






ORIGINAL STUDIES

A patient-specific algorithm to achieve commissural alignment with Acurate Neo: The sextant technique

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Abstract

Aims: The aim of this proof-of-concept study was to investigate safety and efficacy of a CT-scan based patient-specific algorithm to maximize coronary clearance and secondarily to achieve anatomically correct commissural alignment with the Acurate Neo device.

Method and results: A total of 45 consecutive patients undergoing TAVR with the Acurate Neo THV were prospectively enrolled in the study. Mean age was 81.6 ± 5.5 years, mean STS score was 6.1 ± 3.7 . Device success rate was 100%. Aim of the technique was to rotationally deploy the TAVR device with a commissure lying on the bisector between the coronary ostia as calculated on the pre-procedural CT-scan. At post-TAVR CT-scan, coronary clearance was achieved in 98% of patients with no cases of severe coronary artery overlap. In 42 out of 45 patients, THV was aligned or, at most, mildly misaligned; there were 2 cases of moderate misalignment without any case of severe misalignment. Post-TAVR selective coronary artery engagement was attempted and succeeded in all patients (100%).

Conclusion: Our CT-scan based patient-specific algorithm is safe and proven to be effective in avoiding coronary artery overlap and providing commissural alignment with Acurate Neo in all treated patients.

KEYWORDS

coronary access, commissural alignment, TAVR, TAV-in-TAV

Abbreviations: AR, aortic regurgitation; BMI, body mass index; CABG, coronary artery by-pass graft; CO, coronary obstruction; COPD, chronic obstructive pulmonary disease; CT, computed tomography; LCC, left coronary cusp; LM, left main; LVEF, left ventricular ejection fraction; NCC, non-coronary cusp; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PPM, permanent pace-maker; PVL, paravalvular leak; RCA, right coronary artery; RCC, right coronary cusp; TAVR, transcatheter aortic valve implantation; THV, transcatheter heart valve; TTE, transthoracic echocardiography.

1 | INTRODUCTION

Transcatheter heart valves (THVs) are now approved across the entire spectrum of risk, from patients ineligible for surgery to those at low risk.^{1,2} However, as transcatheter aortic valve implantation (TAVR) indications are moving towards younger patients with longer life expectancy, concerns about coronary access after THV implant, risk

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of coronary obstruction after TAV-in-TAV procedure and valve durability raise.

In a recent published registry analyzing post-TAVR computed tomography (CT)-scan of 411 patients it has been shown that coronary access might be particularly challenging in patients undergoing supra-annular self-expanding THV implantation with almost 35% of them having left main (LM) or right coronary artery (RCA) located in an unfavorable position (below the skirt, in front of the commissural triangles or commissural diamonds).³ In an effort to limit geometrical interaction between THV and coronary ostia, Tang et al. found that a specific initial orientation in the insertion of the delivery system of supra-annular self-expanding THVs (Evolut R/Pro and Acurate Neo) achieves the highest likelihood of commissural alignment. However, this approach does not account for patients' differences in aortic root and vascular anatomy and, when applied, up to 14.3% of Acurate Neo patients may present a severe overlap between THV commissures and coronary artery.⁴

Beyond simplifying coronary access, commissural alignment might enhance feasibility of BASILICA (bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction) in case of TAVR within a failed THV. Indeed, if compared to valve-in-valve with THV in a surgical valve, BASILICA may be less effective in TAV-in-TAV procedures when neo-commissures are not aligned to those of native aortic valve or when they lie in-front of coronary ostia.⁵ Finally, correct anatomical alignment of THV commissures with native aortic anatomy may increase long-term durability by reducing the impact of stent distortion on leaflet function.⁶

In this proof-of-concept study we investigate the feasibility of a CT-scan based patient-specific algorithm and implantation technique to avoid overlap between Acurate Neo's commissural posts and coronary artery ostia and to achieve an anatomically correct commissural alignment.

2 | METHODS

2.1 | Patient population

Starting from June 2020 up to November 2020, 45 consecutive patients with symptomatic severe aortic stenosis undergoing TAVR with Acurate Neo or Acurate Neo 2 THV (Boston Scientific) at I.R.C.C. S. Policlinico San Donato (Milan, Italy) were prospectively enrolled in the study. Consensus to proceed with TAVR was reached after Heart Team discussion and all patients provided written informed consents for participating in the study. Transfemoral TAVR was performed in all cases, under local anesthesia and mild sedation if needed.

