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Transcatheter Aortic Valve Neo-Commissure Alignment with the Portico System

Short title: Portico neo-commissures alignment

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Abbreviation: inner aorta curve (IAC); outer aorta curve (OAC); Transcatheter aortic valve implantation (TAVI); transcatheter heart valve (THV).

Introduction:

With transcatheter aortic valve implantation (TAVI) rapidly spreading its indication to lower-risk and younger patients, reliable and reproducible guidance on how to orient the transcatheter heart valve (THV) to avoid coronary overlap and improve hemodynamic performance become an urgent need. It has been recently suggested that the orientation of the neo-commissures during the navigation of the delivery system could be correlated with their final position in the aortic annulus, and consequently, modified to improve final THV orientation [1]. However, no previous study has considered the effect of different aorta angulations and how to add this variable to a neo-commissure alignment model; and none reported the feasibility of neo-commissure alignment with the Portico system (Abbott Structural Heart, St. Paul, MN, USA). Therefore, this article aims to provide a step-by-step recommendation on how to align the Portico THV, in a reproducible and standardized way, and to present the initial results obtained in patient-specific 3D printed aortic models.

Methods and results

To validate the proposed model, computed tomography scans from patients with distinct aorta angulations (standard, horizontal, and anteriorized) were used to print three different 3D models. The steps to develop the models are described in Figure 1. To evaluate neo-commissure alignment feasibility, the full resheathable self-expanding Portico THV was used. This device has intra-annular leaflets, large stent cell geometry, and a low-profile delivery system, which provides remarkable flexibility and smooth tracking. It has 3 markers indicating the neo-commissures (Figure 1C), thus facilitating their identification and reorientation. To align the neo-commissure, we followed the steps described in Figure 2 and Supplementary Videos 1-2. Neo-commissures were considered aligned if the degree of deviation, having the native commissures as a reference, was between 0-15°.

To evaluate the proposed concept's reproducibility and consistency, two different operators performed five deployments on each model, counting 15 deployments per operator, 30 deployments in total. Neo-commissure alignment was obtained in all tests, which means 100% success (Figure 2F-G). The deviation between neo and native commissures and the degrees of rotation employed in the delivery system are shown in Supplementary Table 1. Overall, the delivery system was clockwise rotated between 70-120°, varying according to aorta angulation.

Discussion:

With TAVI rapidly spreading to younger and lower-risk patients, concerns about future coronary reaccess, THV durability, and redo-TAVI feasibility have become particularly relevant. Among the factors related to THV durability and coronary reaccess, THV orientation has received

growing interest since it is a potentially modifiable factor. It has been demonstrated that an asymmetrical or non-aligned THV deployment may result in coronary obstruction, challenging coronary reaccess, poor hemodynamic performance, intraluminal thrombosis, accelerated leaflet deterioration, and reduced prosthetic functional life [2]. Ochiai et al. reported unfavorable coronary access in 25.8% and 34.8% (for the right and left coronary, respectively) of patients submitted to an Evolut R/PRO implant; and in 8.1% and 15.7% of those who received a SAPIEN 3 [3]. Similarly, Tang et al. [1] retrospectively reported overlap with at least one coronary artery in 30% to 50% of patients. For the Evolut THV, the authors achieved significantly less overlap if the Evolut “Hat” was located at an outer curve (OC) or center front (CF) position in the descending aorta. Despite the relevance of these pioneer studies, the impact of different aorta angulation on final THV orientation was not considered, and even with the “Hat” position modification proposed by Tang, overlap with 1 or both coronaries was still present in 20.2% of the cases. Furthermore, no study evaluating Portico neo-commissure alignment feasibility is available so far.

Taking into consideration these facts, the present article is innovative since:

1. We describe in a detailed way how to develop a patient-specified 3D printed aortic model, which provides a reliable TAVI simulated environment.
2. We provide a step-by-step recommendation on how to reorient the Portico delivery system to reach final neo-commissure alignment, which proved to be consistent and reproducible, even in different aorta angulation models.

