

# Clinical and structural outcomes of neocommissural alignment in transaxillary and transcatheter aortic valve implantation with a self-expandable transcatheter heart valve



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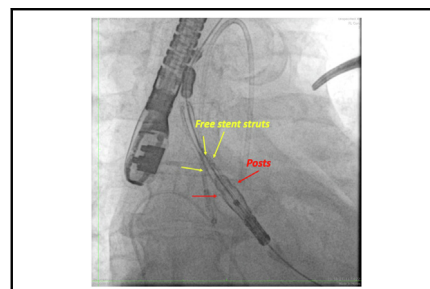
## ABSTRACT

**Objectives:** This study analyzes neocommissural alignment and the clinical and hemodynamic outcomes after transaxillary and transcatheter implantation of the Acurate neo2 transcatheter heart valve.

**Methods:** We performed a retrospective, single-center analysis of early outcomes after transaxillary and transcatheter implantation of the Acurate neo2 transcatheter heart valve. Primary outcomes were neocommissural alignment, in-hospital mortality, and valve hemodynamic performance. Commissural alignment between native and transcatheter heart valves was assessed by transesophageal echocardiogram before and after the procedure.

**Results:** Between October 2021 and November 2022, 40 consecutive patients were treated with the Acurate neo2 through a transaxillary or transcatheter approach. Access was achieved via the left subclavian artery in 30 cases and the left common carotid artery in 10 cases, with a mean vessel diameter of 6.7 mm. Implants most commonly used were size M (37.5%), L (35%), and S (27.5%). On the basis of transesophageal echocardiogram analysis, there was no significant difference in mean commissural orientation between native (mean, 65.1°; SD, 41.3°) and neocommissures (mean, 64°; SD, 44.1°) ( $P = .661$ ). Mean commissural orientation did not significantly differ between native and neocommissures ( $P = .661$ ). Optimal alignment or mild commissural misalignment was achieved in 99.5% of cases. There were no cases of severe commissural misalignment. Postprocedural mean values for peak and mean gradients were 12.7 mm Hg and 5.2 mm Hg, respectively. There were 2 cases of moderate paravalvular leak and 4 cases of mild paravalvular leak.

**Conclusions:** This patient-specific technique for transaxillary and transcatheter insertion of the Acurate neo2 delivery system prevents implantations with more than mild commissural misalignment and with a high device success rate. (*JTCVS Techniques* 2023;22:150-8)



The Acurate neo2 THV has 3 radiopaque commissural posts and “free stent struts.”

## CENTRAL MESSAGE

This patient-specific technique for transaxillary and transcatheter TAVI with the Acurate neo2 THV prevents implantation with more than mild CMA, providing a high device success rate.

## PERSPECTIVE

Neocommissural malalignment after TAVI may be associated with mid- and long-term valve-related complications and might even have an impact on valve durability. The described transaxillary and transcatheter approaches allows an easy, safe, and reproducible implantation of the Acurate neo2 THV with a low rate of more than mild neo-CMA.

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The study was approved by the regional research ethics committee (Comité Ético de Investigación Clínica de Galicia, registry code 270/2022).

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**Abbreviations and Acronyms**

AR	= aortic regurgitation
CMA	= commissural misalignment
IQR	= interquartile range
LCC	= left coronary cusp
MDCT	= multidetector computed tomography
NCC	= noncoronary cusp
RCA	= right coronary artery
RCC	= right coronary cusp
SE	= self-expandable
THV	= transcatheter heart valve
TAVI	= transcatheter aortic valve implantation
TEE	= transesophageal echocardiogram
VARC-3	= Valve Academic Research Consortium 3

 Video clip is available online.

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recent years, increasing attention has been paid to achieving neocommissural alignment in transcatheter aortic valve implantation (TAVI) with self-expandable (SE) transcatheter heart valves (THVs). Neocommissural alignment after TAVI refers to the rotational orientation of the aortic THV in relation to native valve commissures.<sup>1,2</sup>

A neocommissural malalignment could impair a future coronary access,<sup>2,3</sup> make a future transcatheter aortic valve-in-transcatheter aortic valve procedure more difficult,<sup>4</sup> lead to a relative THV mean gradient increase of more than 50% in the early postoperative period,<sup>5</sup> lead to increased rates of central THV regurgitation,<sup>1</sup> and even have an impact on valve durability.<sup>4</sup>

Recent studies have shown that achieving neocommissural alignment with certain SE THVs is more feasible than with others.<sup>6</sup> On the other hand, balloon-expandable THVs have shown to be randomly oriented when it comes to neocommissural alignment with the native aortic valve.<sup>1,5</sup> However, published studies to date addressing neocommissural alignment have specifically excluded nontransfemoral approaches from their analysis.<sup>6</sup>

The aim of this study is to analyze the neocommissural alignment after the transaxillary and transcarotid implantation of the Boston Acurate neo2 SE THV, as well as to report its early clinical and hemodynamic outcomes.