2.2 | Computed tomography image acquisition

All patients underwent pre-procedural electrocardiographically gated, contrast-enhanced CT using a second-generation 128-row

multidetector scanner (Somatom Definition; Siemens healthcare, Forchheim, Germany). For aortic root dimensions and commissural alignment projection (*see dedicated paragraph*), multiplanar reconstruction analysis was made with 3-Mensio valves software (version 8.2, Pie Medical Imaging, Maastricht, the Netherlands). As per study protocol, these patients underwent post-procedural electrocardiographically gated, contrast-enhanced CT-scan unless renal function precluded iodinated contrast administration. In this case, a post-procedural electrocardiographically gated non-contrast CT using a second-generation 128-row multidetector scanner (Somatom Definition; Siemens healthcare, Forchheim, Germany) with subsequent fusion with pre-procedural CT was performed. The commissural orientation was assessed for each patient both in the native aortic valve (on the pre-TAVR CT scan) and in the prosthetic aortic valve (on the post-TAVR CT scan) in the end-diastolic phase of the heart cycle.⁷ Evaluation of commissural alignment was made according to Bailey et al.⁷: three angles from RCA to the right coronary cusp (RCC)/left coronary cusp (LCC) commissure, from RCA to the LCC/non-coronary cusp (NCC) commissure, and from RCA to the NCC/RCC commissure were measured. For each of these three angles, a Δ angle deviation between the pre-TAVR and post-TAVR scan was measured and, subsequently, one mean angle deviation was calculated to evaluate commissural alignment.

2.3 | Transthoracic echocardiography

Transthoracic echocardiography (TTE) was performed with a GE Vivid 9 ultrasound unit (GE Healthcare, Horten, Norway) before and after TAVR. Postprocedural TTE was performed the same day of procedure and repeated at discharge. Post-procedural PVLs were assessed according the Valve Academic Research Consortium-2 (VARC-2) criteria and classified in absent/trivial, mild, moderate and severe by experienced echocardiographers.⁸ In case of discrepancies between post-procedural and discharge TTE, data from the latter were used for the analysis.

2.4 | Implanting the Acurate neo avoiding coronary overlap and respecting anatomical alignment: "The Sextant Technique"

The aim of this technique is to position the THV so that one of the commissural posts of the THV lies upon the internal bisector of the angle between the coronary arteries (Figure 1) with a rotational error which is less than 15° in either direction. Positioning any one of the three commissural posts on the bisector maximizes the distance between the coronary ostia and the commissural posts and so enhances coronary clearance. Moreover, since in most anatomies, the angle between the coronaries is slightly larger to 120°, this strategy should provide a correct anatomical orientation of the THV in most of the cases (Figure 1). The secondary objective of the technique is to

