

# Atraumatic Braided Stent for Textile Valve Endoprosthesis

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## INTRODUCTION

Percutaneous approach is now investigated [1] to replace diseased aortic valve. Less invasive than open heart surgery, this solution requires a substitute to usual surgeon acts on the implantation site, called stents. These metallic structures are used to maintain the valve prosthesis on the beating heart and help to implant the valve via a vascular access. Most of existing device [2] are not specifically designed to undergo heart valve solicitations and consequently tend to injure the aortic environment. This could lead to recovery complications. In this work we present a stent specifically designed for percutaneous aortic valve replacement, which respects the aortic root features and minimizes tissue traumatism.

## APPROACH

### Stent Components

In order to position properly the stent in its environment and respect it, the native aortic root features were taken into consideration [3]. The adopted stent geometry is defined with 4 main features as represented on Figure 1 which shows the stent geometry matching the aortic root shape. Valve prosthesis commissures are supported by 3 posts. Three shaped arms, deployed radially in sinuses, orient the prosthesis around the flow axis while cylindrical head centers the device in the aorta. At least, axially oriented movements and paravalvular leakage will be prevented with a conical basis support. That support is positioned on the aortic annulus and applies a force in opposition to the one applied by the flexed arms in the sinuses. Anchorage and sealing are thus geometrically ensured rather than by force or hooks on tissue. Each part of the stent is backed to the aortic wall and thus blood flow disturbance and related thrombosis risk are avoided. This stent geometry induces no coronary ostia or mitral valve impairment.

### Stent Manufacturing

To reduce tissue traumatism, the stent has to be flexible enough to adapt the aortic root while remaining strong enough to avoid collapsing. To ensure a permanent contact between stent and aortic tissues, in spite of root dimensions changes,

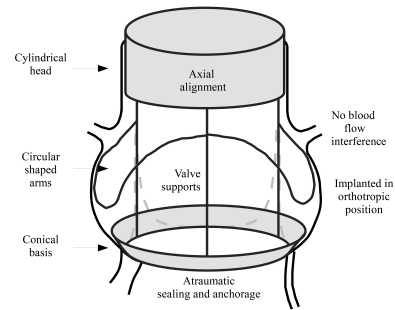


FIGURE 1. Aortic Root Stent Matching.

the stent has to deform elastically with minimal stress concentration. Stent parts are therefore obtained by Nitinol wire braiding and shape setting. Nitinol is a Nickel and Titanium shape memory alloy [4] with superelastic properties. Consequently, the stent is self-expandable and complex geometry that respects aortic root can be obtained. The discontinuous braided structure allows minimal local stress concentration over compression, while high coverage distributes uniformly pressure on tissues.

Optimized stent dimensions could be controlled with 3 main parameters. Width and angle of the conical basis should be figured out to reduce flow obstruction with no excessive contact surface with tissues, while the stent head height should facilitate percutaneous implantation procedure. Ideal values were obtained experimentally. Figure 2 represents the whole assembled stent and the stent parameters.

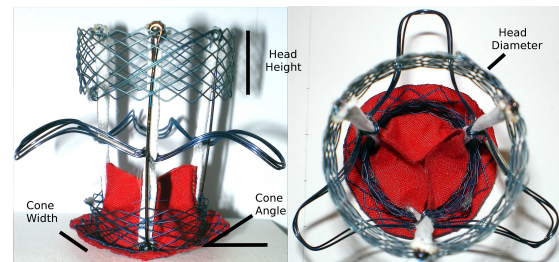


FIGURE 2. Front and top view of the whole assembling stent.

### Stent testing procedure

The endoprosthesis was evaluated in terms of static and dynamic regurgitation, i.e. leakage versus pressure on closed valve and leakage upon pulsatile

flow. In order to reproduce the aortic environment, the stented valve was delivered in a rubber mold which dimensions were close to those of native aortic root during all the cardiac cycle.

Performances of the stented valve were analyzed and compared to mechanical, biological and non-stented valve to assess the influence of the stent parameters on textile valve performances.

## RESULTS AND DISCUSSION

### Global behavior of the stent under flow conditions

Under pulsatile flow, the stent remained in the aortic root and showed good anchorage. Relative axial translation was well prevented by conical basis contact on aortic annulus and stent arms deployment in sinuses. Correct sizing of the cylindrical head is relevant for proper stent axial alignment and to prevent tilting. The stent radial extension freedom helps to keep in contact with the mock aorta even when deformation occurs. The stent geometry ensures the anchorage of the endoprosthesis only by contact surface, even under flow pressure.

### Stented valve performances

Figure 3 shows the performances obtained for the stented valve in comparison to a non-stented textile valve and commercially available valves.

While static regurgitation of the endoprosthesis is close to the results for a textile valve, a significant increase of dynamic regurgitation was observed. Evolution of dynamic regurgitation flow during the cardiac cycle, shows that valve closure is delayed. A close observation of the stent dynamic movement in the root shows that, as soon the valve was closed, the backflow pushed the stent against the aortic annulus. Although the stent basis geometry ensures an effective sealing of the endoprosthesis under pressure, sealing is temporarily interrupted during the cardiac cycle, leading to regurgitation increase. This seems to be related to Valsalva sinuses dilatation, related to changes occurring at the contact zone between the stent arms and the upper sinuses. Coupling between sinuses enlargement, stent arms and stent conical basis should be optimized with a better control of arm's stiffness and positioning.

When compared to biological and mechanical valve prostheses, stented valve regurgitation values were in the range of what can be expected for such kind of prostheses.

## CONCLUSIONS

To improve the reliability of percutaneous heart valve implantation, a new stent concept has been

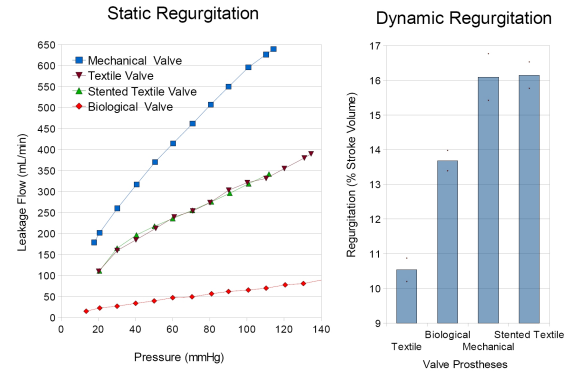


FIGURE 3. Static and dynamic regurgitation of a biological Mitroflow, a mechanical Bileaflet St Jude, a non stented and a stented textile valve prostheses.

proposed. The main features of the device are a geometry and design that match the aortic root environment. The stent is maintained in expected position by surface contact rather than by anchoring in surrounding tissues. Traumatism should therefore be reduced. The manufacturing braiding technique of Nitinol wire allows obtaining a stent that is flexible enough with however no excessive collapsing. The dynamic in vitro performances of the device are close to what is expected for a valve in terms of regurgitation. Even in a compliant root, the stent keeps the implantation site. These results show the feasibility of an aortic valve prosthesis anchorage without need of traumatic means. Tests currently in process will assess the influence of stent's parameters on the endoprosthesis performances.

## ACKNOWLEDGMENT

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