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Case Report

Coronary Alignment by the OctaAlign Technique Using a Myval Octacor Transcatheter Heart Valve in a Bicuspid Aortic Valve: A Case Report

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Conflict of Interest
The authors have no conflicts of interest.

ABSTRACT

The indications for transcatheter aortic valve replacement (TAVR) are expanding to include patients with lower surgical risk and younger individuals. Therefore, achieving commissural/coronary alignment during transcatheter heart valve (THV) deployment is crucial for the lifelong management of aortic stenosis. Proper coronary alignment not only facilitates future coronary access but also aids in redo-TAVR procedures and may reduce leaflet stress, thereby decreasing the rate of bioprosthesis degeneration. Various techniques have been developed to achieve coronary alignment in self-expanding valves, each with varying levels of success. However, attempts with first-generation balloon-expandable (BE) THVs have been less promising. Additionally, current coronary alignment techniques are primarily designed for tricuspid aortic valve leaflet anatomy and may not be appropriate for bicuspid aortic valves, where the coronary cusps are asymmetric and the coronary arteries are eccentric. In this report, we introduce a novel coronary alignment technique known as "OctaAlign," which utilizes a BE valve. This technique is versatile and suitable for use in both tricuspid and bicuspid valves.

Keywords: Aortic stenosis; Bicuspid valve; Transcatheter aortic valve replacement

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has become the standard treatment for severe aortic stenosis (AS) across all levels of surgical risk. As TAVR indications expand to include younger patients with low surgical risk,[1] it is important to consider the lifetime management of severe AS during the initial procedure. In contrast to surgical aortic valve replacement, where the native aortic leaflets are removed and the bioprosthetic valve commissures are aligned with the native commissures during surgery,[2] the alignment of transcatheter heart valve (THV) commissures with native commissures occurs randomly. Therefore, the commissural alignment (CA) of the THV is significant for ensuring future coronary access, facilitating redo-TAVR, and enhancing the longevity of the index THV.[3]

Coronary obstruction following THV placement is influenced by multiple factors, such as aortic root anatomy (including the height of the coronaries from the annular plane,

Author Contributions

Conceptualization: Nukavarapu RR, Daggubati R, Pothineni RB; Formal analysis: Nukavarapu RR; Investigation: Nukavarapu RR, Daggubati R, Pothineni RB; Methodology: Nukavarapu RR; Supervision: Nukavarapu RR; Visualization: Nukavarapu RR, Daggubati R, Pothineni RB; Writing - original draft: Nukavarapu RR, Daggubati R, Pothineni RB; Writing - review & editing: Nukavarapu RR, Daggubati R, Pothineni RB.

the width of the aortic sinuses, the height of the sino-tubular junction [STJ], and the length of the native leaflets), features of the THV (such as frame height and internal skirt height), and the alignment of THV commissures with the native commissures during deployment. The positioning of the THV commissural post against to the coronary ostium can complicate the engagement of the ostium for coronary stenting after TAVR.[4]

Due to structural degeneration of the THV, a sizeable proportion of younger patients require redo-TAVR in the future. Some of these patients require Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction (BASILICA). This procedure is particularly important when deploying the initial THV with CA of the coronary arteries.[5,6] This becomes more relevant with tall frame self-expanding (SE) valves, although the shorter STJ height with balloon-expandable (BE) THVs can pose a similar challenge.[7]

The commissural/coronary alignment of the THV is important for coronary access and its longevity. Proper CA reduces stress on THV leaflets and THV degeneration by reducing hypoattenuated leaflet thickening and hypoattenuation affecting motion.[6] Therefore, CA is important for both SE and BE valves.