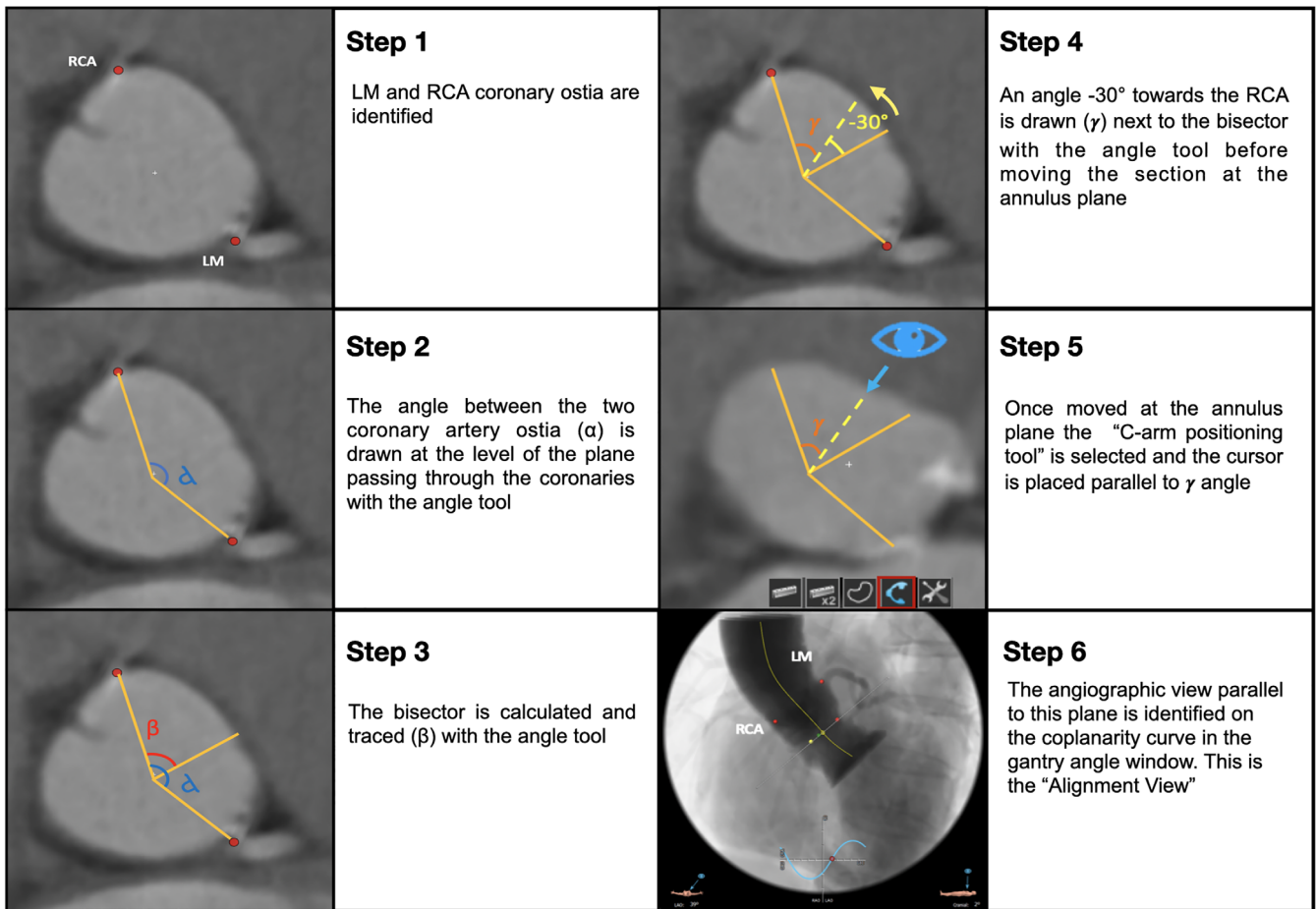


FIGURE 1 Method for identification of the "Alignment View," in this case using 3Mensio software with Aortic package (version 8.2, Pie Medical Imaging, Maastricht, the Netherlands), but this can be easily be applied to any CT imaging package

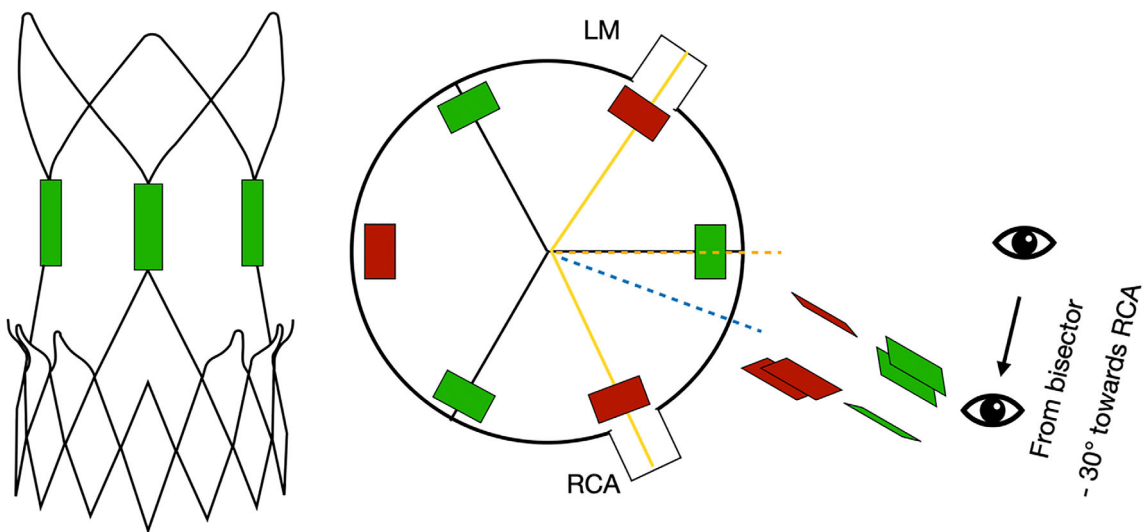


FIGURE 2 Rationale of Alignment View: correct anatomical orientation can easily be recognized by the fact that the commissural post appearing as a line must lie on the left of the screen and the two angle commissural posts are superimposed

