Hydrodynamic ex-vivo analysis of valve sparing techniques: assessment and comparison

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Visual Abstract

• Key question: what is the impact of the valve-sparing procedure and graft configuration on the predicted aortic valve performance?
• Key findings: dynamics and performance of the aortic root strongly depend on the graft configuration.
• Take-home message: grafts replicating Valsalva sinuses can restore more physiological valve dynamics and performances.

Abstract

Objectives: Valve-sparing procedures are surgical techniques allowing to restore adequate function of the native aortic valve by replacing the dysfunctional ascending aorta with a prosthetic conduit. A number of techniques are currently used, such as Yacoub’s remodelling and David’s reimplantation, based on a regular straight conduit. More recently, the De Paulis proposed the use of bulging conduits to reconstruct the shape of the Valsalva sinuses. This work investigates the impact of the valve-sparing technique on the aortic valve function.

Methods: The performance of three porcine aortic roots (Medtronic Freestyle™) was assessed in a cardiovascular pulse duplicator before and after performing three alternative valve-sparing procedures: David’s reimplantation, Yacoub’s remodelling and De Paulis’ reimplantation.

Results: The porcine aortic roots, representative of the healthy native configuration, were characterised by the highest efficiency, with a mean energetic dissipation under normal operating conditions of 26 mJ. David’s and Yacoub’s techniques resulted in significantly lower performance (with mean energetic loss of about 70 mJ for both cases). The De Paulis’ procedure exhibited intermediate behaviour, with superior systolic performance and valve dynamics similar to the native case, and a mean energetic loss of 38 mJ.

Conclusions: The dynamics and performance after valve-sparing strongly depend on the adopted technique, with the use of conduits replicating the presence of Valsalva sinuses restoring more physiological conditions.

Keywords: Valve-sparing implants; Aortic root prosthesis; Hydrodynamic performance; Ex-vivo analysis; Valsalva sinuses

1. Introduction

Despite its apparently simple anatomical morphology, the aortic root has the function to establish and maintain a haemocompatible intermittent laminar flow, proper coronary perfusion and optimum left ventricular function at the different operating conditions [1]. This involves a synergistic interplay between its different constituent elements at both, microscopic and macroscopic level. Dysfunctional pathologies such as aneurysms of the ascending aorta can alter these delicate mechanisms, resulting into major complications. In fact, abnormal dilation of the arterial vessel in proximity of the aortic valve can cause dislocation of the commissures, with consequent lack of coaptation of the valve leaflets, independently of their structural
integrity. This may result in a clinical condition of aortic insufficiency, associated with reduced left ventricular function and ejection fraction, potentially leading to acute pulmonary edema [2].

Aneurysmal pathology of the aortic root is normally treated through traditional surgical therapies, aimed at repairing the aortic root and resolve aortic insufficiency. When the insufficiency has functional nature, and the native valve leaflets have maintained their integrity, their physiological function and anatomy can be restored by adopting common valve-sparing procedures [3], such as the David’s ‘reimplantation’ technique [4], and the Yacoub’s ‘remodelling’ technique [5]. In both approaches, the three sinuses of Valsalva are excised from the native root and replaced with a tubular straight graft. In particular, in David’s procedure, the proximal edge of the graft is sutured at the annulus, whilst in the case of Yacoub’s procedure it is cut into a crown shape and sutured just above the leaflets attachment. Over the years, several reports have suggested that although Yacoub’s remodelling procedure is physiologically superior to David’s reimplantation procedure, with a more natural motion of the aortic annulus, it may be associated with higher risk of annulo-aortic ectasia and recurring insufficiency [6], [7]. David’s technique, instead, provides a better stabilisation of the aortic anulus, but the total removal of the Valsalva sinuses has been associated with suboptimal hemodynamics [8].

