDICATIONS

The Portico™ Transcatheter Aortic Valve Implantation System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

CONTRAINDICATIONS

The valve is contraindicated for patients with inability to tolerate antiplatelet/anticoagulant therapy or nitinol alloy (nickel and titanium), or who have active infections, including endocarditis.

WARNINGS

Carefully read all warnings, precautions, and instructions for use for all components of the system before use. Failure to read and follow all instructions or failure to observe all stated warnings could cause serious injury or death to the patient.

- Perform Portico™ valve implantation in a facility where emergency aortic valve surgery is available.
- Verify that the patient's anatomy is consistent with the specifications set forth in the anatomical specifications tables 2 and 3 (found in IFU).
- For single use only. Do not reuse, reprocess, or resterilize the valve, delivery system, or the loading system. Reuse, reprocessing, and/or resterilization creates a risk of contamination of the devices and/or device failure, which could cause patient injury, illness or death.
- Do not manipulate or handle the valve with sharp or pointed objects.
- Rinse the valve as directed before loading the valve onto the delivery system.
- Do not use the valve, the delivery system, or the loading system if the "USE BY" date has elapsed.
- Exercise care to prevent kinking of the delivery system when removing it from the packaging.
- This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/ hypersensitivity to these materials.
- Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, young adults, or patients with altered calcium metabolism.

PRECAUTIONS

Pre-Implantation Precautions

- The safety, effectiveness, and durability of a Portico™ valve implanted within a surgical or transcatheter bioprosthesis have not been demonstrated.
- Long-term durability has not been established for the Portico valve. Regular medical follow-up is advised to evaluate valve performance.
- For transaortic access, ensure the access site and trajectory are free of internal patent right internal mammary artery (RIMA) or pre-existing patent RIMA graft.
- For subclavian/axillary access, use caution in patients with mammary artery grafts.
- Balloon aortic valvuloplasty (BAV) of the native aortic valve is recommended prior to delivery system insertion. The balloon size chosen should be appropriate, not exceeding the minimum diameter of the native aortic annulus as assessed by CT imaging to minimize risk of annular rupture and not undersized to minimize risk of stent under-expansion which could lead to paravalvular leak (PVL) or device migration.
- Do not use the valve if the shipping temperature indicator on the product package has turned red, or if the valve has been improperly stored in temperature conditions outside of the 5°C–25°C (41°F–77°F) range.
- Do not use the valve if the tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging.
- Do not advance the delivery system without the guidewire extending from the tip.
- Do not use the valve without thoroughly rinsing as directed.
- Do not use the delivery system without thoroughly flushing as described in the "Directions for Use" section.
- The safety and effectiveness of the Portico™ valve and FlexNav™ delivery system have not been evaluated in the following patient populations:
  - Congenital unicuspid or bicuspid valve, or any leaflet configuration other than tricuspid
  - Severe ventricular dysfunction with left ventricular ejection fraction <20%
  - Non-calcific aortic annulus
  - Echocardiographic evidence of intracardiac mass, thrombus or vegetation
  - Patients at low or intermediate surgical risk
  - Patients who are pregnant or breastfeeding
  - Pediatric patients (less than 21 years of age)
  - Patients with a pre-existing prosthetic heart valve or prosthetic ring in any position
  - Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+)
  - Patients with severe circumferential mitral annular calcification (MAC) which is continuous with calcium in the LVOT, severe (greater than 3+) mitral insufficiency, or severe mitral stenosis with pulmonary compromise
  - Blood dyscrasias as defined: leukopenia (WBC<3000 mm^3), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count <50,000 cells/mm^3)
  - Patients with untreated clinically significant coronary artery disease requiring revascularization
  - Patients with bulky calcified aortic valve leaflets in close proximity to coronary ostia
  - Hypertrophic cardiomyopathy with or without obstruction (HOCM)
  - Renal insufficiency (creatinine > 3.0 mg/dL) and/or end stage renal disease requiring chronic dialysis
  - Hemodynamic instability requiring inotropic support or mechanical heart assistance
  - Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta
  - Patients with known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media which cannot be adequately premedicated
  - Patients with access characteristics that would preclude safe placement of the introducer sheath, when necessary, such as severe obstructive calcification, or severe tortuosity

Implantation Precautions

- To minimize risk of guidewire perforations in the left ventricle, a manufacturer pre-shaped guidewire should be used during the procedure and during valve deployment.
- Do not deploy the valve if excessive resistance to deployment is encountered. If the valve does not deploy easily, re-sheath the valve, remove it from the patient, and use a different valve and delivery system.
- Follow the procedure in "Implanting the Valve" to reposition the valve or to remove the valve from the patient.
- Do not attempt to reposition the valve by advancing it distally unless the valve has been fully re-sheathed within the delivery system.
- Do not re-sheath the valve more than two times prior to final valve release. Additional re-sheath attempts may compromise product performance.
- To minimize likelihood of permanent pacemaker implantation (PPI): a) maintain implant depth of 3mm, and b) limit manipulations across the LVOT.

Post-Implantation Precautions

- In the event that a post-implant balloon dilatation is performed to address paravalvular leak (PVL), valve size, patient anatomy, and implant depth must be considered when selecting the size of the balloon for dilatation. The balloon size chosen should not exceed the mean diameter of the native aortic annulus. Moderate or Severe PVL should be addressed at the time of the TAVI procedure.
- Exercise care when removing the delivery system from the patient.
- Exercise care when crossing the valve with adjunctive devices.
- Once the valve is fully deployed, repositioning and retrieval of the valve is not possible. Attempted retrieval (e.g., use of a guidewire, snare, or forceps) may cause aortic root, coronary artery, and/or myocardial damage.
- Valve recipients should be maintained on antiplatelet and/or anticoagulant therapy post procedure, per institutional standards and established guidelines, except when contraindicated, using individualized treatment as determined by their physician.
- Post-implant monitoring and/or possible electrophysiology evaluation may be considered in patients with transient high degree or complete AV block or other conduction disturbances during or following implantation of the valve. This may include continuous ECG monitoring after hospital discharge.

POTENTIAL ADVERSE EVENTS

Adverse events potentially associated with the use of transcatheter bioprosthetic heart valves include but are not limited to:

- access site complications (e.g., pain, bleeding, infection, hematoma, pseudoaneurysm, etc.)
- acute coronary obstruction
- acute myocardial infarction
- allergic reaction to antiplatelet agents, contrast medium, or valve components
- aortic rupture
- ascending aorta trauma
- atrio-ventricular node block
- cardiac arrhythmias
- conduction system injury
- conversion to open surgical procedure
- death
- dissection
- embolism
- emergent balloon valvuloplasty
- emergent percutaneous coronary intervention (PCI)
- emergent surgery (i.e., coronary artery bypass, heart valve replacement)
- endocarditis
- explantation
- heart failure
- hemodynamic compromise
- hemolysis
- hemolytic anemia
- hemorrhage
- hypotension or hypertension
- infection
- myocardial ischemia
- mitral valve insufficiency
- multi-organ failure
- non-structural dysfunction (i.e., entrapment by pannus, paravalvular leak, inappropriate sizing or positioning)
- pannus
- pericardial effusion
- perforation of the myocardium, ventricle, or a blood vessel
- permanent disability
- permanent pacemaker
- regurgitation
- renal insufficiency or renal failure
- reoperation
- respiratory failure
- sepsis
- stroke
- structural deterioration (i.e., calcification, leaflet tear)
- thrombosis
- tamponade
- transfusion
- valve embolization or migration
- vessel dissection or spasm

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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