**MATERIALS AND METHODS**

Since January 2009, more than 400 consecutive patients underwent a nontransfemoral TAVI at our institution. Among them, between October 2021 and November 2022, 40 patients were treated with the SE Acurate neo2 THV through a transaxillary or a transcarotid approach. All those patients had previously been deemed of high or prohibitive risk for

conventional aortic valve replacement and unfit for a transfemoral approach by the institutional heart team. The only exclusion criterion for this study was patients with a bicuspid aortic valve.

**Ethical Statement**

The study was approved by the local research ethics committee (Comité Ético de Investigación Clínica de Galicia study identification number 270/2022, January 26, 2022). The local research ethics committee approved a request to waive written informed consent for this study.

**Operative Technique**

The TAVI approach was performed through the left axillary artery or the left common carotid artery, depending on the size and anatomy of the access vessel. All vascular accesses were surgically performed through a 4-cm skin incision. The procedures were carried out in a hybrid operating room under fluoroscopic and 2-dimensional and 3-dimensional transesophageal echocardiogram (TEE) guidance.

Valve sizing was based on the aortic annulus perimeter and aortic annulus diameter derived from the perimeter measured in a preoperative multidetector computed tomography (MDCT) in all patients, following the manufacturer's recommendations. Preimplant balloon valvuloplasty was performed using a semi-compliant VACS III (OSYPKA) valvuloplasty balloon or a non-compliant Mammoth (Meril) valvuloplasty balloon, the size of which was selected 1 or 2 mm below the assessed aortic annulus diameter.

Preprocedural MDCT analysis also allowed determination of the patient-specific fluoroscopic projection in which the right coronary cusp (RCC) and left coronary cusp (LCC) will be overlapping at fluoroscopy (RCC/LCC cusp overlap view). This patient-specific fluoroscopic projection in combination with a prespecified orientation of the THV at the level of the native aortic valve was used to facilitate THV implantation with neocommissural alignment. The Acurate neo2 THV has 3 radiopaque commissural posts and "free stent struts" in line with the THV commissures (Figure 1).

The orientation of one of the posts and one of the free stent struts to the right of the screen in the RCC/LCC cusp overlap view facilitated the THV implantation with neocommissural alignment. This technique is depicted in Figure 2.

The implantation technique began with the insertion of the delivery system, with the flush port positioned at 6 o'clock, and later advancement of the THV in the ascending aorta in a 3-cusp coplanar view. With the THV at the level of the aortic root, the fluoroscopy was moved to the RCC/LCC cusp overlap view, and the orientation of the THV neocommissures was checked, as explained in Video 1. If required, a slowly clockwise torque of the delivery catheter allowed to achieve the 2:1 configuration of the valve free cells in the RCC/LCC cusp overlap view. Finally, fluoroscopy was moved back to the 3 cusps coplanar view, and the THV was deployed with the central mark in line with the bottom of the NCC (Video 2).

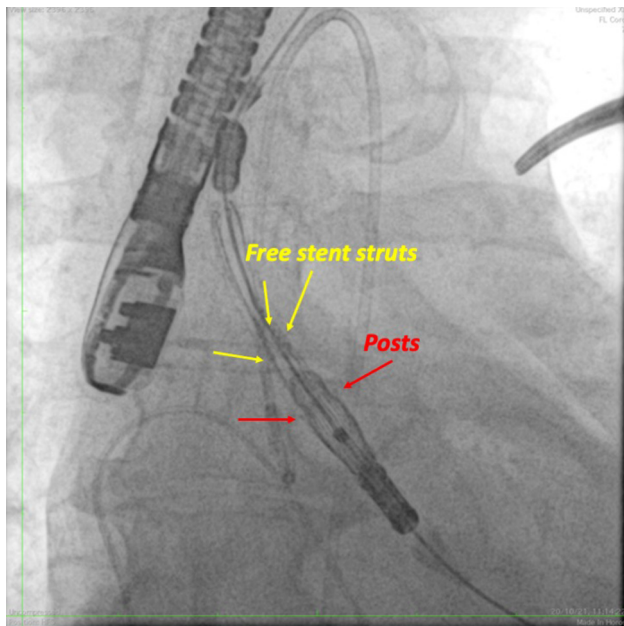
The technique for neocommissural alignment in the transcarotid and transaxillary approaches is similar to that previously described by other authors for the transfemoral approach.<sup>6</sup> However, in the transcarotid and transaxillary accesses, the shorter distance between the end of the introducer sheath and the aortic valve reduces the torque needed, resulting in nearly a 1:1 correspondence between the handle twist and the distal valve rotation.