Pre-procedural computed tomographic (CT) analysis of the aortic root is crucial for cardiac procedures, focusing particularly on cuspidity, the origin of the coronaries, and the fluoroscopic angles required to deploy the THV in alignment with the native commissures. This method is widely used for CA. When using SE valves, positioning the delivery catheter at a specific clock orientation while introducing it at the femoral artery level, and aligning certain markers on the valve frame with the aortic root during THV deployment, can minimize commissural misalignment (CMA). For the Evolut platform, positioning the flush port of the delivery system at 3 o'clock at the femoral site and aligning the hat marker of the valve frame towards the outer curvature or central front of the aorta can facilitate some degree of CA. Similarly, for the ACURATE neo platform, positioning the flush port of the delivery system at 12 o'clock at the femoral site and aligning the commissural post of the valve frame towards the inner curvature or central back of the aorta can also achieve some degree of CA.[7] For BE valves, crimping one of the commissures at different clock positions (3, 6, 9, 12 o'clock) was attempted with the Edwards Sapien valve. However, this method did not successfully achieve CA.[7]

All techniques used for CA are effective only when the valve is tricuspid, characterized by symmetrical sinuses and the coronaries originate from the centre of the sinuses. However, achieving CA with current techniques is challenging due to the asymmetry of sinuses and the eccentric origin of coronaries in bicuspid valves.[8] Therefore, in bicuspid valves, the focus should be on achieving coronary alignment rather than CA during THV deployment.[3] In this report, we introduce a novel CA technique named "OctaAlign," which utilizes the newer-generation BE Myval Octacor THV (Meril Life Science Pvt. Ltd., Vapi, Gujarat, India). This technique is also applicable to bicuspid aortic valves.[9]

CASE DESCRIPTION

A 78-year-old man with a history of coronary artery bypass graft (CABG) presented with New York Heart Association III dyspnea. Upon evaluation, he was diagnosed with severe AS, evidenced by an echocardiographic peak gradient of 118 mmHg and a mean gradient of 66 mmHg (**Fig. 1A**). Following a consultation with the heart team and considering the high