Using these models and the steps described above, we demonstrated an excellent correlation between the neo-commissures marker's orientation in the descending aorta and their final position in the aortic annulus. Therefore, simple delivery system rotational maneuvers, concurrently with native and neo-commissures overlap, led to a satisfactory final THV orientation. Using these same steps, with slight adaptations, we extrapolate that neo-commissures alignment could also be reached in real-life TAVI deployments (Supplementary Figure 1).

Limitation: The results reported here apply to experimental models and are limited by lack of clinical validation. We are currently performing a prospective clinical study to validate this concept in real-life TAVI procedures.

Conclusion:

Neo-commissure alignment is a crucial issue once misalignment has been associated with post-procedural challenging coronary reaccess and faster THV deterioration. Experimental tests using 3D-printed aortic models demonstrated the feasibility and effectiveness of Portico neo-

commissures alignment. The proposed orientation steps were simple and straightforward, with success in all deployments performed.

Impact on daily practice:

1. With TAVI moving to lower-risk and younger populations, reliable and reproducible guidance on how to reach neo-commissures alignment becomes an urgent need.

2. Patient-specific 3D-printed aorta models are useful for studying the Portico THV alignment technique.

3. Since the realignment steps described here were successful in providing neo-commissure alignment, they could be translated, with slight adaptations, to a real-life scenario, contributing to improve THV orientation and facilitate coronary reaccess.

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Conflict of Interest:

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Figure 1.

A. Patient-specific CT scans were segmented using a free and open-source 3DSlicer software. Segmented aorta was exported as STL 3D model and processed using the Meshmixer software (Autodesk, San Rafael, California, USA). A shell was designed, representing the aortic wall. 3D models were printed on the Prusa I3 MK3 3D printer, with plastic filament polylactic acid material. Native commissures were marked using radiopaque markers and additional adapters were attached to the model.

B. 3D models printed in different aorta angulations (horizontal, standard, anteriorized).

C. Portico neo-commissures markers.

Figure 2. Neo-commissure alignment concept.

Three native commissure markers were separately identified (**A**). A fluoroscopic projection depicting 2 native commissures in overlap in the inner aorta curve (IAC) and 1 isolated in the outer aorta curve (OAC) was set (**B**). Keeping this projection, the Portico delivery system was advanced to the descending thoracic aorta (**C**). The 3 neo-commissures markers were oriented similarly to the native ones (2 in the IAC and 1 the in OAC) by rotating clockwise the delivery system until the desired position (red box) was achieved (**D**). This concept considers the premise that structures localized in descending aorta's medial aspect will be projected in the IAC once the delivery system is advanced (**E**). Standard fluoroscopic projection was resumed (avoiding parallax effect), the delivery system advanced (keeping the employed rotation), and THV deployed as usual. At the end of the implant, the X-Ray tube was rotated to check the final alignment in different projections (**F**). Final neo-commissure alignment evaluation in the benchtop model. Since the deviation between native commissures (black dots) and neo-commissures (red dots) was $<15^\circ$, the implant was considered aligned (**G**).