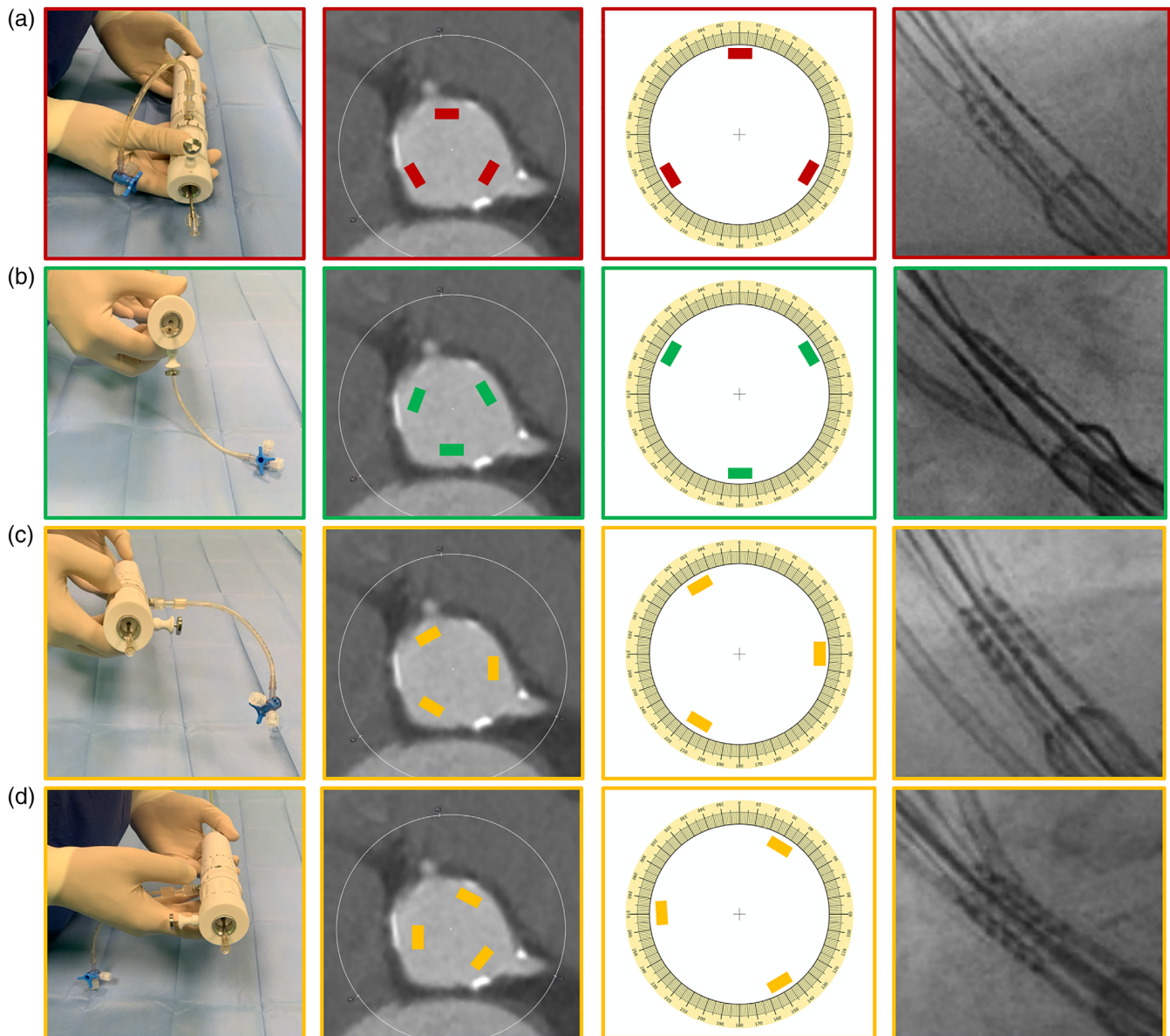


FIGURE 3 Example of angiographic appearance of the correct anatomical orientation of the commissural tab (“Totems”) in the Alignment View. (a) Red Box (worst orientation) the totem appearing as a line is located on the right: with this orientation two totems are in front coronary ostia. (b) Green Box (correct orientation) the totem appearing as a line is located on the left: with this orientation the THV is anatomically oriented. (c),(d) Yellow Box (wrong orientation) none of the posts appears as a line: in this case one totem is in front of the right or left coronary ostium

achieve a correct anatomical orientation with commissural tab lying as close as possible to native commissures.