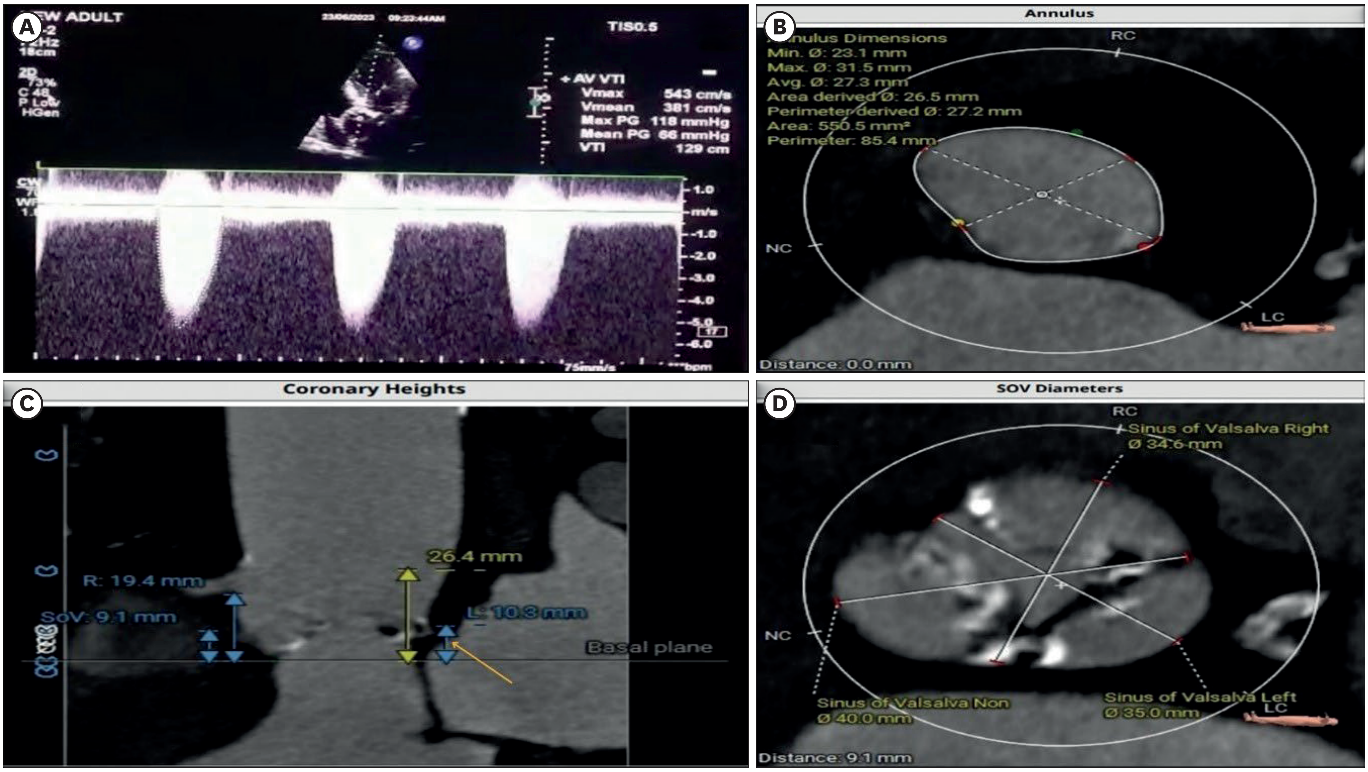

Fig. 1. Baseline echocardiographic and CT findings of the patient. (A) Doppler imaging across the aortic valve indicates severe aortic stenosis, with a peak gradient of 118 mmHg and a mean gradient of 66 mmHg. (B) CT imaging of the aortic root reveals an annulus area of 550.5 mm^2. (C) CT imaging of the aortic root shows a borderline left coronary artery height from the aortic annulus, as indicated by the arrow. (D) CT imaging of the aortic root demonstrates adequate Sinus of Valsalva diameters.
CT = computed tomography.

surgical risk, transcatheter aortic valve implantation (TAVI) was planned. CT analysis revealed a severely calcified type IA bicuspid valve with an annular area of 550.5 mm^2 (**Fig. 1B**). Additional findings included a borderline left coronary artery height of 10.3 mm (**Fig. 1C**), spacious sinuses of Valsalva (**Fig. 1D**), and iliofemoral vessels of adequate size for access. A 27.5 mm intermediate-size BE Myval Octacor THV was selected, featuring an oversize of approximately 6.5%. CA was planned using the OctaAlign technique. The clock angle for CA, determined from CT to mid-right coronary artery (RCA) (given its bicuspid nature), was set at 3:05° (**Fig. 2A**). The valve was then crimped with one commissural post aligned to this angle (**Fig. 2B**). Following pre-dilatation, the valve was deployed under rapid pacing in a coplanar view. The accuracy of CA was verified through fluoroscopy (**Fig. 2C**) and post-procedural CT (**Fig. 2D**). Written informed consent for the publication of this case report and accompanying images was obtained from the patient.

It was performed according to the recommendations of the CARE guidelines (**Supplementary Table 1**).

DISCUSSION

Due to the inherent cusp asymmetry in bicuspid aortic valves, achieving precise CA poses a greater technical challenge compared to tricuspid aortic valves.[3] In this case report, we discuss a complex scenario involving a geriatric patient post-CABG, who presented with