**Evaluation of the Procedural Outcomes**

Morbidity and mortality outcomes were reported according to the Valve Academic Research Consortium 3 (VARC-3)<sup>7</sup> definitions for periprocedural complications after TAVI.

**Evaluation of the Neocommissural Alignment**

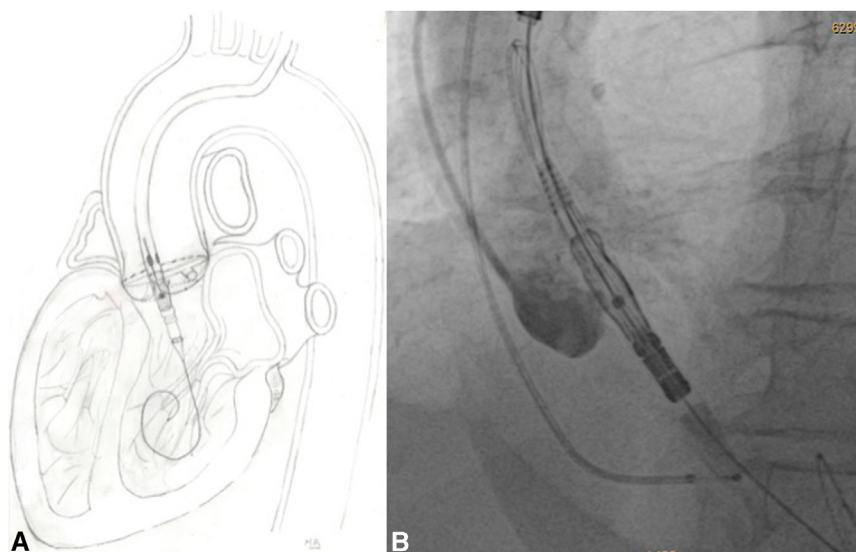
Predeployment positioning of the prosthesis was monitored with transesophageal echocardiography.<sup>8,9</sup> A long-axis view, using 2- or 3-dimensional<sup>10</sup> imaging, was used.



**FIGURE 1.** The Acurate neo2 THV has 3 radiopaque commissural posts (red arrows) and “free stent struts” (yellow arrows) in line with the valve commissures.

Commissural alignment between native and THVs was assessed by TEE before and after the procedure. The midpoint of the junction between the interatrial septum and the noncoronary sinus was identified in a short-axis aortic valve view perpendicular to the aortic root axis in end-diastole. The virtual line between this landmark and the center of the aortic leaflet coaptation was taken as a reference, and the angles with the lines between the center of the aortic valve and each of the native (pre) and prosthetic (post) aortic valve commissures were measured. The technique is shown in Figure 3.

Mean differences in native commissures and prosthetic commissures angulation were calculated for each patient adding the 3 commissural angulations per patient (pre- and post-TAVI) and dividing the total number by 3.



**FIGURE 2.** Technique for neocommissural alignment. A, Depiction of how one of the posts and one of the free stent struts must be orientated toward the intercoronary RCC and LCC commissure. The orientation of one of the posts and one of the free stent struts to the right of the screen in the RCC and LCC overlap view (B) facilitates the THV implantation with neocommissural alignment.

The technique for TEE assessment of the neocommissures alignment was validated comparing a MDCT performed before the TAVI procedure and another MDCT performed 3 months after the TAVI procedure in 4 patients.

The commissural orientation was assessed for each of those 4 patients both in the native aortic valve (on the pre-TAVI MDCT) and in the THV (on the post-TAVI MDCT) in the end-diastolic phase of the heart cycle. To evaluate commissural alignment, we performed the technique previously described by Bailey and colleagues<sup>11</sup> and Fuchs and colleagues.<sup>1</sup>

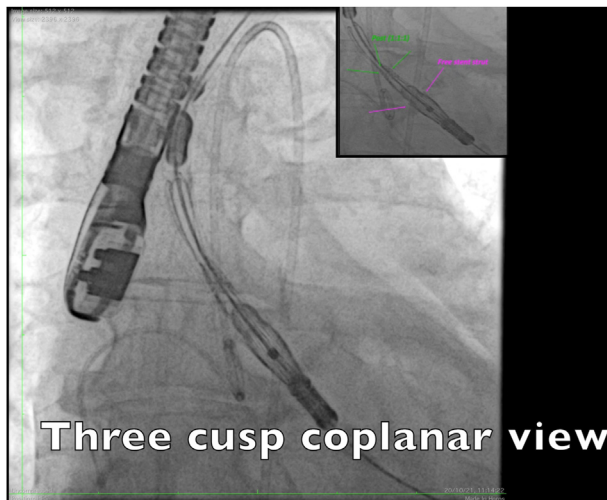
The origin of the right coronary artery (RCA) was identified in a cross-section perpendicular to the axis of the aorta, and then it was rotated around the center of the aorta until it was on top at 12 o'clock in the image. A vertical line was drawn through RCA and the center of the aorta. Thereafter, 3 angles were measured through the center of the aorta from the RCA to the RCC/LCC commissure, from the RCA to the LCC/noncoronary cusp (NCC) commissure, and from the RCA to the NCC/RCC commissure. The technique is shown in Figure 4.