More recently, De Paulis et al. proposed a readaptation of both techniques, replacing the tubular graft with a Gelweave Valsalva™ (Vascutek, UK) graft, that incorporates a bulging segment that can replicate the presence of the Valsalva sinuses [9]. In this case, the commissures of the native valve are stitched to the graft at the level of the suture between the bulging segment and the tubular portion of the prosthesis, acting as a sino-tubular junction (STJ). Although the use of this graft is described for both, reimplantation and remodelling procedures, De Paulis et al. indicate it as particularly suitable to perfection the David’s technique, as it could allow a more physiological leaflets dynamics, whilst stabilising the annulus diameter. Over the years different studies investigated the performances of tubular and Valsalva conduits and the efficacy of reproducing Valsalva sinuses, finding discordant results [10], [11]. These results clearly expose that the optimal conduit for valve-sparing still needs to be identified [12], and the role of the Valsalva sinuses on the hemodynamics is far from being agreed upon.

This work presents an analysis and comparison of the hydrodynamic performance of the most common aortic root repair procedures, namely the David’s reimplantation, Yacoub’s remodelling and De Paulis’ reimplantation, with the healthy native reference. The aim of the work is to assess the ability of each technique to restore healthy operating conditions by means of systematic in-vitro testing, and verify if the attempt to restore the morphology of the Valsalva sinuses can provide a clinical advantage.

2. Materials and Methods

2.1. Prosthesis implants

The Medtronic Freestyle™ bioprosthetic aortic root was selected to represent healthy native operating conditions. This device consists of a porcine aortic root, cross-linked in dilute glutaraldehyde solution while
applying 40 mmHg of internal pressure on the root (after ligating the coronary arteries at their inlet), to
counteract shrinkage and maintain the natural commissural configuration. Leaflets undergo chemical fixation
at zero differential pressure, thus minimising changes in their flexibility and function. The valve inflow edge
is covered with PET fabric, that extends over the ventricular muscle band present below the right coronary
ostium, in order to strengthen this region (see Error! Reference source not found.) [13]. Despite some
difference of proportion between the leaflets and the position in the coronary ostia, this prosthesis is recognised
to closely emulate the healthy human aortic root in terms of anatomy and function [14]. Three prosthetic roots
of size 25 mm (corresponding to the annulus diameter) were selected to represent healthy native conditions,
and tested in the pulse duplicator to assess their hydrodynamic performance. They were then used to perform
three surgical valve-sparing techniques, and retested for each configuration. The surgical procedures were
performed by the same experienced surgical team, in the following order: David’s, Yacoub’s and De Paulis’.

Before the implants, each graft was prepared by washing out the collagen coating and dipping the clean
fabric in a silicone suspension (1-2577 Low VOC) to make it impermeable to the saline solution used as test
fluid in the in-vitro assessments. For the David’s and Yacoub’s techniques, a straight tubular graft made of
surgical PET knitted fabric (Intergard) of 28 mm was used to achieve an increased sinuses diameter. David’s
reimplantation technique was performed by excising the Valsalva sinuses from the native root, just leaving
few millimetres of aortic wall at the valve outflow. The proximal end of the tubular graft was sutured at the
annulus, immediately below the aortic valve. The outflow edge was sutured to the graft wall (see Error!
Reference source not found.). The Yacoub’s configuration was directly derived from the David’s, by
removing the suture points at the aortic annulus and trimming a three-pointed crown below the sutured line at
the outflow edge. Subsequently, the graft was removed and the valve sutured into a Gelweave Valsalva™
conduit of 26 mm diameter, performing the reimplantation procedure as described by De Paulis et al. [9]
details about the surgical technique are reported in the Supplementary data, S1).

All implants were fixed to a specifically designed 3D printed resin support, in order to minimise distortion
during handling and allow easy and consistent positioning into the Pulse Duplicator for the hydrodynamic
assessment (see Error! Reference source not found.).

2.2. In-vitro testing

The hydrodynamic performance assessment of each implant was conducted in-vitro on a hydro-mechanical
pulse duplicator (ViVitro Superpump, SP3891, Canada). The system is composed of a servo controlled
volumetric pump that allows the fluid circulation in three cardiac chambers separated by exchangeable heart
valves. The fluid sections are equipped with an electromagnetic flowmeter (Carolina Medical, USA) and
pressure transducers (Utah Medical, USA) placed in all cardiac cambers.

All roots were tested in the aortic position, following the order of the procedures (healthy native, David,
Yacoub and De Paulis). A St Jude 29 mm bileaflet mechanical valve was used in the mitral position. In
compliance with the in-vitro test procedure of the ISO5840 standard [15], tests were carried out at six cardiac
outputs (CO: 2, 3, 4, 5, 6 and 7 l/min), at a heart rate 70 bpm, with systolic duration 35% and mean aortic
pressure equal to 100 mmHg. Buffered saline solution at room temperature was used as test fluid. For each test, results were acquired over ten consecutive cycles, reporting their mean and standard deviation (SD).

