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Technical note

Preoperative Ozaki technique measures on tridimensional engineered root

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ABSTRACT

Background: The aortic valve neocuspidalization (AVNeo) is an innovative surgical technique aiming at the reconstruction of the aortic valve using autologous pericardium. One of the main criticisms to AVNeo is the longer duration of the aortic clamping time (ACT) as compared to standard aortic valve replacement due to the sizing of the valve neocusps.

Methods: We retrospectively enrolled 30 consecutives patients underwent AVNeo. For each patient we developed a 3D aortic root model (ARM) based on CT-scan datasets. We retrospectively compared the leaflets measurements performed during surgery with those obtained on the corresponding ARMs.

Results: In 100% of cases no difference between the in vitro and in vivo measurements exceeded the acceptable error limit of 2 mm. The correlation of each single in vitro versus in vivo measurements demonstrates a strong coincidence between the two different methods of sizing ($r > 0,9$, $p < .0001$). By analyzing the data considering the annulus perimeter and not the single cusp size, the perfect coincidence was to be found in 89.9% with a slight acceptable discrepancy (2 mm on total) in the remaining 10.1%.

Conclusions: 3D-ARMs, printed from CT-scan, represent a reproducible process to obtain overlapping cusp sizes compared to those measured in-vivo, possibly reducing the ACT.

1. Introduction

In the past 10 years, the aortic valve neocuspidalization technique (AVNeo) has received increasing interest.[1]

Otherwise, AVNeo presents a specific surgical time, significantly extending the duration of the aortic clamping time (ACT), related to the sizing of the valve neocusps.[2]

In our experience, the percentage of neoleaflet measurements over mean ACT is 16% and 19% for the tricuspid and bicuspid aortic valves, respectively, plus an extra 5 min average time to draw and cut out the neoleaflets from the patient's pericardium.[3]

Therefore, the possibility to perform an accurate three-dimensional measurement before the surgical direct vision analysis could lead to a significant reduction of the ACT.

Here we describe a self-developed method to create an accurate, preoperative, three-dimensional 1:1 scale patients' aortic root model (ARM) starting from cardiac CT imaging dataset, suitable for the use of the same sizers utilized in AVNeo (Fig. 1).

2. Material and methods

Thirty consecutive patients (52,1 ± 13,5 y.o.) who underwent isolated AV-Rec between February 2019 and April 2020 were retrospectively included in this study.

In compliance with the declaration of Helsinki, the local ethics committee approved the conduction of this study (CCM 1120).

CT images were imported into an anatomic modeling software (MIMICS®, Materialise, Belgium) utilized to generate a digital three-dimensional root for each patient, ready to be printed.

We printed ARMs with Heart Print Flex Plus® (HPF+), a special

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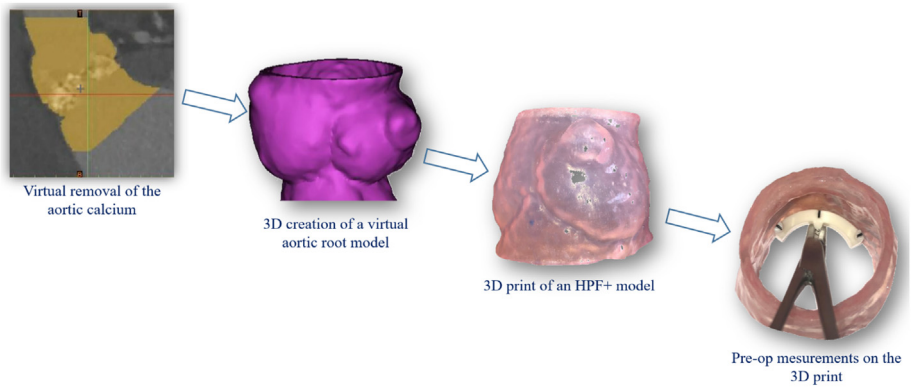

Fig. 1. Steps of creation of the 3D-aortic root models.

patented material produced by Materialise designed to simulate the mechanical characteristics of arterial tissue. This enables us to obtain more accurate measurements compared to other common printable materials such as polylactic acid Fig. 2.[4] All the required measurements were performed by the same surgeon.

2.1. Segmentation

To contour the aortic root, we used the MIMICS' automatic segmentation algorithm based on Hounsfield units, whilst, in those cases in which CT quality was not brilliant, we utilized the manual segmentation.