Commissural misalignment (CMA) according to the angle deviation between the native commissures and the neocommissures was classified as optimal ( $0^{\circ}$ - $15^{\circ}$ ), mild ( $>15^{\circ}$ - $30^{\circ}$ ), moderate ( $>30^{\circ}$ - $45^{\circ}$ ), and severe ( $>45^{\circ}$ - $60^{\circ}$ ). Likewise, optimal or mild CMA was considered in any patient with a neo-CMA less than  $30^{\circ}$ .<sup>1</sup>

### Statistical Analysis

Descriptive results were presented as counts and percentages for categorical variables. Continuous data were described as mean and SD. Those continuous variables with skewed distributions were presented as median and interquartile range (IQR). Normal distribution of continuous data was evaluated by visual inspection of QQ plots and histograms, as well as using the Kolmogorov–Smirnov test. For univariable analysis, proportions were compared with contingency tables by means of chi-square with Yates' correction or Fisher exact tests. Student *t* test was used to compare continuous variables. Wilcoxon signed-rank test was used to compare the difference between the mean commissural orientation of the native commissures and the neocommissures.

Statistical tests were conducted without adjustment for multiple testing because this study was of exploratory nature. Actual estimates of survival were accomplished with Kaplan–Meier methods. SPSS version 25.0 and R Statistical Software version 3.2.0 were used to perform data analysis.



**VIDEO 1.** The commissural alignment technique starts with the Acurate neo2 in the aortic root in a 3 cusps coplanar view, which must show 1 strut of the THV at each side and the free cells disposed in a 1:1:1 configuration. Then, the fluoroscopy is moved to the RCC/LCC cusp overlap view so that only 1 strut must be visible toward the right of the screen (RCC/LCC commissure) and the free cells disposition changes in a 2:1 configuration. Video available at: [https://www.jtcvs.org/article/S2666-2507\(23\)00220-1/fulltext](https://www.jtcvs.org/article/S2666-2507(23)00220-1/fulltext).

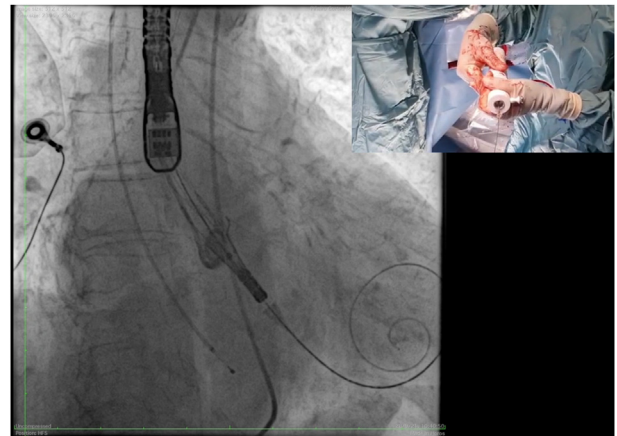
## RESULTS

The clinical and demographic characteristics of the 40 consecutive patients enrolled in this study are shown in [Table 1](#) (57.5% female; mean age 82.7 [SD, 5.8] years). Median logistic European System for Cardiac Operative Risk Evaluation I was 19.7% (IQR, 10.11%-26.2%), and median logistic European System for Cardiac Operative Risk Evaluation II was 4.47% (IQR, 3.28%-7.65%).

The main indication for TAVI in all the patients was severe symptomatic aortic valve stenosis. The mean aortic annulus perimeter was 76 mm (SD, 7.4), and the mean aortic annulus area was 451.9 mm<sup>2</sup> (SD, 88.9). Preoperative evaluation data and procedure characteristics are shown in [Table 2](#).

Ten patients (25%) were operated on an urgent basis. The 2 main reasons for performing this procedure on an urgent basis (during the same hospital admission) were admission for congestive heart failure requiring intravenous diuretics and syncope due to severe aortic stenosis. The left subclavian artery was accessed in 30 cases, whereas in the remaining 10 cases the left common carotid artery was used. The mean diameter of the target vessel was 6.7 (SD, 0.7) mm. The most frequently implanted size was M (37.5%), followed by size L (35%) and size S (27.5%). Only 5 patients (12.5%) required counterclockwise or clockwise rotation to achieve neocommissural alignment.