2.4.1 | STEP 1: CT-derived fluoroscopic angulation to guide commissural alignment

The correct alignment of the THV device before deployment can easily be checked in a dedicated fluoroscopic view (“Alignment View”). This view lies 30° from the bisector towards the right coronary artery (Figure 1) and the relative gantry angle is calculated on the coplanarity

curve (Figure 1). The rationale for this view lies in the fact that, by rotating 30°, one of the commissural posts is seen sideways and the radiological appearance in such a view is that of a line, which is easily recognizable (Figures 2 and 3b). The correct anatomical orientation can easily be recognized by the fact that the commissural post appearing as a line must lie on the left of the screen (Figures 2 and 3b) and the two angled commissural posts are superimposed. If the orientation is not anatomically correct (Figures 2 and 3a,c,d examples of non-correct orientation in the Alignment View) the delivery system is retracted in the descending aorta, rotated and then re-advanced until the correct anatomical orientation is matched (*see next paragraph*).

TABLE 1 Baseline characteristics

Variables	N = 45
Age, years	81.6 ± 5.5
Female sex	31 (69%)
BMI, kg/m ²	24.8 ± 5.1
Atrial fibrillation	7 (16%)
Hypertension	39 (87%)
Diabetes	22 (49%)
Chronic kidney disease	23 (51%)
COPD	14 (31%)
Prior CABG	0 (0)
Prior PCI	11 (24%)
Prior stroke	6 (13%)
Prior permanent pace-maker	7 (16%)
STS score, %	6.1 ± 3.7
NYHA class III-IV	35 (78%)
LVEF, %	57.6 ± 13.1
Mean gradient, mmHg	42.4 ± 12.8
AR ≥ moderate	14 (31%)
The sextant technique	
Mean coronary angle, °	142.5 ± 11.2
Alignment view LAO, °	19.5 ± 12.9
Alignment view CRA, °	9.8 ± 19.4

Note: Values are mean ± SD or n (%).

Abbreviations: AR, aortic regurgitation; BMI, body mass index; CABG, coronary artery by-pass graft; COPD, chronic obstructive pulmonary disease; CRA, cranial; LAO, left anterior oblique; LVEF, left ventricle ejection fraction; NYHA, New York Heart Association; PCI, percutaneous coronary interventions.

2.4.2 | STEP 2: Intra-procedural THV rotation (or manipulation) to achieve commissural alignment

In order to achieve such a deployment, the delivery system of the Acurate Neo device is advanced at the annulus level and the position of the commissural posts relative to the anatomy is checked in the dedicated fluoroscopic view ("Alignment View," calculated on the pre-procedural CT scan) before THV deployment (Step 1, see above). Rotational symmetry of the Acurate Neo device is such that the device has an identical configuration every 120° of rotation in either direction. In case the commissural posts are not correctly positioned, the THV device is rotated 30° in a stepwise fashion up to three times until a correct alignment is obtained and the device is released with the desired rotation. Considering that the flush port of the delivery system aligns with one of the commissures, a technique has been developed in order to obtain the alignment. Firstly, the delivery system is pulled back until the THV is in the descending aorta to allow an easier transmission of the rotation over its major axis. Then, a 180° rotation is given to the proximal end of the delivery system, sending the flush port and safety button down. This 180° delivery system rotation translates into a 60° equivalent

TABLE 2 Procedural and in-hospital outcomes

Variables	N = 45
General anesthesia	1 (2%)
Transfemoral access	45 (100%)
Pre-dilatation	33 (73%)
Post-dilatation	25 (56%)
Acurate valve size	
S	24 (53%)
M	14 (31%)
L	7 (16%)
Acurate neo 2	10 (22%)
Device success	44 (98%)
Peri-procedural death	0 (0)
Second THV implantation	0 (0)
Severe patient-prosthesis mismatch	0 (0)
Mean gradient ≥ 20 mmHg	0 (0)
PVL	
None/trace	18 (40%)
Mild	26 (58%)
Moderate	1 (2%)
Severe	0 (0)
Major vascular complication	0 (0)
Minor vascular complication	1 (2%)
Life-threatening bleeding	0 (0)
Stage 2 or 3 acute kidney injury	1 (2%)
Permanent pace-maker	2 (4%)
All-stroke	0 (0)
Peri-procedural myocardial infarction	0 (0)
Coronary obstruction	0 (0)
Mean gradient, mmHg	5.6 ± 2.4
LVEF (%)	59.5 ± 9.3

Note: Values are mean ± SD or n (%).