Figure 1

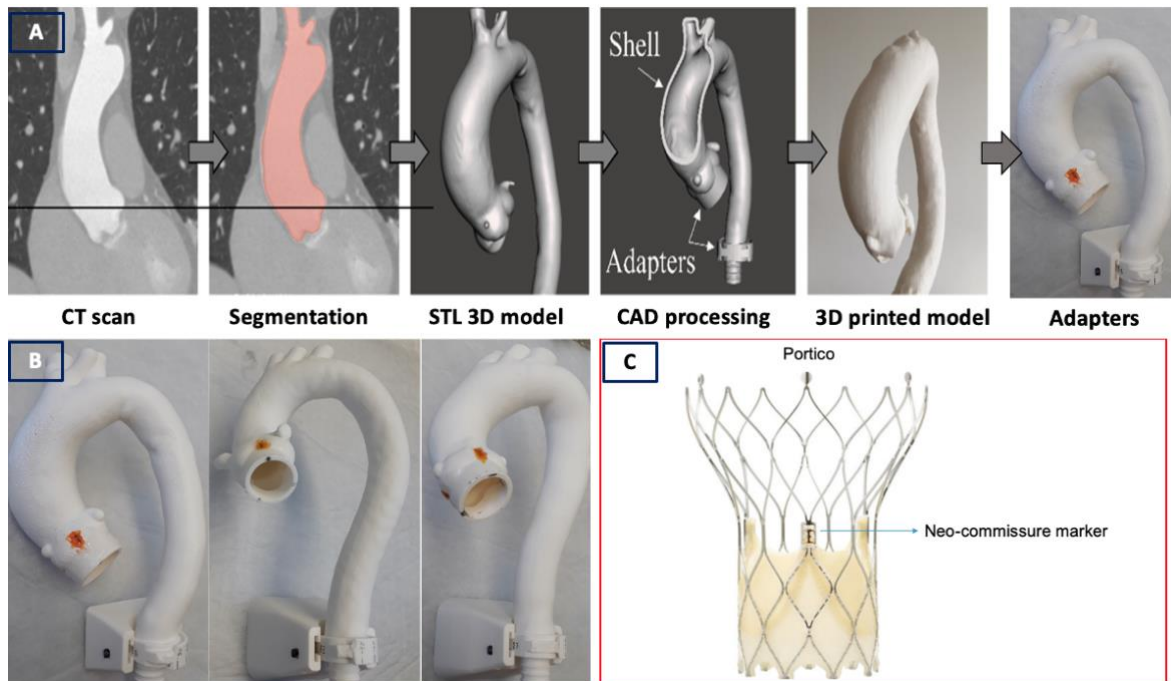
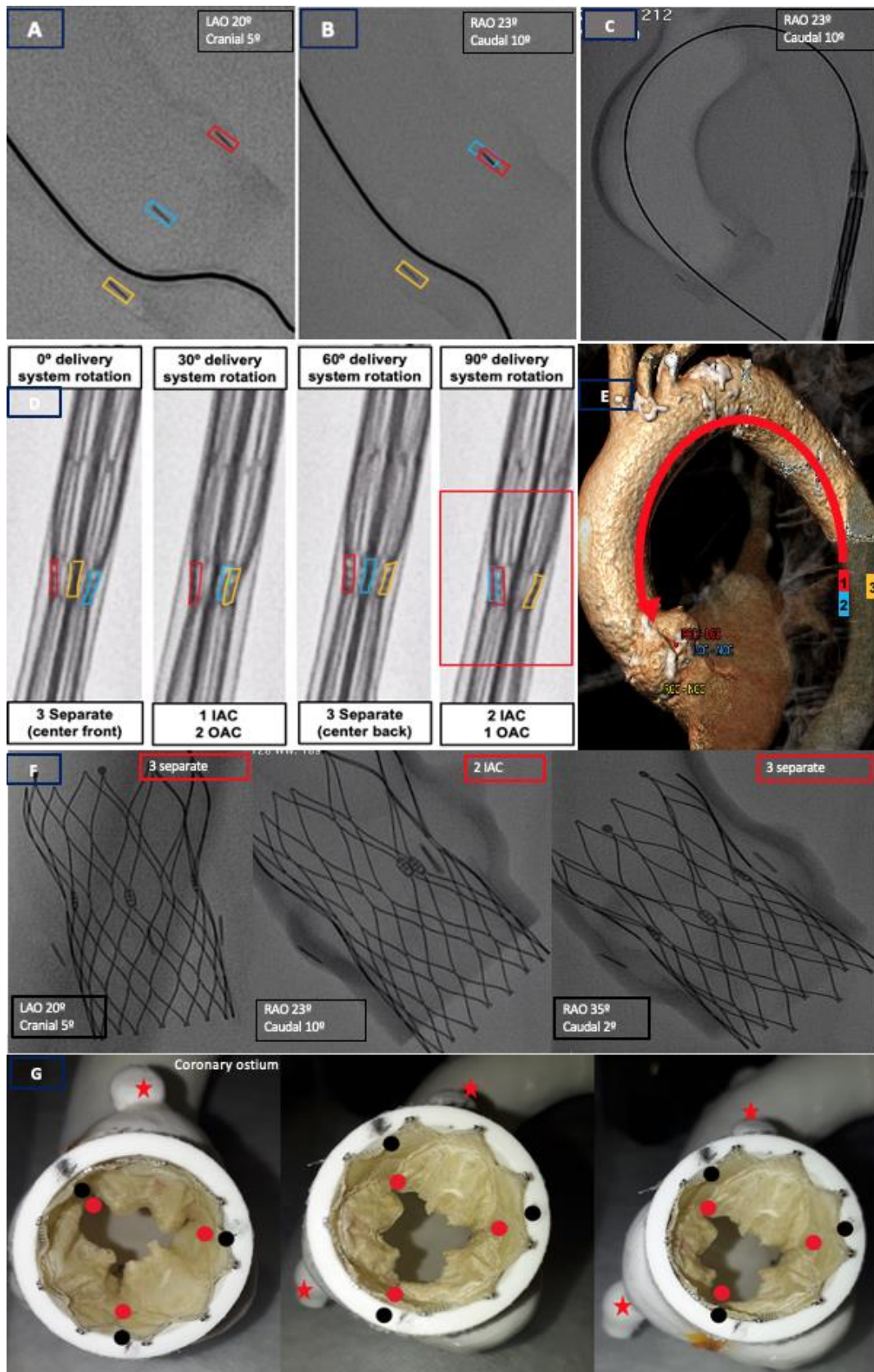