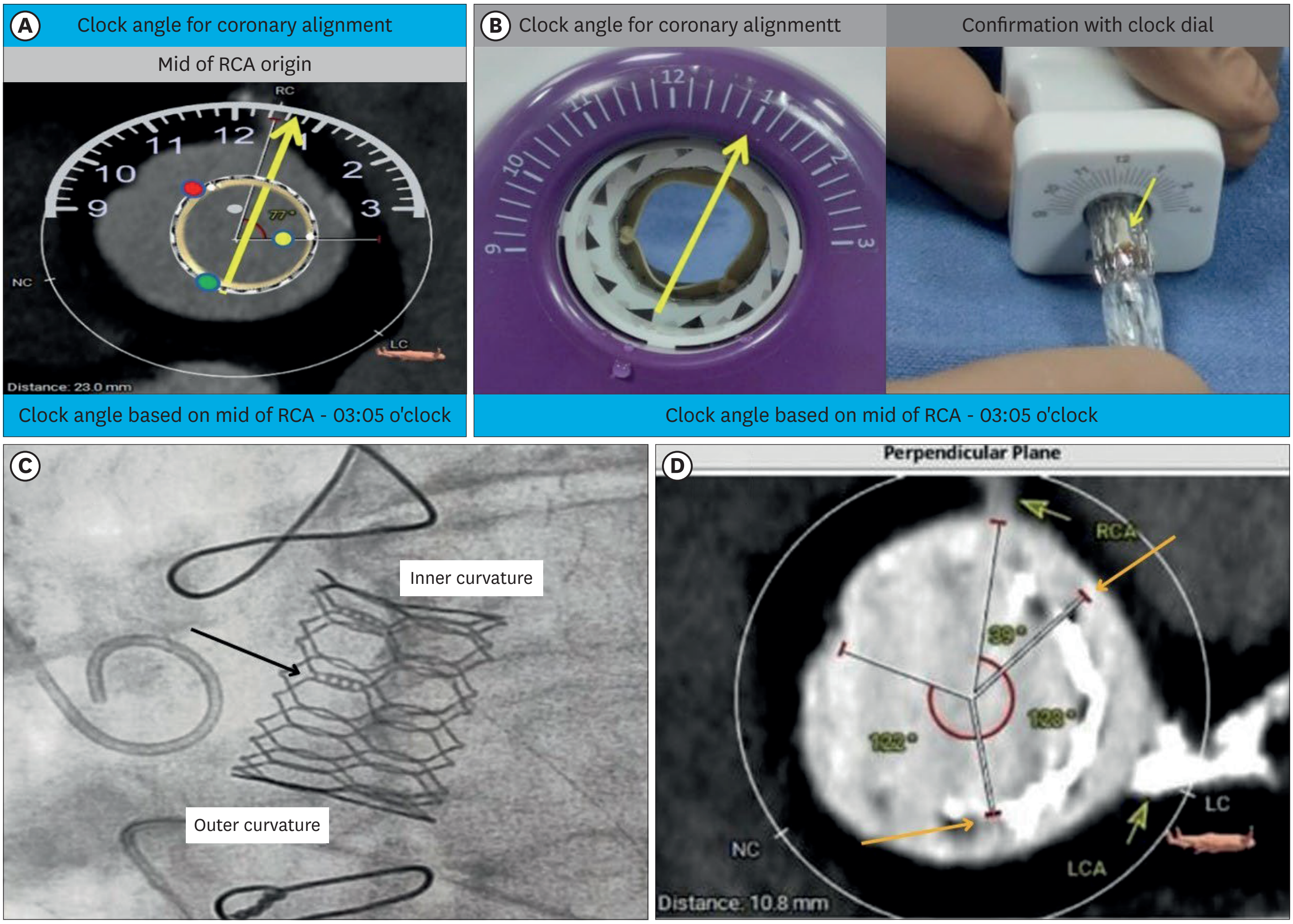

Fig. 2. Clock angle orientation and commissural alignment with Myval Octacor transcatheter heart valve. (A) The mid-right coronary artery at a clock angle of 3:05. (B) The crimping of Myval Octacor oriented according to the clock angle. (C) Commissural alignment in a fluoroscopic coplanar view, as evidenced by the central positioning of a commissural post (arrow) between the outer and inner curvature of the aortic root. (D) Post-procedural computed tomography of the aortic root showing commissural alignment, with the ostia of the coronaries (yellow arrows) unobstructed by commissural posts (orange arrows).
RCA = right coronary artery; LC = left coronary; LCA = left coronary artery; NC = non-coronary.

extremely high-pressure gradients, borderline coronary height, and bicuspid aortic valve anatomy. Despite these complications, successful CA was achieved using the novel OctaAlign technique of the Myval Octacor THV. A detailed description of the OctaAlign technique follows below.

The core concept of the OctaAlign technique involves crimping one of the commissural posts of the Myval Octacor THV towards the middle of the right coronary cusp (RCC) in tricuspid valves, or towards the middle of the RCA in bicuspid valves, based on CT-derived images of the aortic root. Due to a 180° rotation from the abdominal aorta to the aortic root, a commissural post initially directed towards the mid-RCC or mid-RCA will align directly opposite these landmarks (typically at the non-coronary cusp-left coronary cusp [LCC] commissure) during valve deployment. This coronary alignment facilitates coronary access (**Fig. 3A**).