Abbreviations: LVEF, left ventricle ejection fraction; THV, transcatheter heart valve.

rotation of the THV, but has the advantage of allowing for an easier handling of the angle and an easier transmission of the torquing force to the distal tip of the delivery catheter (Figure 3). The device is then advanced again at the annulus level and the correct rotational alignment of the THV with respect to the anatomy is checked again in the Alignment View. In case the commissural post does not lie with ±15° of the coronary bisector, the delivery system is pulled in the descending aorta and up to two other rotations can be carried out and tested sequentially in the Alignment View. The THV rotations to be evaluated are -30° and +30°. To overcome torquing inertia of the delivery system and taking advantage of the 120° rotational symmetry of the Acurate Neo device, rotations of the handle of 90° and 270° are performed to allow for better transmission of the needed torquing force to the capsule and so translating in rotations of -30° and +30° of the THV (Figure 3).

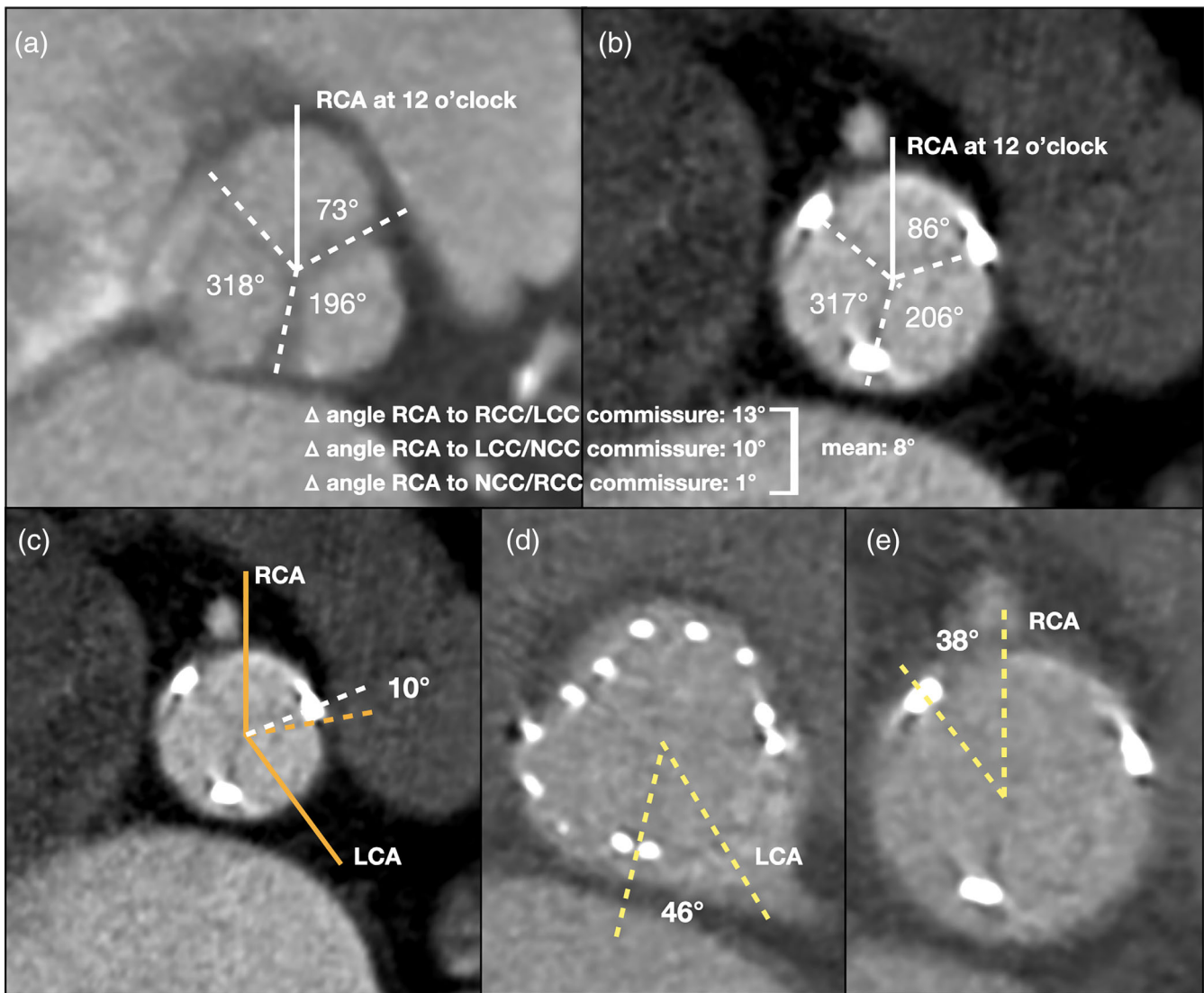


FIGURE 4 Pre- and post-procedural CT commissural alignment evaluation: (a), (b) Pre- and post-procedural angles were measured between a line centered on right coronary artery (RCA) and each native valve commissure (pre-procedural) and each TAVR commissure (post-procedural); the mean of the difference of the three angles before and after implantation was calculated. The bioprosthesis was considered aligned in case of an average deviation between 0° and 15° .¹¹ (c) Angle between the bisector of the angle between coronary arteries (dashed orange line) and the final position of the closest commissural tab. (d) Angle between coronary ostia and commissural tab (yellow dashed lines). LCA, left coronary artery; LCC, Left coronary commissure; NCC, non coronary commissure; RCA, right coronary artery; RCC, right coronary commissure

2.5 | Endpoints and definition

Coronary clearance and commissural alignment between the THV and native aortic valve were determined by post-procedural CT-scan. Coronary artery overlap was deemed severe if a neocommissure and coronary orifice were 0° to 20° apart as reported by other Authors.⁶ According to measurements proposed by Fuchs et al.⁹ THV commissural alignment was defined as: (1) aligned (angle deviation 0 to 15°); (2) mild commissural misalignment (angle deviation 15° to 30°); (3) moderate commissural misalignment (angle deviation 30° to 45°) and (4) severe commissural misalignment (angle deviation 45° to 60°). As the aim was to place a THV commissure on the coronary bisector,

the technique was considered successful if, at follow-up CT-scan, a commissural tab was positioned within $\pm 15^\circ$. All events, including procedural and device success, were classified according to the Valve Academic Research Consortium-2 (VARC-2) criteria.⁸ Horizontal aorta was defined as an aortic angle $>57^\circ$.⁹