The systolic performance was quantified on the basis of the mean systolic transvalvular pressure difference measured during the positive differential pressure period ($\Delta P$), and EOA was calculated based on the Gorlin’s formula [16], as in equation (1):

$$EOA = \frac{Q_{vRMS}}{51.6 \sqrt{\frac{\Delta P}{\rho}}}$$

where $Q_{vRMS}$ is the root mean square forward flow (mm/s), $\rho$ is the density of the test fluid (g/ml), and $\Delta P$ is expressed in mmHg.

The diastolic performance was associated with the closing regurgitant volume (CRV), calculated as the integral of the flow curve during the closing valve period.

The global performance during the whole cardiac cycle was quantified on the basis of the left ventricular energy loss ($E_{loss}$) [17], [18], calculated as the sum of the forward flow energy loss ($E_{lossF}$, measured during the ejection phase) and the closing energy loss ($E_{lossC}$, measured during the closing phase), determined in mJ from equation (2) [19] :

$$E_{loss} = 0.1333 \int_{t_i}^{t_f} \Delta p \cdot q \cdot dt$$

where $t_i$ and $t_f$ are the initial and final time instants of the phase where the energetic loss is quantified, $\Delta p$ is the instantaneous transvalvular pressure, and $q$ is the instantaneous flow rate (mm/s).

High frame rate (HFR) videos were recorded from the valve outflow at a CO of 5 l/min, to observe the valve dynamics in the different implants. These videos were binarised and analysed with a code specifically written in Matlab (MathWorks, USA) to quantify the instantaneous and mean projected orifice area (POA) [20].

Videos of the sagittal view were also analysed in Matlab to determine the variation of diameter occurring at the STJ during the cardiac cycle and compute the compliance as described in the ISO5840 [15].

### 2.3. Statistical analysis

The performance parameters at CO of 5 l/min were analysed using an Anova test for repeated measures. Where a statistical difference was found, the Tukey honestly significant difference test was used to perform the post-hoc pairwise comparison. A p-value $P < 0.05$ was considered statistically significant. The size effect was estimated to evaluate the magnitude of the group differences, computing omega square ($\Omega^2$). A $\Omega^2 > 0.14$ was considered as large size effect [21].
3. Results

3.1. Hydrodynamic performances

The performance parameters determined for each test are summarised in the diagrams in Error! Reference source not found., where each column corresponds to a prosthesis.

For each valve, the ∆P indicates the best performance for the healthy native valve, with a mean value at 5 l/min of 4.49 mmHg, followed by the De Paulis’ (mean of 6.45 mmHg). The David’s and Yacoub’s techniques resulted in similarly higher ∆P (mean of 9.07 and 8.76 mmHg, respectively), with the remodelling approach resulting slightly superior for valve 1 and slightly worse for the other two (see Error! Reference source not found.a-c). Globally, ∆P is statistically different among the groups (P = 0.002) with a large size effect (Ω² = 0.36), however the pairwise comparison does not result in any significant differences. The EOA reflects similar trends (Error! Reference source not found. d-f), resulting maximum for the three healthy native valves (with a mean value for all CO of 3.50 cm²), followed by the De Paulis’ (mean of 3.04 cm²). The David’s and Yacoub’s (mean of 2.53 and 2.44 cm², respectively) mostly overlap at lower values. These differences are statistically significant, with P < 0.001 and a large size effect of Ω² = 0.63. Moreover, the post-hoc comparison identifies significant differences in healthy native vs David (P = 0.015) and healthy native vs Yacoub (P = 0.015) (in Table S2.1 of section ‘Supplementary data S2’, the details of Tukey HSD post-hoc comparison are reported). The energetic contribution of the systolic phase (E_{lossS} in Error! Reference source not found.), is substantially lower for the healthy native configuration, followed by the De Paulis’, which presents values more than 50% higher. For the David’s and Yacoub’s implants, these losses are about twice as for the De Paulis’.