Obtaining the angle of CA:

- After obtaining the axial cross-section image of the mid sinuses of Valsalva from an

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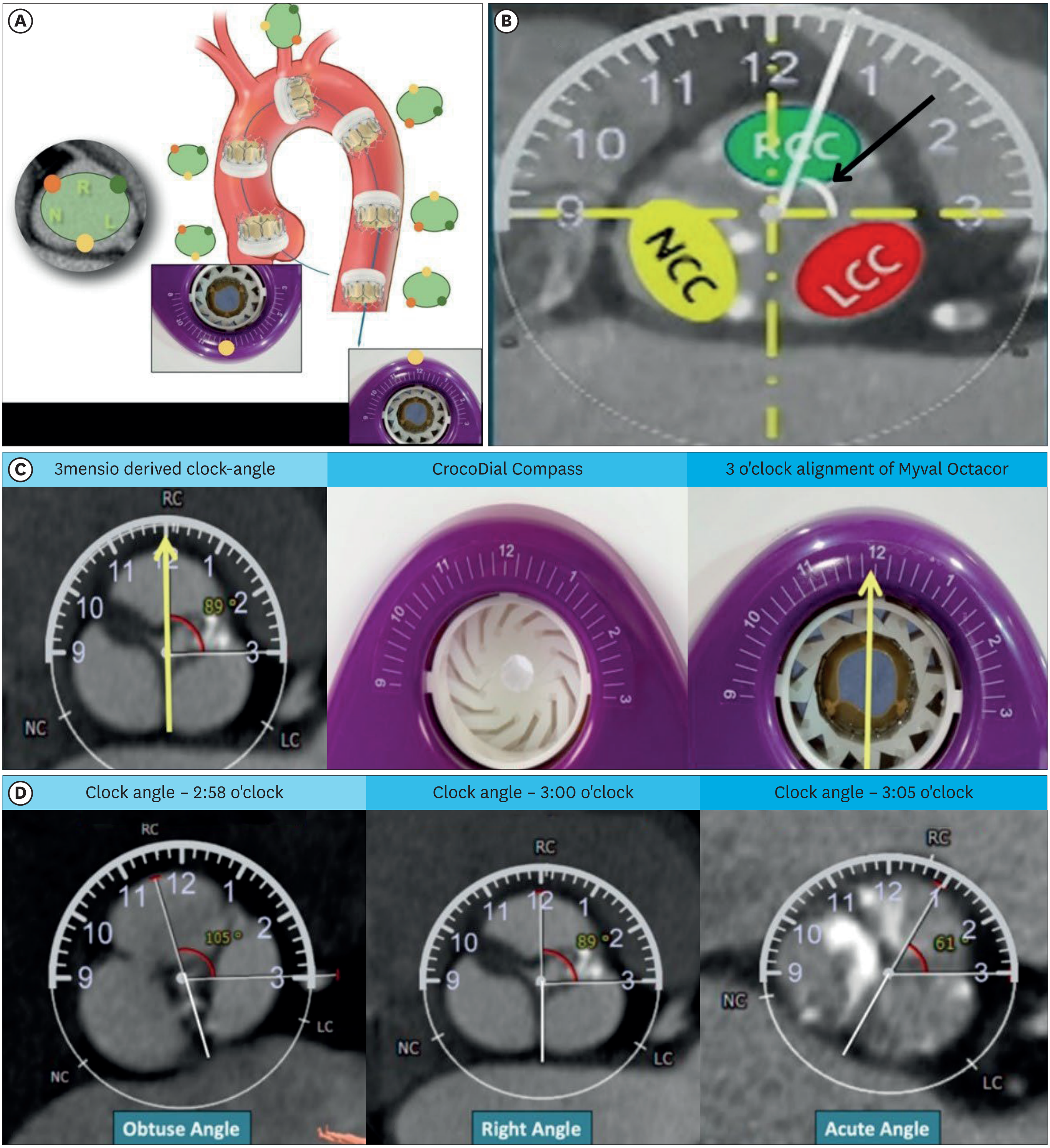

Fig. 3. Steps of commissural alignment with OctaAlign technique. (A) The 180° rotation of the transcatheter valve from the abdominal aorta to the aortic root. (B) Measurement of the commissural alignment angle, as indicated by the arrow. (C) The derivation of the clock angle from the commissural alignment angle by superimposing it on a clock face. (D) Various clock angles for the midpoint of the right coronary artery.
RCC = right coronary cusp; NCC = non-coronary cusp; LCC = left coronary cusp.