Mean volume of iodinated contrast media used was 43.2 mL (SD, 11.3). Most patients (87.5%) stayed in the



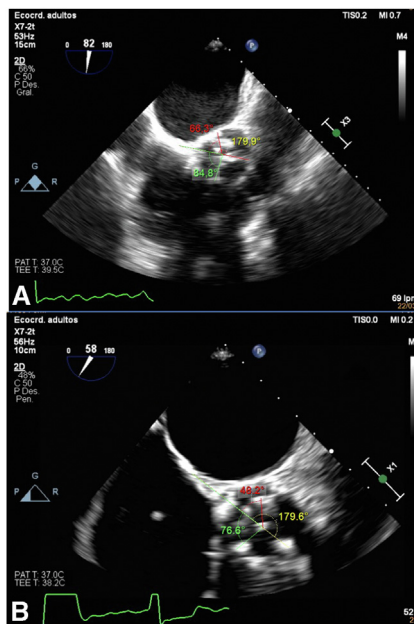
**VIDEO 2.** Deployment of an Acurate neo2 size M through a left axillary approach. Notice that the deployment occurs from the cranial to the caudal end of the prosthesis. A slight push forward must be kept during the whole deployment. The procedure occurs in 2 steps: a slow, controlled deployment of the first crown during which control angiographies must be performed to correct the height of the valve, and a final rapid deployment of the second crown that we usually perform under rapid pacing. Video available at: [https://www.jtcvs.org/article/S2666-2507\(23\)00220-1/fulltext](https://www.jtcvs.org/article/S2666-2507(23)00220-1/fulltext).

intensive care unit less than 12 hours. Median in-hospital stay was 3 days (IQR, 2-4 days).

Two perioperative complications defined by the VARC-3 criteria were identified. There were no vascular complications, infectious complications, bleeding, or stroke. There was a THV migration in the aortic arch due to a deployment too high in the aortic annulus in the seventh patient of the series. This patient required the implantation of a second Acurate neo2 THV without further complication. Another patient required a permanent pacemaker because of a complete postoperative atrioventricular block. Two patients presented an uncomplicated moderate soft tissue hematoma. There was no in-hospital or 30-day mortality. [Table 3](#) summarizes the VARC-3 outcomes.

Based on TEE analysis, the mean difference in native commissures angulation was 65.1° (SD, 41.3), whereas the mean difference in neocommissures angulation was 64° (SD, 44.1). Therefore, mean commissural orientation did not significantly differ between native and neocommissures ( $P = .661$ ). These results are shown in [Figure 5](#).

After the study of the differences in position between the native commissures and the neocommissures, it was shown that optimal or mild CMA was achieved in 95% of cases. In 29 of the 40 cases (72.5%), the neocommissures were precisely aligned with the native aortic valve commissures. Mild CMA (<30°) was observed in 9 patients (22.5%), and moderate CMA was observed in 2 patients (5%). There were no cases of severe CMA (>45°). These 2 cases with moderate CMA were patients in whom commissural



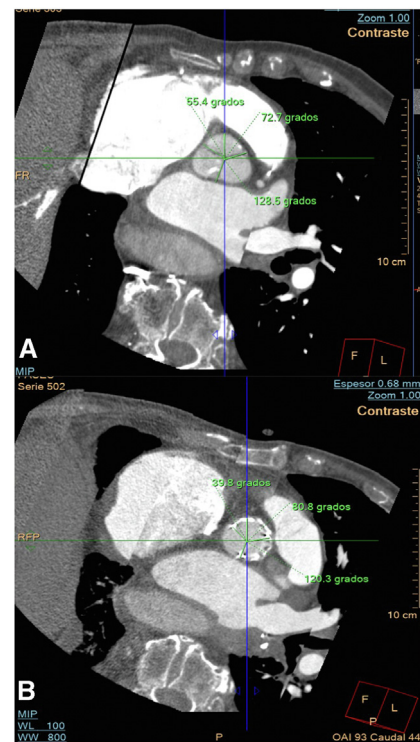
**FIGURE 3.** Commissural alignment between native and THV was assessed by TEE before (A) and after the procedure (B). The midpoint of the junction between the interatrial septum and the noncoronary sinus was identified in a short-axis aortic valve view perpendicular to the aortic root axis in end diastole. The virtual line between this landmark and the center of the aortic leaflet coaptation was taken as a reference, and the angles with the lines between the center of the aortic valve and each of the native (pre) and prosthetic (post) aortic valve commissures were measured.

alignment was not intentionally performed. One case corresponds to the first case performed with this THV. The other case was a patient who critically collapsed after the balloon valvuloplasty; therefore, the THV deployment was swiftly carried out without previous assessment of the commissural alignment.