Figure 2



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Supplementary material

Supplementary Table 1: Neo-commissure alignment evaluation and degrees of delivery system rotation.

Final neo-commissure position		
Degrees of deviation	Degree of deviation (Median)	Degree of deviation (IQR)
Neo and native LCC-RCC commissures	5°	0-10°
Neo and native LCC-NCC commissures	10°	4-15°
Neo and native RCC-NCC commissures	10°	0-15°
Degrees of clockwise rotation employed in the delivery system		
Horizontal aorta model	90°	70-92°
Standard aorta model	87°	85-91°
Anteriorized aorta model	100°	85°-120°

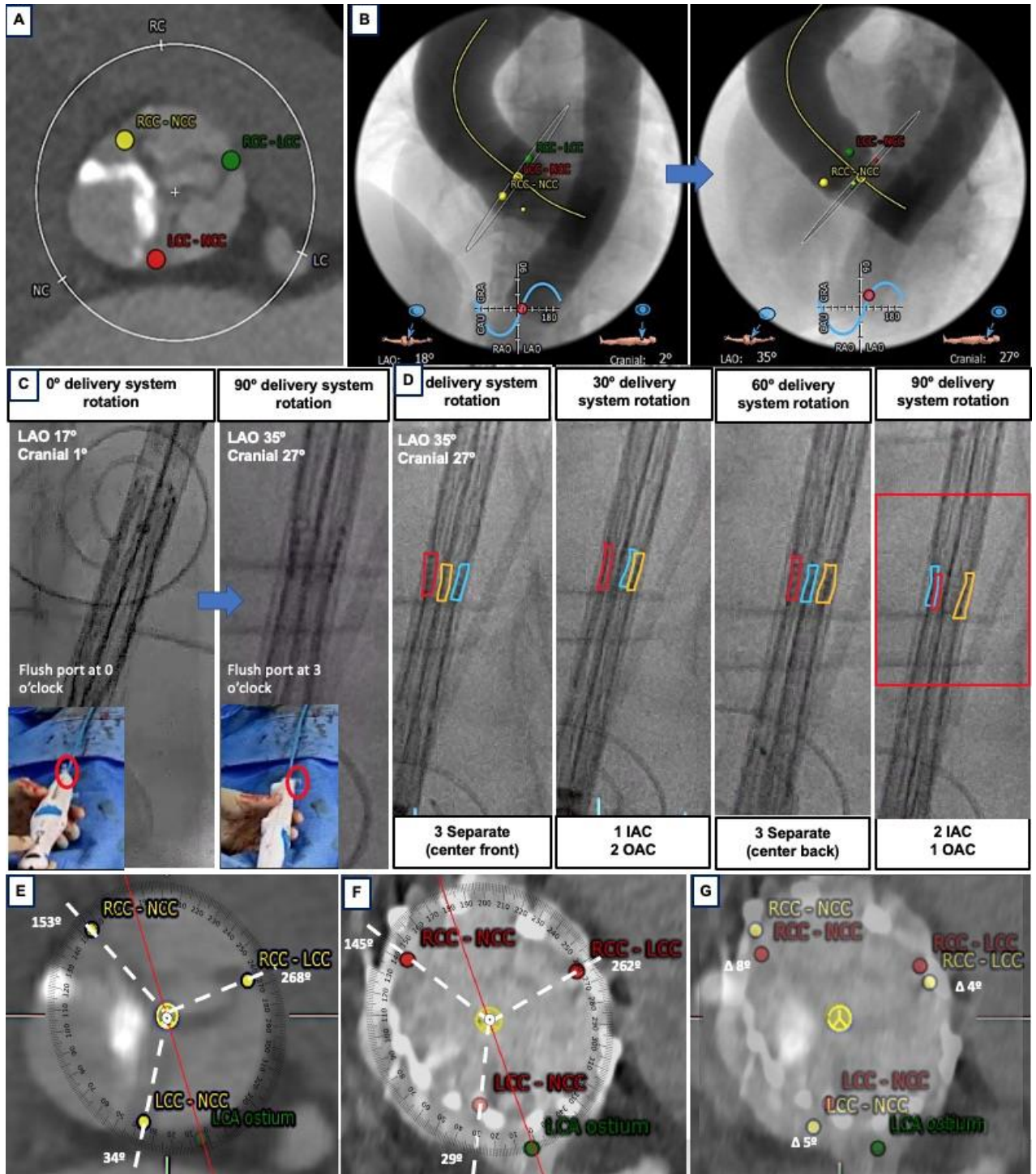
LCC (left coronary cusp); RCC (right coronary cusp); NCC (non-coronary cusp); IQR (interquartile range (IQR)).