aortic root CT, a central line is drawn through the center of the sinuses, intersected perpendicularly by another line. The intersection point is referred to as the geometric nodule of the sinuses.
- A line is drawn from this point to the midpoint of the RCC or RCA, depending on the valve's cuspidity. The resulting angle is referred to as the angle of CA (**Fig. 3B**).
- When superimposed on the face of a clock in this image, the resulting angle is referred to as the clock angle (**Fig. 3C**), which is utilized during valve crimping. Depending on the anatomy of the aortic root, this angle may be acute, right, or obtuse (**Fig. 3D**).
- While crimping the THV, one of the commissures is aligned with the derived clock angle before the valve is deployed.

The CA achieved through the OctaAlign technique can be verified using fluoroscopy, transesophageal echocardiogram, and post-procedure CT. During fluoroscopy, it is necessary to obtain both coplanar and cusp overlap views. In the coplanar view, optimal alignment is indicated if one of the commissural posts is centered within the valve frame and the 3 commissural posts are equidistant from the inner to the outer curvature of the aortic root. This configuration increases the likelihood of achieving CA (**Fig. 4A**).[10]

In the cusp overlap view, if 2 commissural posts are separated at the inner curvature while being aligned at the outer curvature, this indicates CA[9] (**Fig. 4B**). A post-procedure CT scan of the aortic root is considered the gold standard for directly evaluating CA (**Fig. 4C**).

Previous studies have shown promising results with the OctaAlign technique. Initial experiences with the Myval Octacor THV indicate that the OctaAlign technique was effective in 25 of the first 30 cases (83%) for achieving optimal CA.[11] In research conducted by Ielasi et al.,[12] precise CA of the Myval Octacor THV was achieved in an 83-year-old patient using the OctaAlign technique. This method resulted in a mean difference angle of 5° between the native and neo-commissures, with no post-implantation PVL or significant conduction abnormalities.[12] Revaiah et al.[9] found that the OctaAlign technique is equally effective for both bicuspid and tricuspid aortic valve anatomies. It achieved ≤ mild CMA in 10 out of 13 (77%) patients with bicuspid anatomy and in 12 out of 19 (63%) patients with tricuspid anatomies. Severe CMA was observed in only 2 patients from each group. Additionally, in a larger patient cohort, the Myval Octacor THV continued to show favorable procedural and 30-day clinical and hemodynamic outcomes when using this technique.[13]

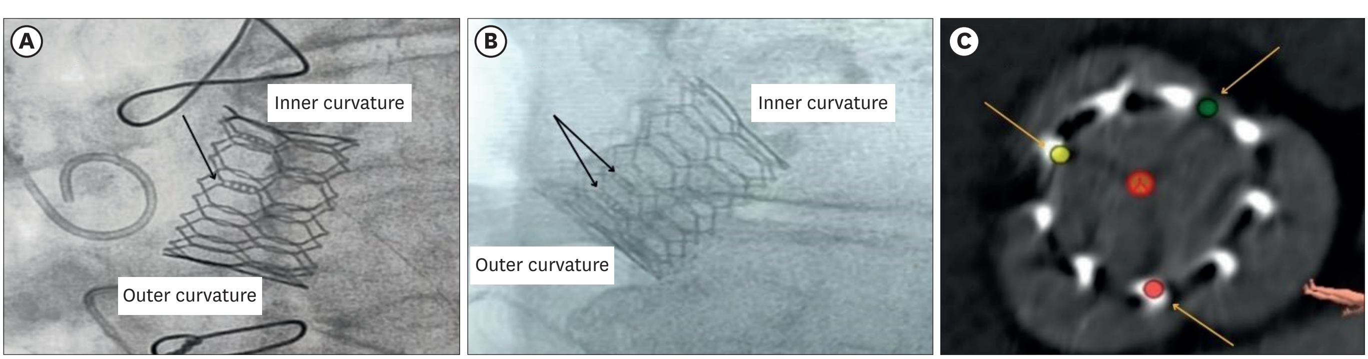

Fig. 4. Confirmation of commissural alignment via OctaAlign technique in fluoroscopic view and computed tomographic imaging. (A) This image demonstrates commissural alignment in a fluoroscopic coplanar view, as indicated by the central positioning of one of the commissural posts (arrow) between the outer and inner curvature of the aortic root. (B) Commissural alignment in a fluoroscopic cusp overlap view, as indicated by 2 of the 3 commissural posts (arrows) located at the outer curvature of the aortic root. (C) A post-procedural computed tomographic image of the aortic root displays commissural alignment, as indicated by the arrows.