Intraoperative echocardiographic data showed a peak and a mean aortic valve gradients of 12.7 mm Hg (SD, 5.4) and 5.3 mm Hg (SD, 2.3), respectively. Moderate intraoperative aortic regurgitation (AR) was present in 3 patients (7.5%), and mild AR was present in 13 patients (32.5%). In the first month postoperative control echocardiography, peak and mean aortic valve gradients evolved to 17.3 mm Hg (SD, 7.7) and 8.7 mm Hg (SD, 3.7), respectively. In the first month postoperative echocardiography, there were 2 cases of moderate AR (5%) and 4 cases of mild AR (10%). Echocardiographic results are summarized in Table 3.

## DISCUSSION

To the best of our knowledge, this is the first study focusing on neocommissural alignment of an SE THV using nontransfemoral approaches. Our findings can be summarized as follows: (1) Our patient-specific technique for transaxillary and transcrotid insertion of the Acurate neo2 delivery system effectively prevents Acurate neo2



**FIGURE 4.** Commissural alignment between native and THV was assessed by a preoperative MDCT (A) and a 3-month postoperative MDCT (B) in the end-diastolic phase of the heart cycle. The origin of the RCA was identified in a cross-section perpendicular to the axis of the aorta, and then it was rotated around the center of the aorta until it was on top at 12 o'clock in the image. A vertical line was drawn through the RCA and the center of the aorta. Thereafter, 3 angles were measured through the center of the aorta from the RCA to the RCC/LCC commissure, from the RCA to the LCC/NCC commissure, and from the RCA to the NCC/RCC commissure.

implantations with more than mild CMA, with a device success rate surpassing 97%. (2) The transaxillary and transcrotid accesses for Acurate neo2 implantation proved to be safe, without any associated vascular or neurological complications. (3) Our strategy of TEE assessment has been validated as a reproducible and accurate method for determining postprocedural neocommissural alignment of the SE THV.

Previous studies indicate that THV implantation with moderate or greater CMA is correlated with several complications. Bailey and colleagues<sup>11</sup> described that optimal THV orientation is achieved with commissure-to-commissure alignment ( $0^\circ$ ), whereas orientations between  $30^\circ$  and  $60^\circ$  can potentially increase stress and affect THV durability.<sup>11</sup> Furthermore, Fuchs and colleagues<sup>1</sup> found that THV stent frame deformation and moderate or greater CMA were independent predictors of mild central AR. It has also been suggested that CMA may complicate postimplantation coronary access<sup>2,3</sup> and jeopardize future

**TABLE 1. Demographics and clinical data**

Characteristic	All patients (n = 40)
Sex (female)	23 (57.5%)
Age, y, mean (SD)	82.7 ± 5.8
Body mass index, mean (SD)	27.5 ± 4.9
Body surface area, m <sup>2</sup> , mean (SD)	1.7 ± 0.2
Logistic euroSCORE I, mean (SD)	19.7% ± 11%
Logistic euroSCORE II, mean (SD)	6.8% ± 5.9%
Hypertension	36 (90%)
Diabetes mellitus	9 (22.5%)
Chronic lung disease	8 (20%)
Extracardiac arteriopathy	18 (45%)
History of atrial fibrillation	6 (15%)
Previous pacemaker	3 (7.5%)
Preoperative left ventricle function	
Normal (>55%)	27 (67.5%)
Mild dysfunction (31%-50%)	9 (22.5%)
Moderate dysfunction (21%-30%)	2 (5%)
Severe dysfunction (<20%)	2 (5%)
History of stroke or TIA	10 (25%)
Prior cardiac surgery	3 (7.5%)
Coronary artery disease	13 (39.4%)
Preoperative serum creatinine, mg/dL, mean (SD)	1.4 ± 0.6
Preoperative GFR, mL/min/1.73 m <sup>2</sup> , mean (SD)	49.6 ± 18.1

SD, Standard deviation; euroSCORE, European System for Cardiac Operative Risk Evaluation; TIA, transient ischemic attack; GFR, glomerular filtration rate.

transcatheter aortic valve-in-transcatheter aortic valve procedures.<sup>4</sup>

Raschpichler and colleagues<sup>5</sup> found that more than moderate CMA (>30°) with a balloon-expandable THV was independently associated with a relative aortic valve mean gradient increase of more than 50% from baseline to the first month control, and it might have an impact on the THV durability. More recently, Jung and colleagues<sup>12</sup> have recently reported that CMA is an independent risk factor for hypo-attenuated leaflet thickening, which serves as a marker of subclinical leaflet thrombosis.