All valves were fully competent in all configurations, with minimum leakage. The CRV has a variable trend (see Error! Reference source not found. g-i), with the David’s implants characterised by more stable values among the tested COs (however difference is not statistically significant). In general, at high COs (equal or greater than 5 l/min) the healthy native valve and Yacoub’s (the two cases where the valve annulus is not constrained into the graft) appear to undergo larger CRV. The E_{lossC} results minimum for the De Paulis’, intermediate for the David’s and Yacoub’s, and highest for the Freestyle (see Error! Reference source not found.). However, this loss has lower contribution compared to the systolic, and does not alter considerably the energetic efficiency of the different configurations. In fact, over the whole cycle, the E_{loss} (see Error! Reference source not found. l-n) confirms that the healthy native configuration is more efficient for all COs (with a mean value at 5 l/min of 26.24 mJ). The David’s and Yacoub’s are characterised by substantially higher E_{loss} (70.89 and 73.26 mJ, respectively), while the De Paulis’ is much closer to the healthy native (37.84 mJ). The significance of the observed differences is confirmed by a P < 0.001 and a large size effect Ω²=0.76. The post-hoc comparison results in significant differences between all groups, but David vs. Yacoub (see Table S2.1 of section ‘Supplementary data S2’).

Table 1 summarises the performance parameters obtained for all valves and configurations, at a standard CO of 5 l/min (in Table S3.2 of the Supplementary data S3, performance parameters at all COs are reported).
3.2. HFR video analysis

The mean POA values indicate that the estimated EOA closely correspond to the geometric leaflets opening (see Error! Reference source not found.). Again, the healthy native valve exhibits the widest orifice area, with the De Paulis’ implant is associated with a decrease of POA of at least 10%, and the David’s and Yacoub’s implants with a reduction of about 30% (healthy native > 3.16 cm²; David = 2.20 cm², Yacoub = 2.25 cm², De Paulis = 2.81 cm²).

Regarding the measured compliance, the healthy native displayed the highest value, equal to 11.5%. The David’s implant had the smallest elasticity of 3.3%, whilst Yacoub’s technique was effective in restoring some elasticity, increasing the compliance to 6.7%. The presence of corrugated sinuses in the De Paulis’ provided an increased compliance of 7.9%; the largest after the native root.

4. Discussion

All valves well exceeded the EOA requirements specified in the ISO5840 standard, which for the size of 25 mm requires values ≥ 1.45 cm² at 5 l/min (all implants had a mean EOA > 2.54 cm²). Still, despite the same implantation size, the three aortic roots exhibited some differences in the hydrodynamic behaviour. In particular, valve 2 appeared to be characterised by softer leaflets then the others, allowing wider opening and lower ΔP for all procedures. On the contrary, valve 3 resulted slightly more stenotic, with opening areas 15-20% smaller and ΔP about 60% higher than the other prostheses.

Nevertheless, the changes in performance parameters determined by each procedure were consistent for all three valves, confirming statistically significant trends.

As expected, the healthy native valves were characterised by the best efficiency. This appears to be driven by the superior physiological leaflets dynamics, with the leaflets expanding deep into the Valsalva sinuses to maximise the EOA, so as to minimise the ΔP and the associated E_\text{loss}. Analysis of the images in Error! Reference source not found. shows that large portions of the leaflets expand further than the window of observation (this, represented as a red dashed line, has a diameter of 24 mm), with exception of the leaflet positioned at the bottom. This, for all valves, corresponds to the leaflet adjacent to the ventricular muscle band, stiffened by the presence of the PET fabric covering (represented in Error! Reference source not found.), which reduces the leaflet ability to expand into the right coronary sinus. The opening mechanism appears to be facilitated by the large compliance of the native aortic root, which undergoes relevant radial expansion during systole, increasing the EOA even further.