2.6 | Statistical analysis

Continuous variables following a normal distribution are reported as mean and standard deviation; otherwise, median and interquartile range were employed. Categorical and dichotomous variables are

TABLE 3 The sextant technique

Variables	N = 45
Severe coronary artery overlap (<20°)	0 (0)
Commisural alignment	
Aligned (0–15°)	34 (75.5%)
Mild misalignment (15–30°)	9 (20%)
Moderate misalignment (30–45°)	2 (4.5%)
Severe misalignment (45–60°)	0 (0)
Selective LM engagement	45 (100%)
Selective RCA engagement	45 (100%)
Angle between nearest commisural tab and LM, °	44.8 ± 11.2
Angle between nearest commisural tab and RCA, °	66.4 ± 18.6°
Planned Commisural tab position within 15° of bisector	42 (93%)

Note: Values are mean ± SD or n (%).

Abbreviations: LM, left main; RCA, right coronary artery.

presented as counts and percentages. Analyses were performed using SPSS 22.0 statistical analysis software (IBM Corporation).

3 | RESULTS

3.1 | Baseline characteristics

During the study period, 45 consecutive patients were underwent TAVR with an Acurate device: 35 patients received an Acurate Neo and 10 received an Acurate Neo 2 and were prospectively included in the study. Baseline characteristic are reported in Table 1. Briefly, mean age was 81.6 ± 5.5 years, 69% were female with a mean STS score was 6.1 ± 3.7. The majority of patients (78%) were in NYHA class III or IV at admission. Mean left ventricular ejection fraction (LVEF) was 57.6 ± 13.1% with a mean aortic gradient of 42.4 ± 12.8 mmHg and 14 patients (31%) had at least moderate aortic regurgitation.

Mean annulus perimeter was 72.1 ± 6.1 mm whereas mean aortic angle was 50.7 ± 9.4° with 15 patients (33%) presenting a horizontal aorta. With regards to the presented technique, we found a mean angle between coronary arteries of 142.5 ± 11.2° and the average Alignment View was 9.8 ± 19.4° cranial and 19.5 ± 12.9° left oblique projection (Table 1).

3.2 | Procedural data

Transfemoral access was used in 100%. Pre-dilatation was performed in 73% of the patients while post-dilatation in 56%. Most of patients were treated with an Acurate Neo S (53%) and M (31%) (Table 2). Device success rate was 98% with no cases of in-hospital death, need of second THV, severe patient-prosthesis mismatch and one case of

more than mild PVL reported. One patient experienced a minor vascular complication, two patients required a permanent pace-maker (PPM) implantation and no case of periprocedural stroke or myocardial infarction were described (Table 2). In only seven (16%) patients initial 12:00 o'clock flush port orientation results in correct alignment, while in the remaining 84% of cases at least one delivery system rotation was carried out to achieve alignment.