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Several techniques for CA with SE valves, such as Evolut, ACURATE neo2, and Portico THVs, have been previously described. However, there are no standardized methods for CA with the latest BE THVs. The COMALIGN study employed a patient-specific implantation technique to achieve neo-commissural alignment with SE valves (Evolut R/PRO, ACURATE neo2, and Portico THVs). In this technique, the THV was deployed in the RCC/LCC overlap view, positioning one of the THV commissures at the right side of the fluoroscopic screen. Using this method, ≤ mild CMA (CMA <30°) was achieved in 88% of patients, and optimal CA (<15°) was achieved in 60% of patients.[10] In contrast, the OctaAlign technique, as reported by Revaiah et al.,[11] demonstrated the effectiveness of this method in achieving optimal CA in 83% of cases.

In the ALIGN-TAVR study, Tang et al.[14] assessed the effects of the initial deployment orientation of SAPIEN 3, Evolut, and ACURATE-neo THVs on CA and coronary artery overlap. The study found that for the SAPIEN 3 THV, crimping one of the commissures at specific orientations (3, 6, 9, or 12 o'clock relative to the delivery catheter, with the "Edwards" logo oriented upwards at 12 o'clock) did not affect CA or coronary artery overlap. Notably, the 3 o'clock crimping orientation exhibited less severe coronary overlap, though no significant differences were observed among the various crimped orientations. For the Evolut THV, positioning the "Hat" marker at the outer curve during initial deployment was shown to enhance CA and significantly decrease coronary artery overlap. Similarly, in the ACURATE-neo THV, positioning the commissural post at the center back or inner curve during initial deployment improved CA and reduced coronary artery overlap.[14]

In another study, Santos-Martínez et al.[15] employed CT-based planning and in-silico bio-modeling to predict CA in 10 patients undergoing TAVI with the Myval THV. This study involved pre-calculating patient-specific rotations—either clockwise or counter-clockwise—during crimping to align the commissural posts of the prosthesis with the native commissures in the aortic root bio-model. None of the 10 patients exhibited moderate or severe misalignment. However, it is important to note that all patients had tricuspid aortic valve anatomy, which made the procedure less challenging compared to our study.[15]

This technique has limitations in highly tortuous aortas, which can impact the final positioning of the delivery system. Additionally, the technical complexity of the procedure contributes to a steep learning curve and variability among operators, potentially affecting the consistency and precision of CA. However, selecting patients with less complex anatomical features (i.e., no-to-mild cusp or coronary asymmetry, non-tortuous anatomies) and increasing proficiency with this technique can improve the precision of CA. Moreover, this case report is based on a single case, which limits the ability to generalize the findings. Further research involving larger cohorts with diverse valve anatomies is necessary to confirm the reproducibility and broader applicability of the OctaAlign technique.

In conclusion, commissural/coronary alignment in TAVR is crucial for ensuring coronary access, the success of redo-TAVR, and the longevity of the initial procedure. This alignment is important not only in SE valves but also in BE valves. However, current techniques for achieving CA in bicuspid valves are ineffective. Instead, coronary alignment should be prioritized over CA in bicuspid valves to prevent coronary obstruction. The OctaAlign technique, developed for the Myval Octacor THV, represents a novel yet intuitively simple method for achieving coronary alignment in BE valves, including bicuspid valves. This technique prevents any in-situ rotation of the THV system across the aortic annulus. A previous publication has

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demonstrated that the OctaAlign technique is effective over 80%,[9] which supports its integration into routine TAVR practice.

SUPPLEMENTARY MATERIAL

Supplementary Table 1

The CARE guidelines checklist of items that should be included in case reports

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