Supplementary Figure 1 Legend.

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Supplementary Figure 1. Human implant illustrating the neo-commissure alignment concept.

Preoperatively, the three native commissures were marked using the 3mensio software [yellow dot = commissure between the right coronary cusp and the non-coronary cusp (RCC-NCC); red dot = commissure between the left coronary cusp and the non-coronary cusp (LCC-NCC); green dot = commissure between the right coronary cusp and the left coronary cusp (RCC-LCC)] (**A**). The annulus single S-curve was accessed (first frame) and a point on the curve in which 2 commissures (LCC-NCC and RCC-LCC) were fluoroscopically displayed overlapped in the IAC was defined (LAO 35° Cranial 27°) (second frame) (**B**). Intraoperatively, the predefined fluoroscopic projection (LAO 35° Cranial 27°) was set. Keeping this projection, the Portico delivery system was advanced to the descending thoracic aorta and rotated until the desired neo-commissures orientation was achieved (red box). This meant rotating the delivery system, in a clockwise direction, until 2 neo-commissures were depicted in overlap in the IAC, keeping the third isolated in the OAC. The delivery system rotation, in this case 90° clockwise, was equivalent to turn the flush port from a 0 o'clock to a 3 o'clock position (**C-D**). The standard fluoroscopic projection was resumed (avoiding parallax effect), the delivery system was advanced (keeping the employed rotation), and the THV was deployed as usual. Postprocedural, commissural orientation was assessed in the native valve (on pre-TAVI CT scan) and in the prosthetic aortic valve (on post-TAVI CT scan). First, the ostium of the left main coronary artery (LCA ostium = green dot) was tagged as a fixed landmark. Second, the angle of deviation between each native commissure (yellow dots) and a centerline toward the LCA ostium was measured (**E**). The same was done in the post-TAVI CT scan for the neo-commissures (red dots) (**F**). For each commissure, we calculated the Δ deviation by subtracting the post-TAVI measure from the pre-TAVI measure. Neo-commissures were considered aligned if the Δ deviation was $< 15^\circ$ (**G**).



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Supplementary Video 1 Legend. Native commissures and neo-commissures alignment steps.

Supplementary Video 2 Legend. Step-by-step of the neo-commissure alignment concept.

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