In all patients post-THV implantation selective coronary artery engagement was attempted and was successful. Post-procedural echocardiogram showed a mean LVEF of 59.5 ± 9.3% with a mean aortic gradient of 5.6 ± 2.4 mmHg.

3.3 | Post-procedural CT-scan analysis

All patients underwent post-TAVR electrocardiographically gated control CT using a second-generation 128-row multidetector scanner with fusion with pre-procedural CT capability was used.

No case of severe overlap has been observed with a mean angle between the nearest commissural tab and, respectively, LM and RCA was 44.8 ± 11.2° and 66.4 ± 18.6°. Commissural alignment was achieved in 34 (75.5%) of patients, 9 (20%) and 2 (4.5%) had, respectively, a mild commissural and moderate misalignment (example of analysis in Figure 4). The two cases with moderate misalignment were patients having a horizontal aorta where, probably due to residual stored tension in the system, the TAVR slightly rotated on its axis during the release phase. Of note, however, no case of severe misalignment was documented (Table 3). In 42 (93%) of cases final position of commissural tab was consistent with the pre-procedural planned one with a mean absolute difference of 10.5 ± 5.2° (Table 3).

4 | DISCUSSION

Given the absence of a stent frame encapsulating valve leaflets, coronary access after Acurate Neo implantation may not always be an issue. However, in the analysis provided by Tang et al. 51% of patients undergoing Acurate Neo implantation had one of the three commissural tab in front of the coronary orifice and precluding an easy and direct coronary access.⁶ Moreover, among commercially available THVs and according to the classification proposed by Tarantini et al., Acurate Neo has the tallest risk plane, defined as the plane under which the passage of a coronary catheter will be impossible after the second THV is implanted and risk of acute coronary obstruction is increased.¹⁰ Hence having a chance to achieve a commissural alignment may increase feasibility of novel leaflet splitting techniques such as BASLICA.

Fuchs et al. shown that standard implantation technique of Acurate Neo resulted in a random orientation of THV with the majority of patients (53%) having at least a moderate misalignment.¹¹

In the ALIGN study it has been demonstrated that, even in the best scenario when the Acurate Neo commissural tab was at "center back" or "inner curve," the incidence of coronary overlap for one or

both coronary arteries was 12.5% and 14.3%, respectively. In seven patients, operators attempted to torque clockwise the delivery catheter until one of the commissural tabs faced the inner curve, but this resulted in commissural alignment only in 71.4% of cases.⁴

This non-controlled proof-of-concept analysis demonstrated that this CT-scan based patient-specific algorithm (*Sextant Technique*) is safe and proven to be effective in avoiding coronary artery overlap and providing commissural alignment with Acurate NEO in all studied patients irrespective of native aortic root or vascular anatomies. Furthermore, post-TAVR selective engagement of coronary artery was attempted and succeeded in all cases.

The algorithm we propose is easy to implement as requires only an additional two-step analysis on standard pre-procedural CT-scan to find the so-called “Alignment View” and a maximum of three sequential delivery system rotations in the ascending aorta to achieve the desired anatomical position of commissural tab.

The three Acurate Neo's commissural tab, despite not specifically designed for anatomical alignment, are easily recognizable under fluoroscopy and thus act as a locator for a precise deployment. Moreover, the delivery catheter rotation maneuver, commonly performed with Evolut R/Pro to implement THV alignment to the aortic annulus, is known to have a minimal impact on procedural safety.

Future THV design may include locator to easily achieve an anatomical commissural alignment with native aortic valve and thus not compromising coronary access or possibility of TAV-in-TAV procedure.

5 | LIMITATIONS

This is a single center, proof-of-concept study enrolling a small number of patients and a larger scale validation is needed. Given the lack of a control group, association between commissural alignment and the ability to perform selective coronary angiography or the potential advantages in setting of TAV-in-TAV remain hypothetical. Further, we test our hypothesis only with Acurate Neo THV, but we believe that the *Sextant Technique* can be potentially applied to others self-expanding device.

6 | CONCLUSIONS

This is the first proof-of-concept study providing a standardized patient-specific algorithm to achieve a commissural alignment and avoid coronary artery overlap with Acurate Neo THV. In the near future, as TAVR indication expands to younger patients, improving delivery catheter design to guarantee commissural alignment and minimize overlap with coronaries will be fundamental.

CONFLICT OF INTEREST

Francesco Bedogni, Federico De Marco, and Nedy Brambilla are proctors for Boston Scientific.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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