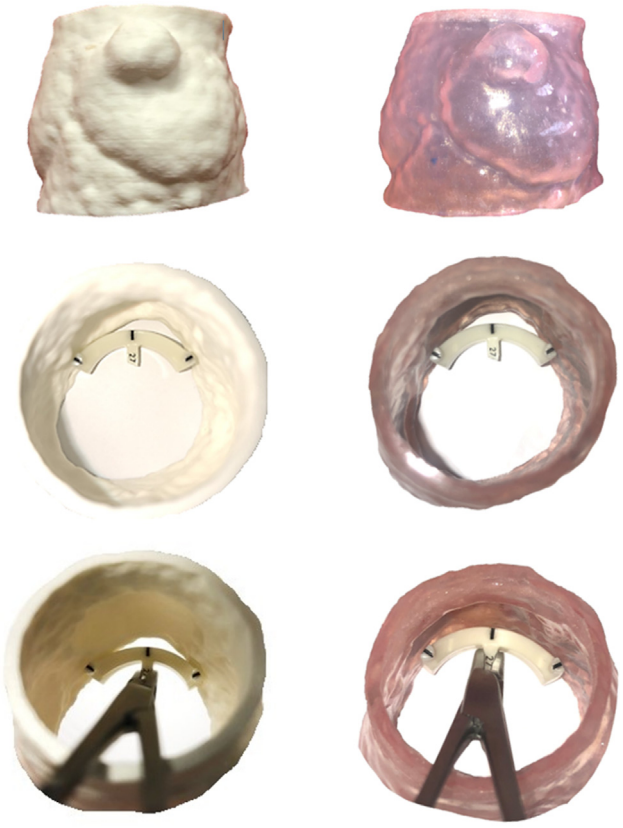

Fig. 2. Comparison between polylactic acid models and HPF+ models. When the surgeon pushes he sizer it perfectly adheres to the HPF+ model wall , exactly how happens in vivo.

2.2. Statistical analysis

The perfect coincidence and the discrepancy of the cusps distribution sizes were showed as frequencies and percentages, respectively. Spearman correlation and the Bland-Altman method were used to compare in vitro versus in vivo measurements considering data obtained in vivo as the gold standard. Data were analyzed using the SAS v.9.4 statistical package.

3. Results

In Table 1 the measurements obtained on HPF + ARMs are compared to the corresponding noted in the surgical reports.

In 100% of cases no difference between the in vitro and in vivo measurements exceeded the acceptable error limit of 2 mm.

In particular, a perfect coincidence of leaflets sizes is present in 56.6% of cases, in 33.3% of cases we observed a discrepancy in the single cusp sizing with no difference in their total width sum.

Table 1
Comparisons of in-vitro and ex-vivo measurements.

Anonymous patient ID	In vivo measurements			3D-ARMs measurements		
	LCC	RCC	NCC	LCC	RCC	NCC
1	23	25	27	23	25	27
2	31	27	27	27	27	31
3	29	31	29	29	31	31
4	33	35	33	33	35	33
5	27	27	29	27	27	29
6	27	31	27	27	27	31
7	33	33	29	33	33	29
8	35	33	31	35	31	33
9	35	31	35	35	33	33
10	35	35	33	35	35	33
11	35	35	35	35	35	35
12	33	33	33	33	33	33
13	33	33	31	33	31	33
14	35	31	33	35	33	31
15	31	33	29	31	33	29
16	33	27	31	33	31	27
17	29	27	31	27	29	31
18	35	35	33	35	35	33
19	33	35	35	35	33	35
20	27	29	31	27	31	29
21	31	35	31	31	35	31
22	31	27	31	31	27	31
23	31	35	31	31	35	31
24	27	27	29	27	27	29
25	29	31	29	29	31	29
26	27	31	25	27	31	27
27	25	23	23	25	23	23
28	33	31	29	33	31	29
29	33	33	35	33	31	35
30	29	31	29	29	31	29

A discrepancy for the cusp sizes and their total width was observed in 10.1% of cases.

Fig. 3 (top) shows the correlation of cusp sum in vitro versus in vivo measurements, demonstrating a strong correlation between the two different methods of sizing ($r = 0,99$, $p < .0001$). Means and average differences as well as Bland-Altman plots of cusp sum from vivo vs. vitro measurements are reported in Fig. 3 (bottom)

By analyzing the data considering the annulus perimeter and not the single cusp size, the perfect coincidence turned out to be found in 89.9% with only a slight acceptable discrepancy (2 mm on total) in the remaining 10.1%.

4. Discussion

The longer ACT and extracorporeal circulation time, compared to aortic valve replacement (AVR), represent a non-negligible disadvantage of AVNeo.