Several SE THVs are preoriented within their delivery systems, and these systems are introduced into peripheral vessels in a standard fashion.<sup>13</sup> Although these features may somewhat aid THV alignment, a significant proportion of TAVI procedures still result in random THV deployment in the aortic root.<sup>1</sup> These issues partially may be partially due to inter-patient anatomic variations of femoral access, aortic arch angulation, and aortic root orientation.<sup>1</sup>

In the COMALIGN study, Bieliauskas and colleagues<sup>6</sup> compared 3 SE THVs: the Acurate neo2, Evolut R/PRO, and Portico. They found that the Acurate neo2 was the superior THV in achieving neocommissural alignment with

**TABLE 2. Preoperative multidetector computed tomography evaluation and procedural results**

Characteristic	All patients (n = 40)
Aortic annulus perimeter (mm)	76 ± 7.4
Aortic annulus perimeter–derived diameter (mm <sup>2</sup> )	24.1 ± 2.4
Aortic annulus area (mm <sup>2</sup> )	451.9 ± 88.9
Aortic annulus area–derived diameter (mm)	23.9 ± 2.4
Access vessel mean diameter (mm)	6.7 ± 7.6
Left coronary artery height (mm)	14.1 ± 3.4
RCA height (mm)	17.2 ± 3.2
Urgent surgery	10 (25%)
Prosthesis size	
S	11 (27.5%)
M	15 (37.5%)
L	14 (35%)
Device success (VARC-3 criteria)	39 (97.5%)
Length of hospital stay (d)	3.9 ± 2.7

RCA, Right coronary artery; VARC-3, Valve Academic Research Consortium 3.

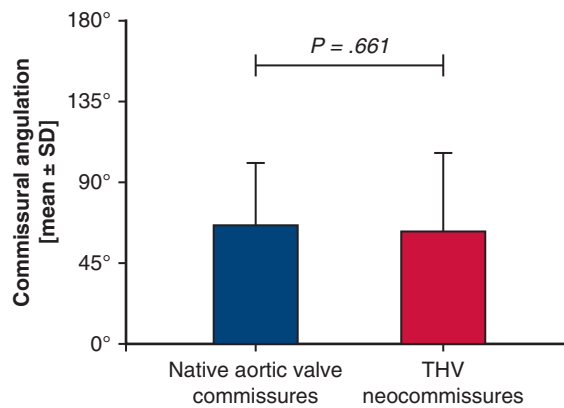
higher optimal alignment rates and no patient exhibiting more than mild CMA.<sup>6</sup>

Our study also highlights that inserting the Acurate neo2 delivery system through the left common carotid artery or the left subclavian artery, with the flush port positioned at 6 o'clock, facilitates fine neocommissural alignment. This obviates the need for substantial posterior correction due to the short distance between the end of the introducer sheath and the aortic valve. This technique results in nearly

**TABLE 3. Echocardiographic data**

Characteristic	All patients (n = 40)
Mean LVEF (%)	62.5 ± 8.1
Postoperative mean aortic gradient (mm Hg)	5.3 ± 2.3
Postoperative peak aortic gradient (mm Hg)	12.7 ± 5.4
Postoperative paravalvular leak grade ≥ +2	3 (7.5%)
1-mo mean aortic gradient (mm Hg)	8.7 ± 3.7
1-mo peak aortic gradient (mm Hg)	17.3 ± 7.7
1-mo paravalvular leak grade ≥ +2	2 (5%)
Mean commissural angle deviation of native aortic valves measured by TEE (°)	65.1 ± 41.3
Mean commissural angle deviation of THVs measured by TEE (°)	64 ± 44.1
CMA	
Optimal (0-15°)	29 (72.5%)
Mild (>15-30°)	9 (22.5%)
Moderate (>30-45°)	2 (5%)
Severe (>45-60°)	0

LVEF, Left ventricular ejection fraction; TEE, transesophageal echocardiography; THV, transcatheter heart valve; CMA, commissural misalignment.



**FIGURE 5.** The bar chart depicts the mean difference in commissural orientation between native and neo-commissures. *SD*, Standard deviation; *THV*, transcatheter heart valve.

1:1 correspondence between handle twist and distal valve rotation due to the reduced torque requirements.

On the basis of our experience in this series, we report that rotating the Acurate neo2 at the level of the aortic annulus by torquing the delivery catheter through transaxillary or transcarotid access was feasible in all patients. Our patient-specific transaxillary or transcarotid implantation technique, aimed at obtaining neocommissural alignment, is feasible and safe, and helps prevent Acurate neo2 implantations with more than mild CMA and severe coronary artery overlap with the THV commissures.

Excluding the 2 patients in whom neocommissural alignment was not attempted, optimal commissural alignment and a less than moderate misalignment were achieved in all cases. The rate of device success was 97.5%. This technique for Acurate neo2 THV deployment not only



**Clinical and structural outcomes of neocommissural alignment in transaxillary and transcarotid TAVI with a self-expandable transcatheter heart valve**

October 2021 and November 2022, 40 patients were treated of non-transfemoral TAVI with the Acurate neo2 THV through:

- left transaxillary access, 30 patients.
- left transcarotid access, 10 patients.