The use of a tubular graft in the David’s and Yacoub’s techniques, with consequent alteration of the sinus chambers, introduces a physical arrest to the valve leaflets which limits the achievable EOA. This levels the performance for the two approaches. The Yacoub’s approach appears to double the compliance of the implant (3.3-6.7%), thanks to the three-pointed crown at the leaflet attachment. In particular, compared to the native root, the two techniques were characterised by a reduction of EOA and a major increase in ΔP (at a CO of 5 l/min, EOA was 25-38% lower and ΔP was 75-140% larger for the three valves). This is well reflected in
the measurement of the POA, which shows a mean reduction of about 30% compared to the healthy native valve, easy to be visually appreciated in Error! Reference source not found.. The attempt to replicate the presence of the Valsalva sinuses in the De Paulis’ procedure appears effective in restoring a more physiological dynamics, with the leaflets allowed to expand into the more pronounced bulging section of the graft. De Paulis’ results in better systolic performance than the other two valve-sparing techniques, with an EOA reduced of just 10-15% compared to the healthy native configuration at a CO of 5 l/min (see Table 1). Again, this is well aligned with the results from the POA measurement.

Performing all sets of implants following the same sequence may introduce an order effect in the results. However, this option was preferred as it allows to minimise the valve manipulations due to the removal and re-suturing of the different grafts. In fact, adopting the selected sequence, only one suturing is requested for the David’s and Yacoub’s, and a second one for the De Paulis. Still, the configuration experiencing the largest number of manipulations, which is always the De Paulis, exhibits the best performance in all the three sparing procedures, proving that any bias introduced during manipulation is not substantial nor sufficient to alter the order of the most favourable conditions.

In general, the wider leaflets expansion characterising the healthy native root is accompanied by some larger closing backflow than the other solutions, except for valve 2, where the leaflets expand substantially also after all valve-sparing procedures. This is a crucial result, as it challenges the most commonly accepted theory in the literature, which regards the presence of the Valsalva sinuses as functional to generate and host the vortices facilitating the valve closing [22], [23]. Instead, the presented tests appear to confirm the mechanism recently proposed by Tango et al. [24] on the basis of a computational study of the idealised aortic root. This identifies the main role of the sinuses in supporting the systolic phase by providing a chamber where the leaflets can fully expand to reduce their interference with the ejected blood flow. In fact, as clearly displayed in Error! Reference source not found., the $E_{\text{loss}}$ typically associated with the systolic forward flow is far more relevant than that produced by the closing regurgitant flow. Hence, optimising the opening phase can offer massive advantages, that make tolerable some collateral, but minor, loss in the closing phase.

From a clinical perspective, the presented study indicates that the De Paulis’ technique can result in better performance than the approaches based on tubular grafts, due to its ability to better reproduce the anatomy of the Valsalva sinuses and their contribution to a larger valve opening [10]. However, it needs to be observed that this result is inconsistent with a recent study reported by Paulsen et al. [11], [12]. This describes similar in-vitro tests, but concludes that valve-sparing techniques based on the De Paulis’ approach provide inferior performance than reimplantation procedures performed with straight tubular conduits. This appears to be associated with some major leakage measured with bulging grafts, possibly due to the implantation of the commissures below the sino-tubular graft suture. This, in fact, may cause excessive radial dislocation of the valve commissures, causing some degree of infra-valvular diastolic backflow (as in operating conditions typical of aneurysmal roots). Hence, although our findings indicate the De Paulis’ technique as potentially superior, this outcome is necessarily procedural dependent, with the positioning of the commissures playing an essential role. In fact, as described, excessively low positioning of the valve may result in the insurgence
of central leakage. On the contrary, excessively high positioning would obliterate the function of the sinuses, making them unable to provide adequate room to host the expanding leaflets. The presented study also reveals the potential role that in-vitro tests may play in perfecting surgical techniques and supporting clinical training.

4.1. Study limitations

The interpretation of the described findings shall take into consideration few approximations and limitations in the performed tests. The anatomy and mechanical properties of the glutaraldehyde treated juvenile pig aortic root are expected to have some difference from the corresponding patient’s component. Also, the saline solution used in the presented tests, and preferred to blood equivalents to prevent tissue changes that may affect the tissue properties between tests, has different physical properties from human blood.

Moreover, the reduction of David’s and Yacoub’s techniques performances compared to the healthy native configuration may be related with the inability of the procedure to generate anatomically ideal sinuses, and to the lower compliance of the fabric graft. The similarity between the David’s and Yacoub’s techniques may be justified by the utilization of a bio-root with a stiffened annulus, trigons and muscular ridge, as opposed to the human valve. This may reduce the compliance achievable in human with the Yacoub’s procedure.