Printed ARMs offer the great advantage to size patient's neoleaflets before starting the operation, reducing ACT.

Our analyses demonstrates that in 100% of cases no difference between the in vitro and in vivo measurements exceeded the acceptable error limit of 2 mm.

However, analyzing the impacts on surgical practice of the slightly discrepancies between the in vivo and ex-vitro measurements it turns out to be irrelevant.

In fact, we obtained two groups of incorrect measurements: one including differences in sizing among each single cusp, but with an identical sum, and the other including diversities in measuring both single cusps and their sum.

Considering the first group, we believe that in AVNeo it is crucial to maintain a constant sum of cusps rather than neoleaflets distribution.

Regarding the second group, the slight difference in the sum of cusps (2 mm in our measurements) is irrelevant to the outcome of the procedure. Since biological and mechanical prostheses routinely used for AVR have an annulus perimeter that ranges between 59.69 mm (19 mm valves) and 91.10 mm (29 mm valves) so that the circumferential difference in two numerically continuous annular valve size prostheses is 6.28 mm, which is three times the difference we found in the second group of our study.

$$(VSx \times \pi)–(VSy \times \pi) = 6.28 \text{ mm}^*$$

*where VS is valve size, x is any valve size, and y is the immediately higher size of the valve.

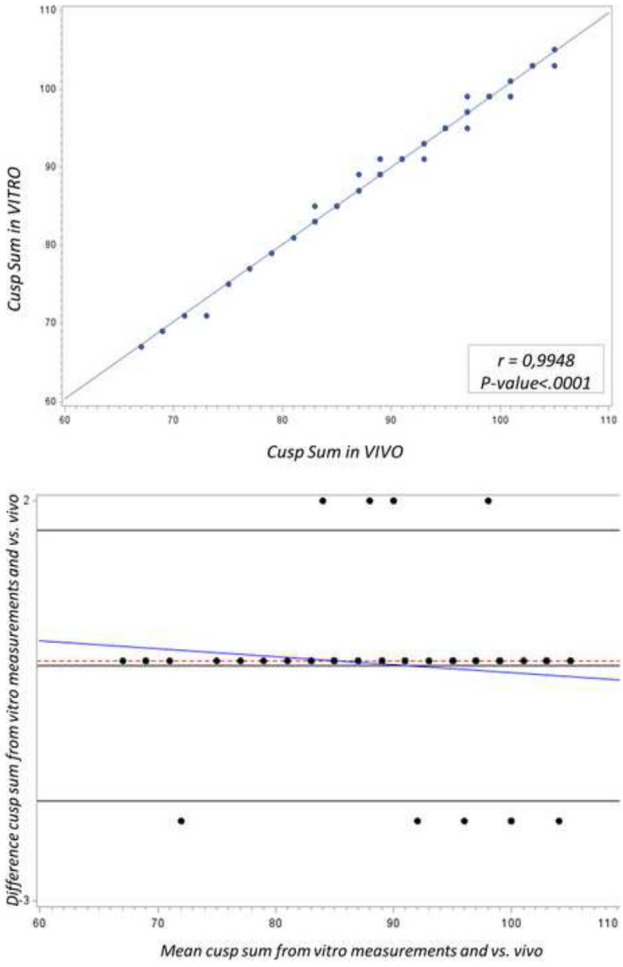

Fig. 3. Correlation of cusp sum in vitro between in vivo measurements (top) and Bland-Altman plots of cusp sum from vivo measurements and vs. vitro measurements (bottom).

5. Conclusions

In conclusion, 3D printed HPF + ARMs, when used preoperatively in AVNeo, could help in reducing the ACT by 16–19%, possibly improving the outcome of the procedure.[5,6]

Moreover, ACT reduction is not the only advantage of the technique we present. During the classic measurements of the Ozaki procedure the aorta is collapsed because it is open and the pressure is zero.During the operation, in order to create a functioning valve, surgeons must reconstruct the leaflets in order to create a valve able to resist the diastolic pressure (which would otherwise result in aortic insufficiency). A great advantage of the PROMOTER procedure (**PR**eoperative **O**zaki technique **M**easures **O**n **T**ridimensional **E**ngineered **R**oot), is that, being based on CT-scan dataset, the operator has the possibility to calculate the size of the cusps by reasoning on the exact geometry that the patient's aortic root assumes during the diastolic phase of the cardiac cycle, thus significantly facilitating her/him during surgery in the choices that lead to the success of the intervention (minimal gradients and zero insufficiency).

Declaration of competing interest

None of the authors above declares any conflict of interest to disclose.

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