**Patient-specific deployment** → **TEE/CT evaluation of commissural alignment**

Mean commissural orientation did not significantly differ between native and neo-commissures ( $P = .661$ ).

Optimal or mild commissural misalignment (CMA) was achieved in 99.5% of cases. No cases of severe commissural misalignment.

No 30-day mortality. No vascular complications, bleeding, nor stroke.

Peak and mean aortic valve gradients were 12.7 mmHg and 5.2 mmHg, respectively. There were 2 cases of moderate aortic regurgitation and 4 cases of mild aortic regurgitation.

This patient-specific technique for transaxillary and transcarotid insertion of the Acurate neo2™ delivery system prevents THV implantations with more-than-mild CMA and with a high device success rate. The transaxillary and transcarotid accesses for Acurate neo2™ implantation are safe and did not associate vascular or neurological complications.

**FIGURE 6.** This patient-specific technique for transaxillary and transcarotid insertion of the Acurate neo2 delivery system prevents THV implantations with more than mild CMA and with a high device success rate. *TAVI*, Transcatheter aortic valve implantation; *THV*, transcatheter heart valve; *TEE*, transesophageal echocardiogram; *CT*, computed tomography.

demonstrated a significantly low rate of complications but also showed an acceptable postimplant hemodynamic outcome.

In our study, the use of TEE assessment proved to be a feasible and accurate method for determining postprocedural neocommissural alignment of the SE THV. This strategy avoids the need for postoperative MDCT and the use of more contrast media in a usually high-risk population of acute kidney injury.

In recent years, several authors<sup>1,11</sup> have proposed evaluating with MDCT scan the commissural alignment of either native or prosthetic aortic valves by measuring the angle between each commissure and a centerline toward the RCA. The latter must be previously identified in a cross-section perpendicular to the axis of the aorta and rotated around the center of the aorta until it is on top at 12 o'clock in the image. Therefore, in that method for MDCT measuring the commissural alignment, the origin of the RCA is used as a fixed reference to measure RCA to the RCC/LCC commissure, from RCA to the LCC/NCC commissure, and from RCA to the NCC/RCC commissure. Afterward, the mean of the 3 angle deviations must be calculated.<sup>1,11</sup>

In our TEE method, the origin of the RCA cannot be used as a valid reference, but the midpoint of the junction between the interatrial septum and the noncoronary sinus serves as an easy and reproducible landmark to measure the angle between this anatomic reference and the 3 commissures. Obviously, the digits would not match those calculated using the RCA as a landmark in the MDCT because the anatomic landmarks are completely different between both methods. However, the calculated mean of the 3 angle deviations measured by TEE should not mathematically differ from the calculated mean of the 3 angle deviations assessed by MDCT scan. Therefore, the TEE determination of the degree of commissural (mis-)alignment should be equally valid.

Our TEE assessment provides a high accuracy of the estimated degree of CMA, making post-TAVR cardiac computed tomography unnecessary for studying neocommissural alignment. This study also underscores the paramount importance of TEE guidance in TAVI. Transesophageal echocardiography has proven to be the best resource for rapid assessment and diagnosis of severe hypotension after TAVI in several studies.<sup>9,14</sup> Furthermore, TEE monitoring in TAVI has been suggested as a protective factor against early and long-term mortality.<sup>15</sup>

In terms of feasibility, safety, and efficacy, our transaxillary and transcarotid deployment has demonstrated a remarkably low rate of complications. Neither vascular nor neurological complications were recorded in our series. These nontransfemoral transarterial extrathoracic approaches have been associated with superior operative outcomes compared with intrathoracic approaches,<sup>16,17</sup> and their outcomes have even been suggested as comparable to those of the transfemoral approach.<sup>17,18</sup>

## Study Limitations

This study presents the limitations inherent in any observational study. The primary limitation is that the number of patients enrolled in this study may be low; thus, this study may lack sufficient statistical power to detect certain clinically relevant effects. A larger number of patients with an MDCT scan during the follow-up after the TAVI is advisable to consolidate the TEE standardized measured as the first-line option.

## CONCLUSIONS

This patient-specific technique for transaxillary and transcarotid insertion of the Acurate neo2 delivery system prevents THV implantations with more than mild CMA and with a high device success rate (Figure 6). The transaxillary and transcarotid accesses for Acurate neo2 implantation are safe and did not associate vascular or neurological complications. Our proposed strategy of TEE assessment has been shown to be a reproducible and accurate method for determining postprocedural neocommissural alignment of the SE THV.

## Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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**Key Words:** computed tomography, self-expandable, transaxillary/transcarotid, transcatheter aortic valve implantation, transcatheter heart valve, transesophageal echocardiography