Despite the adopted sample size provides statistically significant results about the differences between the alternative procedures (with large size effect), larger sizes might, in future tests, increase the confidence in the presented findings.

5. Conclusions

This work analyses and compares the hydrodynamic alterations introduced by the most common aortic root repair procedures: David’s reimplantation, Yacoub’s remodelling and De Paulis’ reimplantation.

The prostheses representative of the healthy aortic root expectedly resulted the most efficient, with maximum EOA, and minimum ∆P and E_loss. This shows that, despite providing generally good performance, current valve sparing techniques are still suboptimal and far from matching the physiological leaflets dynamics. The significantly superior efficiency observed with the De Paulis’ reimplantation technique confirms that replicating the anatomical features of the aortic root may contribute to enhance the efficacy of the treatment. Still, engineering improvement is needed to design conduits that better model the optimum compliance of the native vessel.

Data availability statement

All relevant data are within the manuscript and its Supplementary data files, further data underlying this article will be shared on reasonable request to the corresponding author.

Conflict of interest: none declared.
Table 1 Implant performance parameter at 5 l/min of CO (distance from the healthy native result).

<table>
<thead>
<tr>
<th>Valve</th>
<th>Configuration</th>
<th>$\Delta P$ [mmHg]</th>
<th>$EOA$ [cm$^2$]</th>
<th>$CRV$ [ml]</th>
<th>$E_{lossF} + E_{lossC}$ [mJ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Native</td>
<td>3.74 SD:0.12</td>
<td>3.81 SD:0.07</td>
<td>-2.26 SD:0.15</td>
<td>21.60 SD:1.07</td>
</tr>
<tr>
<td></td>
<td>David</td>
<td>9.53 SD:0.25</td>
<td>2.36 SD:0.02</td>
<td>-1.69 SD:0.07</td>
<td>75.05 SD:1.50</td>
</tr>
<tr>
<td></td>
<td>Yacoub</td>
<td>9.07 SD:0.14</td>
<td>2.52 SD:0.03</td>
<td>-1.83 SD:0.17</td>
<td>68.47 SD:1.63</td>
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<td></td>
<td>De Paulis</td>
<td>5.36 SD:0.19</td>
<td>3.41 SD:0.06</td>
<td>-1.72 SD:0.09</td>
<td>36.81 SD:1.94</td>
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<tr>
<td>2</td>
<td>Native</td>
<td>3.66 SD:0.10</td>
<td>3.96 SD:0.05</td>
<td>-2.38 SD:0.14</td>
<td>25.03 SD:1.08</td>
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<td></td>
<td>David</td>
<td>6.73 SD:0.07</td>
<td>2.91 SD:0.01</td>
<td>-2.52 SD:0.25</td>
<td>58.70 SD:1.54</td>
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<td>Yacoub</td>
<td>6.32 SD:0.09</td>
<td>2.84 SD:0.02</td>
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<td>57.65 SD:1.66</td>
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<td>De Paulis</td>
<td>4.84 SD:0.23</td>
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<td>3</td>
<td>Native</td>
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<td>Yacoub</td>
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<td>41.86 SD:1.26</td>
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Figure legend

Figure 1. FreeStyle prosthesis. Sagiptal, inflow and outflow views.

Figure 2. David implant steps: a) equipment, b) Native valve cutting, c) valve preparation, d) graft suturing, e) transversal and f) sagittal views.

Figure 3. healthy native prosthesis and valve-sparing implants, David, Yacoub and De Paulis, set into resin support.

Figure 4. Implant performance parameter diagram of: a-c) $\Delta P$; d-f) $EOA$; g-i) $CRV$; l-n) $E_{lossF} + E_{lossC}$.

Each diagram reports mean performances value in 10 cycles. The standard deviation is reported as error bars.

Figure 5. Mean $E_{lossC}$ and $E_{lossF}$ for each kind of implant.

Figure 6. HFR images corresponding to the $POA$ maximum value.

Central Image: Stacked bar graph representing the estimated forward (bottom) and closing (top) energy losses for the healthy native prosthesis and for the De Paulis’, David’s and Yacoub’s valve-sparing implants.

References


Energy loss [mJ]

- Native
- De Paulis
- David
- Yacoub

Closing
Forward